



VA Research Currents

VA to boost training of minority researchers

VA's Office of Research and Development will expand its efforts in training and educating minority researchers with three new programs, based on recommendations from a recently convened Blue-Ribbon National Advisory Committee. The programs build on previous VA initiatives, such as the Research Training Initiative, which has provided training in VA biomedical labs for faculty and students at Historically Black Colleges and Universities (HBCUs), Hispanic-Serving Institutions (HSIs) and Tribal Colleges and Universities (TCUs).

Two of the new programs will promote opportunities for individual investigators, while the third will foster collaborations between VA and minority-serving institutions:

- **Mentored-Minority Supplemental Awards** will offer individual training on VA-funded biomedical and clinical research projects for full-time undergraduate, graduate and pre-doctoral students from minority-serving institutions, as well as students from predominantly minority high schools. VA-funded principal investigators are encouraged to recruit suitable candidates for this program. The program is modeled after the Supplemental Underrepresented Minorities Program of the National Institutes of Health.

- **Mentored-Minority Career Enhancement Awards** will provide full salary support for three years for recent HBCU, HSI or TCU graduates who have completed their clinical fellowship or PhD doctoral training within the last two years. Awardees are expected to remain in VA after the

program to pursue additional training through VA's Research Career Scientist and Career Development programs.

- **Minority Research Enhancement Centers** will allow for collaborations between VA research sites and accredited minority-serving institutions. Each MINREC will recruit three to five trainees each year—students and junior faculty—to participate in training and research activities alongside VA mentors. VA will provide money for direct costs and additional funding for equipment purchases and pilot projects as applicable.

Funding for the programs will begin in April 2004. For full details, including deadlines for submitting letters of intent and applications, contact Terri Carlton at (202) 254-0265 or terri.lynn.carlton@hq.med.va.gov. ■

Update from the Cooperative Studies Program

Improving informed consent through follow-up phone surveys

By Steven M. Berkowitz, PhD, *assistant director*

In recent years there has been increasing focus on the importance of informed consent (IC) to protect human research subjects. Yet much attention has focused on the IC documents themselves, leaving other aspects of the process relatively ignored. It is also important to ensure that subjects are competent to make decisions, that they are positioned to do so voluntarily, and that their decisions are based on comprehensive and understandable information about the proposed research.

To advance this effort, VA's Jeremy Sugarman, MD, in Durham and Philip Lavori, PhD, in Palo Alto created a project

titled "Enhancing the Quality of Informed Consent" (EQUIC), aimed at developing and testing tools and interventions to assess and improve the quality of the IC process.

The initial phase of EQUIC involved a telephone interview termed BICEP (Brief Informed Consent Evaluation Protocol). The interview was conducted immediately following the completion of the informed-consent process for a "parent" trial—an actual VA cooperative study actively enrolling participants. The BICEP interviews,

see **CONSENT** on pg. 3

Teasing out the impact of race on diabetes complications

A new study looking at nearly 430,000 diabetic patients who received care from VA in 1998 has confirmed some notions about race and diabetes—and challenged others. The study appears in the August issue of *Diabetes Care*.

Bessie A. Young, MD, MPH, and colleagues at VA's Seattle-based Epidemiologic Research and Information Center found that African Americans, Hispanics, Asians and Native Americans with diabetes are at greater risk than whites for kidney disease. This confirms earlier findings by the authors and others. Overall, research has shown that most minorities with diabetes are at greater risk for kidney, eye and peripheral vascular disease.

But Young's team also showed that racial minorities are at lower risk for cardiovascular disease than non-minority patients with diabetes. And they found that 18-month mortality for African Americans and most other minorities was 7 to 12 percent lower than for whites. On both counts, the findings clash with generally accepted notions on ethnicity and diabetes complications. For example, the Agency for Healthcare Research and Quality reports on its website that "diabetes-related mortality rates for African Americans, Hispanic Americans and American Indians are higher

than those for white people." The American Diabetes Association reports that "African Americans experience higher rates of heart disease" and certain other serious complications of diabetes.

To explain the mixed research findings, Young underscores that her study took place in VA, which provides care regardless of patients' financial or insurance status. She notes that other research on diabetic populations with equal access to care—such as a study by Dr. Andy Karter and colleagues of 62,432 Kaiser Permanente enrollees (*Journal of the American Medical Association*, May 15, 2002)—produced results similar to hers.

"If access to care is comparable, the complications might be a little different than we thought," said Young, a nephrologist whose research has focused on ethnic differences in diabetic nephropathy.

Young was careful to note that while the African American diabetics in her study has a lower *relative* risk of cardiovascular disease, their risk for heart disease is still substantial, especially compared to the non-diabetic population.

As for the higher rate of diabetic nephropathy among African Americans—which persisted even in this VA

see **DIABETES** on pg. 4

Major diabetes study yielding good news on VA blood pressure care

The VA Diabetes Trial, a seven-year study of the effects of intensive glycemic control on cardiovascular outcomes in type 2 diabetes, is finding that VA diabetes patients are achieving surprisingly good control of their blood pressure. Early data from the trial were presented June 20 at the annual meeting of the Endocrine Society by study team member Robert J. Anderson, MD.

The 1,544 patients in the study as of the presentation entered the trial with an average blood pressure of 131/77. Under new blood-pressure guidelines released in May, this is considered "prehypertensive," but not high. It is well below average for most diabetic populations, according to William Duckworth, MD, who is co-chairing the study with Carlos Abaira, MD. Duckworth said the data reflect extremely well on routine VA diabetes care. Patients followed for six months, receiving either standard or intensive therapy to control blood sugar and treatment as needed to manage blood pressure and lipids, further lowered their pressure, to an average of 127/74. "Blood pressure care is exceptionally good in VA patients with diabetes," said Duckworth, "and it can be improved further with additional attention."

By maintaining optimal blood pressure control in both study arms, the team aims to isolate the effects of intensive glycemic control on cardiovascular outcomes. In the current issue of *Clinical Diabetes*, Abaira and Duckworth write, "This trial may answer one of the most important questions in the treatment of diabetes." ■

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researchinfo@vard.org

Recent publications

“Comparison of Characteristics of Patients with Coronary Heart Disease Receiving Lipid-Lowering Therapy vs. Those Not Receiving Such Therapy.” Branko Kopjar, MD, MS, PhD; Anne E.B. Sales, RNS, PhD; Sandra L. Pineros, PA-C, MPH; Haili Sun, PhD; Yu-Fang Li, PhD; Ashley N. Hedeem, MPH, MD. **Puget Sound**. *American Journal of Cardiology*, July 15, 2003.

“Development of Gamma Tocopherol as a Colorectal Cancer Chemopreventive Agent.” Koyamangalath Krishnan, MD. **Mountain Home** (Tenn.) *Critical Reviews in Oncology/Hematology*, online April 26, 2003.

“Effects of Hypoxia and Nitric Oxide on Ferritin Content of Alveolar Cells.” Amy R. O’Brien-Ladner, MD; Lewis J. Wesselius, MD. **Kansas City and Phoenix**. *Journal of Laboratory and Clinical Medicine*, May 2003.

“A Functional Polymorphism of the Mu-Opioid Receptor Gene is Associated with Naltrexone Response in Alcohol-Dependent Patients.” David W. Oslin, MD; Joel Gelernter, MD; Charles P. O’Brien, MD, PhD. **Philadelphia and West Haven** (JG). *Neuropsychopharmacology*, June 18, 2003.

“The Influence of Distance on Utilization of Outpatient Mental Health Aftercare Following Inpatient Substance Abuse Treatment.” Ciaran S. Phibbs, PhD; John D. Piette, PhD. **Palo Alto**. *Addictive Behaviors*, Aug. 2003.

“Insulin Increases CSF A-Beta-42 Levels in Normal Older Adults.” G. Stennis Watson, PhD; Elaine R. Peskind, MD; Sanjay Asthana, MD; Stephen Plymate, MD; Suzanne S. Craft, PhD. **Seattle and Madison** (SA). *Neurology*, June 2003.

“Intensified Blood Glucose Monitoring Improves Glycemic Control in Stable, Insulin-Treated Veterans with Type-2 Diabetes: The Diabetic Outcomes in Veterans Study (DOVES).” Glen H. Murata, MD; Jayendra H. Shah, MD; Richard M. Hoffman, MD, MPH; Christopher S. Wendel, MS; Karen D. Adam, RN, CDE; Patricia A. Solvas, RN; Syed U. Bokhari, MD; William C. Duckworth, MD. **New Mexico, Southern Arizona and Phoenix**. *Diabetes Care*, June 2003.

“A Novel Cadaveric Model for Anterior-Inferior Shoulder Dislocation Using Forcible Apprehension Positioning.” Patrick J. Mahon, MD; Thay Q. Lee, PhD. **Long Beach**. (VA) *Journal of Rehabilitation Research and Development*, July/Aug. 2003.

“Performance of Recently Detoxified Patients with Alcoholism on a Neuropsychological Screening Test.” Sandra Zinn, PhD; Hayden B. Bosworth, PhD. **Durham**. *Addictive Behaviors*, July 2003.

“Processes of Care and Clinical Outcomes in COPD Patients with Community Acquired Pneumonia.” Jacqueline A. Pugh, MD; Eric M. Mortensen, MD. **San Antonio**. American Thoracic Society annual meeting, May 2003.

“Viral DNA Polymerase Mutations Associated with Drug Resistance in Human Cytomegalovirus.” Sunwen Chou, MD. **Portland**. *Journal of Infectious Diseases*, July 1, 2003.

“What Factors Influence Provider Knowledge of a Congestive Heart Failure Guideline in a National Health Care System?” Bonnie J. BootsMiller, PhD; Kimberly D. McCoy, MS; Stephen D. Flach, MD, PhD; Bradley N. Doebbeling, MD, MSc. **Iowa City**. *American Journal of Medical Quality*, May-June 2003.

“When Money is Saved by Reducing Healthcare Costs, Where Do U.S. Primary Care Physicians Think the Money Goes?” David A. Asch, MD, MBA; Peter A. Ubel, MD. **Philadelphia and Ann Arbor**. *American Journal of Managed Care*, June 2003.

CONSENT (cont. from page 1)

developed based on an extensive IC literature review and advice from an expert advisory group, was administered to 632 participants representing eight VA parent studies. The interview was conducted quickly, placing little additional burden on the parent-study participants. Respondents’ reports were largely favorable regarding the parent-study IC process:

- 95 percent said the amount of information they received was “just right”

- 99 percent remembered signing the IC form
- 99 percent said they felt no pressure to give consent
- 98 said they felt good about their decision to participate
- 89 percent were completely satisfied with the IC process

When asked about the primary purpose of the parent study, 80 percent of respondents indicated they understood that the study addressed a research question. Nearly 60

see **CONSENT** on pg. 4

DIABETES (cont. from page 2)

study—Young is determined to explore other factors that may account for this racial difference. In a new study, funded by a Robert Wood Johnson Fellowship and the American Diabetes Association, Young is using smaller but more detailed VA national databases to tease out other risk factors that may explain why diabetes complications appear to differ by ethnic background.

“Using databases with a little more clinical detail, we will try and investigate some of the other risk factors for these differences we are finding,” said Young. “We will try to determine if these findings bear out when we can control for things like duration of diabetes and smoking history.” If the differences in complications are due to genetics, and not socioeconomic or health-related confounders, Young’s work may help clarify this.

Meanwhile, she hopes her newly published data will influence VA to step up its effort to thwart the progression toward end-stage renal disease in minorities with diabetes. The study, co-authored by Charles Maynard, PhD, and Edward J. Boyko, MD, MPH, is one of the first to describe racial differences in kidney disease among pre-dialysis diabetes patients.

“The study might prompt VA to more aggressively target some of the minority population, particularly looking at things like microalbuminuria,” said Young. Albuminuria is the presence of albumin in the urine, and is often the first sign of failing kidneys.

Young, who completed a Health Services Research and Development fellowship under the mentorship of Boyko and Stephan Finn, MD, MPH, is convinced that VA’s health care system can make a vital difference in veterans’ health—in diabetes, kidney disease, and just about all other areas.

“Many of our veterans don’t have any other means of access to health care,” she said. “I think that just having access to care is incredibly important.” ■

CONSENT (cont. from page 3)

percent realized the parent study’s outcomes would ultimately benefit others, but interestingly only 6 percent saw *themselves* as potentially benefiting from the study. In response to the question “When can you stop participating in [the parent study]?” only 55 percent indicated a clear understanding that they could voluntarily stop any time. This item suggests an area that warrants more attention during the IC process.

This study, perhaps the largest empirical evaluation to date of a validity measure of the IC process, showed that the BICEP is a reliable measure that imposes minimal additional burden on research participants. The study also showed there is room to improve the consent process. ■

National Hotline Conference Call schedule:

http://vawww.va.gov/resdev/fr/call_calendar.cfm

- Inside this issue...
- Ensuring the efficacy of informed consent
 - The impact of race on diabetes complications
 - New programs to train minority researchers