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**Duke University
Medical Center**

Research Update

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The Center Begins Psychiatric Advance Directive Study

An ordinarily competent person who is susceptible to an incapacitating mental health crisis and loses their ability to make informed, reliable health care decisions needs a method of letting their treatment preferences be known. Psychiatric Advance Directives, also known as PADs, are legal documents that allow these persons to declare their treatment preferences in advance of an incapacitating mental health crisis. So far, initial research, federal mandates, and the President's New Freedom Commission on Mental Health have lent policy support to PADs and fifteen states have adopted PAD legislation. The Department of Veterans Affairs, however, does not presently have a specific policy that addresses PADs on patient care, nor a formal mechanism of notifying veterans of their rights to prepare PADs. Therefore, investigators at Durham's HSR&D would like to know what PADs would mean for the VA and the veterans it serves prior to initiating efforts for PAD implementation nationally in the VA.

"What the downstream effects of PADs will be on patient care, crisis management, service use, and clinical outcomes is unknown," says Mimi Butterfield, M.D., M.P.H., lead investigator of a new HSR&D grant-funded study "Psychiatric Advance Directives for Improved Mental Health Care." "The VA is an outstanding service system for this study of PADs because they can be archived in Computerized Patient Record System where the VA mental health crisis clinicians can have ready access to them."

Dr. Butterfield and the VA HSR&D PAD research team, Maren Olsen, Ph.D., Hayden Bosworth, Ph.D., Jennifer Strauss, Ph.D., James Tulskey, M.D., Larry Dunn, M.D., Pat Spivey, B.A., and Timothy Wampler, M.S.W., will examine several areas

in this research study, including: PAD effectiveness in guiding treatment during a mental health crisis; the effects of PADs on patients' willingness to engage in treatment; effects of PADs on mental health service use and clinical outcomes, and; describe veteran preferences for PAD content and completion. Consultant Mark Boggs, J.D., at U.N.C. School of Law will assist the research team with the legal issues surrounding PADs in North Carolina. He assisted in the current North Carolina PAD legislation.

The study is a randomized trial conducted at the Durham VA Medical Center drawing on a sample of 340 veterans with severe mental illness and examines the implementation of PADs for one year. Half the group will randomly be assigned to a PAD intervention and half to a "usual care" group. PAD patients will be given individual orientation and assistance in completing a PAD and control patients will be given a brief orientation to PADs as part of informed consent. A healthcare provider orientation to PADs will be given as well. Patients will then be given an interview at one month, six months, and twelve months in order to determine PAD effects on mental health crisis management, involuntary commitment rate, patient perceived coercion, treatment engagement, clinical outcomes, and VA mental health service use.

"The practical impact to this research," says Dr. Butterfield, "ideally, will be improved management of mental health crisis by streamlining care through advanced treatment planning, less coercive treatments, and fewer involuntary hospitalizations while giving severely mentally ill veterans greater care options. Theoretically, it will also improve the working alliance between patients and clinicians, which should enhance

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treatment engagement and possibly shift treatment patterns from inpatient to out patient services, and thus create a more patient-centered care for our veterans. Though there is increasing use of ambulatory mental health care by veterans with severe mental illness, the majority, about 58%, of VA mental health care resources are still spent on inpatient psychiatric care. All of these combined strategies should enhance veterans' care while reducing overall costs for mental health care as well."

This four-year VA-PAD study, with funding of \$894,077 from HSR&D, began July 1 of this year. A collaborative sister study, a NIMH and MacArthur Foundation funded effort, will concurrently allow Duke investigators Jeff Swanson, Ph.D., Marvin Swartz, M.D., and Eric Elbogen, Ph.D., to evaluate PADs in the N.C. state mental health system. This study will also be a health services research interventional trial of PADs. Together, these research efforts will also afford comparisons between VA and the state mental health system.

Faculty Begin New NIH Grant

Can both a nurse administered behavioral intervention and blood pressure self-monitoring intervention improve a patient's blood pressure control? With approximately only 25% of the 50-60 million Americans with hypertension having their blood pressure under effective control, that is what Hayden B. Bosworth, Ph.D. Eugene Z. Oddone, M.D., M.H.Sc., Maren K. Olsen, Ph.D., Rowena Dolor, M.D., M.H.Sc., and Martha Adams, M.D., from the Center of Health Service Research in Primary Care at Durham VA and the Division of General Internal Medicine at Duke University, would like to determine in their "Take Control of Your Hypertension (TCYB) Study."

The five-year randomized trial will enroll 570 hypertension patients from three local Duke General Internal Medicine clinics in the Durham area. Patients will be randomly assigned to one of four options; nurse intervention alone, home monitoring alone, both interventions, or usual care. Patients randomized to the nurse disease management program will receive training to promote medication adherence, support, and reminders, as well as information on the risks of hypertension, health behaviors, patient/provider communication, literacy, and medication side effects through periodic telephone contacts. Patients assigned to the home blood-pressure monitor will record their blood-pressure bi-weekly and will provide this information either to the intervention nurse or their health care provider.

"This study will be an important step in testing the effectiveness of both a nurse and self-administered intervention to improve blood-pressure control among a community sample," says Dr. Bosworth, principal investigator of this study. "One of the national health objectives for the year 2010 is to increase the proportion of patients with controlled blood-pressure to at least 50%, and this study will provide important information that will help meet these goals."

An important aspect of the study site is that it's located in the South. People in the Southeastern United States, and African-Americans in particular, experience greater hypertension-related health problems such as stroke, cardiovascular disease, myocardial infarction, renal failure, and congestive heart failure, than any other region of the country. It is estimated that approximately 40% of the study sample will be from under-represented minority patients.

This five-year study is possible through a \$2.3 million grant from the National Heart, Lung, and Blood Institute. The study began June 1, 2003.

HSR's New Health Economists

Health Services Research would like to welcome Santanu K. Datta, Ph.D., and Courtney H. Van Houtven, Ph.D., as our new health economists. Drs. Datta and Van Houtven mark the beginning of the Center's Health Economics Core as of July 1.

Santanu Datta

Dr. Datta received a B.S. in chemistry (1989), an M.B.A. in finance (1991) and an M.S. in economics (1993) from Florida State University. He received his Ph.D. from the University of North Carolina at Chapel Hill School of Public Health with a focus on health economics in 2002.

"My main research interest lies in developing statistical or decision analytic models to assess the cost-effectiveness and economic impact of alternative technologies, interventions, or screening programs," says Dr. Datta. "I would also like to develop interviews and surveys that assess the preference values, utility scores, and risk perceptions of disease health states. In the future, I will be learning to utilize the various VA cost and resource utilization data sets to conduct economic research studies."



Dr. Datta was an associate in research at Duke Center for Clinical Health Policy Research from 1997 to 2001 where he conducted research in the areas of women's health (hormone therapy, breast cancer, prolonged pregnancy, cervical cancer, uterine fibroids, stress incontinence), cardiovascular disease (coronary heart disease, stroke and coronary artery bypass graft), peptic ulcer disease, hip fracture prevention, and smoking cessation. He began part-time with HSR&D in July 2001 and became full-time this spring. His current research involves working with Dr. John Whited to assess the cost-effectiveness of various telemedicine interventions in dermatology and ophthalmology. He has started collaborative research with HSR&D faculty members Drs. Eugene Oddone, Will Yancy, Lori Bastian, David Edelman and Morris Weinberger in assessing the impacts of various diseases and interventions.

“I’m excited by the vast resources of expertise that is available at the Durham VA and Duke University Medical Center,” says Dr. Datta, “and I look forward to establishing more research collaborations in the future.”

Courtney Harold Van Houtven

Dr. Van Houtven comes to us from the University of North Carolina at Chapel Hill where she has been in the AHRQ/NRSA Postdoctoral Fellow Program at the Cecil G. Sheps



Center for Health Services Research since 2000, and an adjunct assistant professor in the School of Public Health’s Department of Health Policy and Administration since 2001. Much of her research there has focused on economic aspects of informal care of elderly parents by their adult children, and examining how a home and community based

waiver program for disabled adults on Medicaid has affected home and nursing home services and costs.

Dr. Van Houtven received her B.S. in managerial economics from the University of California at Davis in 1989; her M.S. in applied economics from the University of Minnesota in 1991; and her Ph.D. in health policy and administration from the University of North Carolina at Chapel Hill in 2000. As a result of her work at U.N.C., she received the prestigious Academy for Health Services Research and Health Policy Dissertation Award.

Here at HSR&D, Dr. Van Houtven plans to continue her research interests from U.N.C. “I want to examine the long-term care issues and the economics of aging, the economics of informal caregiving, and the access to care for elderly adults and disabled adults,” says Dr. Van Houtven. “I am very interested in designing projects that will allow the collecting of data that will help us better understand aspects of informal and long-term care for elderly adults and persons with mental illness.”

Dr. Van Houtven recently received a two-year grant from N.I.H.’s National Institute on Aging for a study titled “Informal Care and Medicare Expenditures.” She will use data from the Health and Retirement Survey and Medicare claims in order to quantify how informal care of elderly parents by adult children affects Medicare expenditures.

“I’m also interested in mental health policy and the economics of mental health,” adds Dr. Van Houtven. “I’d like to explore the rich databases that the VA has on expenditures and costs of care and for pharmaceutical care.”

Dr. Van Houtven is a member of the Academy for Health Services Research and Health Policy and the International Health Economics Association.

Quality of Life at the End of Life

Within the last decade, public and private efforts have intensified to improve care of dying patients and their families. Millions of dollars have been spent on education of medical personnel, advance directives, and hospice and palliative care. However, if health care institutions are to provide high quality compassionate end-of-life care, researchers and clinicians must establish a valid means of assessing the experiences of dying patients. In fact, the Institute of Medicine, the American Medical Association, the Robert Wood Johnson Foundation and other institutions have highlighted outcomes assessment as a high priority in efforts to advance care of dying patients. In response, Karen Steinhauser Ph.D., along with her research colleagues, Hayden Bosworth Ph.D., Elizabeth Clipp R.N., M.S., Ph.D., Maya McNeilly Ph.D., Nicholas Christakis M.D., Ph.D., M.P.H., Joanna Parker M.A., and James Tulsky M.D. have developed a new instrument to measure quality of life at the end of life. The assessment tool, known as the QUAL-E, is described fully in the December 2002 issues of the *Journal of Palliative Medicine*.*

“The purpose of this study,” says Dr. Steinhauser, “was to create and validate an instrument to assess the quality of life of patients with a range of advanced serious illness, such as cancer, congestive heart failure, chronic obstructive pulmonary disease, and end-stage renal disease, who may be receiving care in a variety of settings, and may or may not define themselves as ‘dying’.”

She and her research colleagues developed the instrument inductively based on qualitative and quantitative accounts of what seriously ill patients, recently bereaved family members, and various health care providers considered important at the end of life. The initial validation was completed with a sample of two hundred patients with advanced serious illness enrolled from the Durham VA and Duke University Medical Centers. The study yielded a 31-item instrument representing five domains: life completion, relationship with health care providers, preparation for the end of life, pain and symptom impact, and affective social support.

Dr. Steinhauser and her colleagues note that, “In recent years, palliative care researchers have been working to develop tools specifically designed to capture the unique experiences of dying patients.” The QUAL-E was intended to build on the strengths of existing instruments and extend their work in several ways. First, as noted, the QUAL-E was derived not primarily from expert opinion, but rather based on the experiences of patients themselves. Second, each domain or sub-scale includes patient importance-ratings to accommodate individual differences in the definition quality at the end life. Third, the QUAL-E’s content differs from other available instruments. For example, items assessing concern about the family’s preparation for the end

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of life, having an opportunity to contribute to the well-being of others, and relationship with health care providers are novel. Furthermore, QUAL-E domains similar to those in other instruments are extended. For example, pain and symptom impact was expected to be important; however, the QUAL-E includes patients' concerns about symptom expression not only in the present but in the future. Patients often have anticipatory fears about waking in the night with pain or shortness of breath. The new tool accommodates those future concerns. Finally, spiritual or transcendent issues are captured in the domain of life completion, which accounted for the most variance explained in overall quality of life. Life completion included items such as sharing important things with family, having a sense of meaning, being at peace, and contributing to others. Interestingly, "we often focus on what dying persons need to receive, and these findings remind us of the importance of giving as a quality at the end of life."

The QUAL-E was designed primarily as a research instrument to evaluate the effectiveness of interventions designed to improve care of dying patients. However, clinicians also may find it helpful as a communication guide or survey to assess what individual patients regard as important in their experience at the end of life. The QUAL-E is available for download at the Center's Program on the Medical Encounter and Palliative Care website: <http://hsrd.durham.med.va.gov/pmepec>.

*Steinhauser KE, Bosworth HB, Clipp EC, McNeilly M, Christakis NA, Parker J, Tulsy JA. "Initial Assessment of a New Instrument to Measure Quality of Life at the End of Life" *Journal of Palliative Care* 2002 (December); 5(6): 829-841.

HSR&D Welcomes New M.D. Fellows

The Center welcomes five new M.D. research fellows, Adi Cohen, Christopher E. Cox, Suneet Kaur, Jay R. McDonald, and Shahnaz Sultan who began this July. Each year The Center supports physicians interested in the structure, process, and effects of healthcare services that can be used to improve the VA medical system through two-year medical fellowships.

Adi Cohen

Adi Cohen, M.D., will be funded on the Office of Academic Affairs' Women's Health Fellowship. She has just finished a three-year Endocrinology fellowship where her focus was on osteoporosis and metabolic bone diseases in relation to women's health.

"During my fellowship, I was involved in a project on prospective evaluation of bone metabolism and bisphosphonate therapy in a population of postmenopausal women with breast cancer who were being withdrawn from tamoxifen as part of their routine care. I also had the opportunity to act as a fellow-coordinator on a cross-sectional study evaluating bone health in adult survivors of pediatric cardiac transplantation," says Dr. Cohen. "These

research activities allowed me to gain hands-on experience in study design, patient recruitment, patient-oriented research techniques, basic statistical analysis, and scientific writing."

Dr. Cohen received her B.S. in Molecular and Cellular Biology from Haverford College where she was Phi Beta Kappa and graduated magna cum laude in 1993. She graduated from New York University School of Medicine in 1997, and did her residency in Internal Medicine at New York University Medical Center/Bellevue Hospital from 1997 through 2000. From there, Dr. Cohen went on to the College of Physicians and Surgeons of Columbia University for a fellowship in Endocrinology and Metabolism from 2000-2003.



"I feel this fellowship will provide me with formal training in patient-oriented research, give me a chance to improve my teaching skills, and provide me the solid foundation I'll need for my future academic career," says Dr. Cohen. "I believe it will help me develop a women's health research focus within Endocrinology as well."

Dr. Cohen is board certified in Internal Medicine and in Endocrinology, Diabetes and Metabolism. She is the lead-author of a number of journal articles and abstracts.

Christopher E. Cox

Christopher Cox, M.D., began his Agency for Healthcare Research and Quality fellowship in July. His overall interest is in critical care outcomes research, psychometric measurement and methodology, and health economics research.

Dr. Cox received a B.S. in biology from the University of North Carolina at Chapel Hill, graduating Phi Beta Kappa, in 1992. He received his M.D. from the Medical University of South Carolina at Charleston in 1997, graduating Alpha Omega Alpha. He then completed his residency in Internal Medicine at New York University in 2000. From there he received a National Research Service Award and completed a Masters of Public Health and clinical research fellowship at UNC-CH in 2002. He is currently a fellow in Pulmonary and Critical Care at Duke University Medical Center.



"During my HSR&D fellowship, I plan to focus on outcomes of critical illness survivors," says Dr. Cox, "as well as their families or surrogates. Specifically, I'm

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interested in how best to measure outcomes in terms of quality of life, functional status, and economic outcomes. I'm primarily interested in a social science-oriented approach to patient-centered outcomes measurement."

Dr. Cox is a member of the American Thoracic Society and American College of Chest Physicians.

Suneet Kaur

Suneet Kaur, M.D., began her Office of Academic Affairs Women's Health Fellowship in July. Her interest is in clinical research related to women's health issues, with a specific interest in Polycystic Ovary Syndrome.

Dr. Kaur received her B.S. in Biology from the Rochester Polytechnic Institute, graduating summa cum laude in 1995. She graduated from the Albany Medical College in 1999 and completed the Internal Medicine Primary Care Program Women's Health Track in Internal Medicine at the University of Rochester in 2000. She completed her residency in Internal Medicine at the Strong Memorial Hospital at the University of Rochester in 2002. She worked as an attending physician at the General Medical Unit at the Rochester General Hospital for several months since the completion of her residency.



After completing her fellowship here, Dr. Kaur plans to go into academia. "I enjoy teaching as much as I enjoy practicing medicine," she says, "and would also like to become more involved in clinical research."

Dr. Kaur is a member of the American College of Physicians.

Jay R. McDonald

Jay McDonald, M.D., comes to us through an Agency for Healthcare Research and Quality fellowship. His research interests are in nosocomial infections and antimicrobial resistance, and in particular the interface between hospital and community, and how the epidemiology of resistant bacteria crosses that interface.

Dr. McDonald received a B.A. in economics from Duke University in 1991 and a B.S. in Biology from Portland State University in 1994. He received his M.D. from the Oregon Health Sciences University in 1998 and completed his residency in Internal Medicine at the Duke University Medical Center in 2001. He also completed the clinical year of his infectious diseases fellowship at Duke in 2002 and has just completed a one-year chief residency in Internal Medicine at the Durham VA



Medical Center.

Dr. McDonald's research interest at the VA is the spread of resistant bacteria in the community population. "The spread of nosocomially-acquired resistant bacteria into a community setting is a relatively recent phenomenon which has huge implications on antibiotic use, infection control practices, and public health," says Dr. McDonald. "I hope to use the VA and other hospital communities to better define the nature and extent of the problem of the spread of resistant bacteria into the community. I would like then to begin to find ways to limit this spread, as well as identifying high-risk populations in order to adapt our infection control practices and antibiotic prescribing patterns accordingly."

Dr. McDonald is a member of the American College of Physicians and the Infectious Diseases Society of America.

Shahnaz Sultan

Shahnaz Sultan, M.D., began her Health Services Research and Development Fellowship in July. Her interest is in gastroenterology, with a particular emphasis on colorectal cancer. Her long-term career goal is to be a clinical academician primarily involved with clinical research.

Dr. Sultan received a B.A. in Biology from Brooklyn College of The City University of New York, graduating magna cum laude in 1991. She received her Doctor of Medicine from State University of New York College of Medicine in 1996. She did her residency in Internal Medicine at the New England Medical Center in Boston from 1996 to 1999, and completed a three-year fellowship in Gastroenterology at Duke University Medical Center in 2003.



"As a fellow," says Dr. Sultan, "I spent one year focusing on the genetics of colon cancer and this experience gave me the opportunity to acquire some fundamental knowledge in tumorigenesis. My desire to apply this knowledge to patient care has been the impetus for my interest in clinical research in the field of colorectal cancer."

"The HSR&D Fellowship will provide me with a unique opportunity to learn the fundamentals of clinical research in a protected and supportive environment. My research focus will be to examine the barriers to colorectal cancer screening and to examine factors associated with the quality of colorectal cancer care."

Dr. Sultan is the first and co-author of a number of journal articles, book chapters, and abstracts. She is also a member of the Gastroenterology Research Group, the American Gastroenterology Association, and the American Society of Gastrointestinal Endoscopy.

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Research Update



Department of
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Faculty Publications

DOMINICK KL, Ahern FM, Gold CH, Heller DA. "Relationship of health-related quality of life to health care utilization and mortality among older adults" *Aging Clinical and Experimental Research* 2002; 14:499-508.

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BUTTERFIELD MI, BOSWORTH HB, Meador KG, STECHUCHAK KM, Essock SM, Osher FC, Goodman LA, Swanson JW, BASTIAN LA, Horner RD, and the Five-Site Health and Risk Study Research Committee. "Gender Differences in Hepatitis C Infection and Risks Among Persons With Severe Mental Illness" *Psychiatric Services* 2003 (June); 54(6): 848-53.

Research Update is published by the Health Services Research and Development Service, Department of Veterans Affairs Medical Center, Durham. For questions or comments contact Ed Cockrell, Administrative Officer, VAMC (152), 508 Fulton Street, Durham NC, 27705. Telephone: (919) 286-6936, Fax: (919) 416-5836. E-mail: COCKR001@mc.duke.edu Web Page: <http://hsrd.durham.med.va.gov/> The Institute's mission is to provide quality information on issues regarding the organization, financing, and delivery of veterans' health care, and to build the epidemiological capacity of the Veterans Health Administration through the generation, synthesis, and dissemination of epidemiological information. The Institute also has a mission to educate health professionals through a spectrum of training grants in the techniques of health services and epidemiological research.