



the Research Monitor

Veterans Affairs Health Services Research & Development Center of Excellence
and Section of Health Services Research, Department of Medicine, Baylor College Of Medicine

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Julianne Soucek, PhD
Maria Suarez-Almazor, MD, PhD
Mary J. York, PhD

HCQCUS Bridges Quality Chasm with New Leadership

Carol M. Ashton, MD, MPH, HCQCUS Director and Baylor HSR Section Chief



Carol Ashton

Effective January 1, 2003, the Houston Center for Quality of Care & Utilization Studies is proud to announce the appointment of four new associate directors. They are: Rebecca J. Beyth, MD, MS; Marvella E. Ford, PhD; Mark E. Kunik, MD, MPH; and Maria Suarez-

Almazor, MD, PhD. Michael Johnson, PhD, who has been the associate director since 1999, will be stepping down to turn his attention to his research career. He was notified recently that he is the recipient of a VA Career Development Award. Mike's energies, devotion, and competence have been a critical help to me over the past years.

Our Center has changed considerably over the past three years, and we are facing major changes now related to our successes. Consequently, I am envisioning a new role for the associate directors. In addition to being a part of the Center leadership team, participating in strategic planning, implementation and decision-making, each new associate director will be responsible to develop a self-selected area of research leadership within our Center's broad focus of quality of care and utilization. This self-selected area will encompass some of the parts of research team leaders and may well involve new resources depending, in part, on the success and ingenuity of the associate director.

I see this new Associate Director program as fundamental and absolutely essential to the continued growth and evolution of our Center. It is my opinion that the entire VA HSR&D Services and all other health services research centers are facing a dearth of developed leaders. This is because of the extremely successful research capacity building that has occurred in the VA HSR&D Services and in the non-VA sector over the past decade. The problem is that no attention has been given to developing leaders of research units. VA HSR&D now has 13 full-fledged centers and nearly 15 "mini Centers." These places may have leaders now, but what will happen when those people move on? I have been relentless in championing this issue, and if we are indeed going to bridge the quality chasm, we must begin at home. Even our junior team leaders who are not yet established scientists, and therefore were not eligible to be considered as new associate directors, have my word that I will do my utmost to ensure that they still have opportunities to develop as leaders.

Since 1989, when Dr. Nelda Wray and I began to write the application that got this Center established in 1990, my professional life has been the most satisfying and the most profoundly challenging and rewarding that a person could ever imagine. It is not only that I have had the chance to create new knowledge in the process of doing research with you, my top-notch colleagues and friends. It is having had the indescribable pleasure of helping to create an organizational entity that did not exist before and that exists to make medical care better, and in the process is a place where people can fulfill their professional dreams.

Mission Statement

The Center impacts health and health care by conducting and translating outstanding research and by developing influential leaders in health outcomes, quality, access, utilization and cost.

HCQCUS Appoints Four New Associate Directors



Rebecca Beyth

Rebecca J. Beyth, MD, MS, graduated from Case Western Reserve University, Cleveland, Ohio with honors in 1982. She attended Jefferson Medical College, Philadelphia, Pennsylvania and graduated in 1987. She completed her internal medicine residency training at

Michigan State University Associated Hospital System in East Lansing in 1990. Additionally, she completed a general internal medicine research fellowship in 1992 and a clinical geriatric medicine fellowship in 1994, both at Case Western Reserve University. She also received a Master's degree in clinical research design and statistical analysis at the University of Michigan in Ann Arbor in 1999. She had previously been on faculty at Case Western Reserve University School of Medicine, Program in Health Care Research, and was an attending at University Hospitals of Cleveland, and the Cleveland Veterans Affairs Medical Center.

Dr. Beyth's research agenda includes improving the process of care and outcomes of chronic illnesses using stroke prevention for patients with chronic atrial fibrillation as a model. She has recently completed a 5-year career development award from the NIA on improving the use of anticoagulant therapy in older patients, as well as a project grant from the American Heart Association. In addition, she has recently received a 5-year R01 from the National Heart Lung and Blood Institute for improving stroke prevention in atrial fibrillation, as well as an advanced career development award from the Department of Veterans Affairs. She has also assumed the position of research coordinator for the VA CHF QUERI coordinating center. She also is collaborating with Dr. Tracie Collins on a VA grant to improve the process of care for veterans with peripheral arterial disease.

Her self-selected area of research leadership will be focused on gaining the necessary skills and tools to be able to understand and effectively translate

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Marvella Ford

Marvella E. Ford, PhD, received her doctorate in social work and social psychology in 1992 from the University of Michigan in Ann Arbor. She received her MS in social psychology in 1989 and her MSW in social work in 1987, also from the University of

Michigan. Dr. Ford's undergraduate work was conducted at Cornell University in Ithaca, N.Y., from which she graduated in 1986.

Some of Dr. Ford's research highlights include numerous grants on which she serves as principal investigator or co-investigator. The purpose of Dr. Ford's grant "*Improving Informed Consent in Diverse Populations*" is to identify factors associated with improved comprehension and recall of the information contained on informed consent forms. This R01 grant is funded by the National Cancer Institute.

The long-term objective of her grant "*Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial-Recruitment of African American Men (AAMEN Project)*" is to identify a method for increasing the recruitment of African American men to cancer screening trials. The AAMEN Project grant is funded by the Centers for Disease Control and Prevention and the National Cancer Institute.

The goal of Dr. Ford's grant "*Understanding Factors Related to Prostate, Lung, and Colorectal Cancer Screening Among African American Men*," funded by the Department of Defense, is to identify factors associated with cancer screening adherence and cancer screening perceptions among African American men.

The purpose of her grant "*Examining the Effects of a False Positive Result on Subsequent Cancer Screening Behavior*," funded by the National Cancer Institute, is to ascertain whether having a false positive result on a PSA test for prostate cancer or on a chest x-ray for lung cancer affects subsequent screening behavior for these cancers.

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Mark Kunik

Mark E. Kunik, MD, MPH, graduated from the University of Texas with honors in 1983. He received his MD from Baylor College of Medicine in 1987, completed his residency in psychiatry at Baylor College of Medicine in 1991, and was a geriatric psychiatry fellow at Western Psychiatric

Institute and Clinic, University of Pittsburgh School of Medicine, 1991-1992. In December 2000, Dr. Kunik received his MPH at the University of Texas School of Public Health. In addition to his appointment as an HCQCUS associate director, Dr. Kunik is currently an associate professor, Department of Psychiatry & Behavioral Sciences, Baylor College of Medicine and Co-Director, South Central Mental Illness Research, Education, and Clinical Center (MIRECC) Special Fellowship in Advanced Psychiatry and Psychology.

Dr. Kunik was the director of geropsychiatry at the Houston VAMC from 1993-1999. In 1999, Dr. Kunik received an VA HSR&D Advanced Research Career Development Award. This career award provided the experience and training to transition him into health services research career. Through the award, he completed an MPH, and moved into health services research at HCQCUS and the South Central MIRECC. Dr. Kunik has published more than eighty articles in peer-reviewed journals.

Dr. Kunik's work has primarily focused on developing better care for persons with comorbid medical and psychiatric diseases. For example, historically, many practitioners have accepted aggression as an inevitable part of dementia (e.g., Alzheimers dementia) and consequently make no effort to prevent it, choosing instead to treat it with physical and chemical restraints. Dr. Kunik's research has help to better define the causes, assessment and treatment of psychiatric problems that develop in persons with dementia. Currently, Dr. Kunik has a VA HSR&D grant that compares the use of two educational interventions in improving quality of life in persons with chronic obstructive pulmonary disease (e.g., emphysema).

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Maria Suarez-Almazor

Maria Suarez-Almazor, MD, MS, PhD, received her MD from Universidad Nacional de Buenos Aires, Argentina in 1979, a Master of Science degree in medicine from the University of Alberta, Canada in 1989 and a Doctor of Philosophy degree in medical sciences, epidemiology from the

University of Alberta in 1993. Dr. Suarez-Almazor has over 120 peer-reviewed publications indexed in Medline. She is principal investigator on three grants, including: *"Treatment Adherence in Minorities with Rheumatic Disease,"* funded by the National Institutes of Health; *"Impact of Patient Provider Interaction on the Response to Acupuncture,"* also funded by the NIH; and *"Outcome Assessment in Scleroderma,"* funded by the Scleroderma Foundation.

In addition, Dr. Suarez-Almazor is co-investigator on three grants. These include: *"Racial and Ethnic Variation in Medical Interactions,"* funded by the Agency for Health Research and Quality; *"Cost Analysis of Secondary Conditions in disabled Women,"* funded by the Centers for Disease Control and Prevention; and *"Process of Care in Peripheral Disease,"* funded by the Department of Veterans Affairs.

Dr. Suarez-Almazor has trained as a rheumatologist and an epidemiologist, and her specific interest is in clinical epidemiology. "Clinical epidemiology" can be defined as the application of scientific epidemiologic principles and methods to problems encountered in clinical medicine. It can be interpreted broadly to be the study of the determinants and effects of clinical decisions. It attempts to answer clinical questions relevant to the daily practice of medicine and other health sciences, to bridge the gap between research and clinical practice, and to improve patient care.

The scope of clinical epidemiology is broad, and it involves a number of distinct research areas, including the identification of risk factors and prognostic factors in diseases, efficacy, effectiveness and utility of interventions, patient preferences, and clinical decision-making. Within this broad spectrum, the field Dr. Suarez-Almazor is the most interested in developing and expanding is 'health

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Feature Article

Feature Article

Beyth

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findings from clinical trials into real world settings using stroke prevention in chronic atrial fibrillation and CHF care as a model.

This goal is consistent with the HCQCUS's broad focus on quality and health services utilization. It is also of importance because the prevalence of chronic illnesses increases with age and our population is aging. Thus, both clinicians and researchers will need to understand how to effectively treat patients with chronic illnesses. Good chronic care requires continuity over time, multidisciplinary teamwork and collaborations between medical and non-medical service providers; areas that the VA health care system has already recognized as important. She will use her past research and leadership experience in the role as associate director to work with the Center Director to develop this line of research. Although her particular interest is in thromboembolic disorders, this research agenda is inclusive of any component of a chronic illness and the collaborative care model.

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Ford

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Currently, Dr. Ford serves as a co-investigator on Dr. Kimberly O'Malley's Measurement Excellence Initiative (MEI). The purpose of the MEI, funded by the VA Health Services Research and Development unit, is to increase the quality of measurement in health services research. The MEI creates tools and mechanisms that aid in efficient information gathering for research projects and provides "on-line" access to these tools and the information. Additionally, the MEI educates researchers on recent advances in measurement knowledge and use.

Dr. Ford is also a co-investigator on Dr. Rebecca Beyth's grant *Improving Anti-Thrombotic Use in Stroke Prevention*, funded by the National Heart, Lung, and Blood Institute. The goal of this study is to increase the appropriate use of anti-thrombotic therapy for stroke prevention in patients with chronic atrial fibrillation in accordance with national practice guidelines. The study incorporates a randomized, controlled trial design.

Dr. Ford also serves as a co-investigator on research grant applications led by Drs. Mark Kunik, Paul Haidet, Howard Gordon, Tracie Collins, and Mary York.

Dr. Ford also currently serves as a co-investigator on Dr. Jennifer Elston-Lafata's study *"Understanding Racial Disparities in Mammography Use among Breast Cancer Survivors."* The purpose of this study, funded by the Department of Defense, is to develop and pilot a survey instrument to elicit breast cancer survivors' preferences for different surveillance care attributes. Pilot test results will be used to describe the characteristics of care that are likely to foster surveillance care use among African American and Caucasian women.

Dr. Ford recently served as a co-investigator on Dr. Ed Wagner's study *"Increasing Effectiveness of Cancer Control Interventions."* The purpose of this study, funded by the National Cancer Institute, was to determine and improve the effectiveness of cancer control interventions that span the natural history of major cancers among diverse populations and health systems. Dr. Ford will also serve as a co-investigator for Phase II of the Cancer Research Network, which will begin in the spring of 2003.

Dr. Ford recently served as a co-investigator on Dr. Vic Strecher's study *"Tailored Interventions for Multiple Risk Behaviors."* The purpose of this study, funded by the National Cancer Institute, is to examine, through a randomized, 2x2 factorial trial, the effectiveness of two generalizable interventions, both individually and in combination, in achieving behavior change of four targeted health risk behaviors.

Dr. Ford has published 21 manuscripts in peer-reviewed journals. In addition, she has written five chapters in well-respected edited books, and has made 20 presentations at scientific meetings to disseminate her research findings.

She also holds current membership on an NIH study section (Health Risk, Prevention & Health Behavior IRG - Study Section 3), has conducted past work on an ad hoc study section for the Centers for Disease Control and Prevention, conducts current work as a consulting editor for *Health & Social Work*, and is currently an ad hoc work manuscript reviewer for *Nicotine & Tobacco Research*, *Medical Care*, *Journal of the National Medical Association*, and *Cancer Epidemiology, Biomarkers & Prevention*.

In March 1998, Dr. Ford was awarded the Anthony V. DeVito II Memorial Award in Professional Excellence, Personal Integrity, and Dedication to Geriatrics Education from the University of Michigan Geriatrics Center.

Dr. Ford's proposed research agenda as a newly appointed HCQCUS associate director is to build upon existing research conducted at the Center to develop a Health Disparities Research Program. The Program would focus on increasing the amount of scientifically sound health disparities research conducted at the Center, using a health services research paradigm. Key strategic goals related to the proposed health disparities research program include the following:

1. To increase the amount of federal funding for health disparities research awarded to the Center
2. To increase communication and collaboration among Center investigators conducting health disparities research in order to develop cohesive action plans for future funding opportunities
3. To partner with investigators at minority serving institutions in order to build on their unique perspectives in addressing health disparities issues
4. To increase the amount of federal funding to the Center related to training programs for members of minority serving institutions. The purpose of the funding would be to provide training in health services research to faculty and students at minority serving institutions, so that they can gain research and administrative skills that will allow them to become competitive in applying for federal funding opportunities designed to increase and improve disparities research
5. To develop a local and national identity as a Health Disparities Research Program

Kunik

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In addition, Dr. Kunik has two pending grants that aim to determine the antecedents and consequences of aggression in persons with dementia, and then use this information to develop a preventative strategy.

Improving quality of care for those with chronic illnesses through more effective systems of care is Dr. Kunik's chosen research area in his role as

associate director. Serving the needs of the chronically ill through coordinated, seamless care across settings and clinicians is a collaborative process. He plans to champion the chronic care model which includes the following components:

1. Definition of clinical problems in terms that both patients and providers understand.
2. Joint development of an evidence-based care plan with goals, targets, and implementation strategies.
3. Provision of self-management training and support services.
4. Active, sustained follow-up visits that may include telephone calls, e-mail, or web-based monitoring.
5. Connection to community resources.

Dr. Kunik hopes that the emphasis on developing research that improves the processes of care through the chronic care model approaches will serve to strengthen our Center's work to improve quality of care and increase our Center's involvement in real world community health settings such as community clinics, large health care systems, and long term care.

Suarez-Almazor

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decision making." Medical and clinical decision-making are terms that have been extensively used in the past, but health decision-making is a better, more descriptive and up-to-date term, which encompasses not only clinical decisions by patients and physicians, but also, behavioral decisions that individuals make about their health at large.

The past decade has seen a major emphasis in research related to decision-making sciences in health care. There is an implicit recognition that individual decision-making at policy, clinical or patient levels is a major determinant of health care and health outcomes. For this reason, she believes that this research field is of major relevance to the mission and goals of the Houston Center. Much of the past research in health care has been primarily descriptive, documenting variation, inequity, differential outcomes and system inefficiencies. As these issues have gained recognition, there has been increased emphasis in causation and analytical research at the individual level (patients and professionals), with the expectation of identifying and understanding the foundations and determinants of health decision-making and its effects on

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Feature Article

Funding Updates

New Research Grants

PI: **Hashem B. El-Serag, MD, MPH**

Source: Janssen Pharmaceutica

Title: "Outcomes of Surgical Fundoplication in Children with GERD"

Amount/Period: \$19,344; 4/02-4/03

PI: **Hashem B. El-Serag, MD, MPH**

Source: Schering-Plough

Title: "The Effect of HCV C-Infection on the Clinical Course of HIV-infected Patients"

Amount/Period: \$49,891; 8/02-7/03

PI: **Hashem B. El-Serag, MD, MPH**

Source: National Cancer Institute

Title: "Analysis of SEER-Medicare Data on Hepatocellular Carcinoma"

Amount/Period: \$39,190; 10/02-9/03

PI: **Marvella E. Ford, PhD**

Source: Department of Defense

Title: "Understanding Factors Related to Prostate, Lung and Colorectal Cancer Screening Among African American Men"

Amount/Period: \$151,934; 2/02-12/03

Prostate, lung, and colorectal cancers affect the mortality of African American men in disproportionate numbers relative to Caucasian men. For example, African Americans, who appear to have more locally advanced prostate cancer upon presentation to a physician than Caucasian men, have the highest prostate cancer incidence and mortality rates of any other racial group. Retaining African American men in cancer clinical trials is of vital importance, given their relatively small number in these trials. Information is also needed about the knowledge, attitudes, and beliefs of trial participants toward cancer screening because these factors affect adherence to trial processes. Also, more information is needed to ascertain whether having a false positive result on an earlier PSA screening test affects subsequent PSA test screening behavior. Specific Aims of the study are:

- (1) To evaluate the efficacy of an intervention (begun in Phase I) aimed at retaining African American men in the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO Trial);
- (2) To assess the psychometric properties of a survey

designed (in Phase I) to measure perceptions of cancer screening among African American men; (3) To ascertain whether having a false positive PSA cancer screening test result affects subsequent adherence to PSA cancer screening testing among PLCO Trial participants; and (4) To assess racial differences in the rate of false positive PSA cancer-screening test results.

The findings from this study will lay the foundation for a future trial of an innovative retention intervention. The survey could be used in a cohort of African American male cancer screening trial participants, to assess beliefs about cancer screening and to identify those for whom more intensive interventions might be necessary in order to reduce attrition. Further, the study results will identify whether having a false positive PSA cancer screening test result is likely to inhibit or facilitate subsequent PSA test screening behavior. Interventions could be developed to assess and respond to the meaning of a false positive PSA screening test result among study participants.

PI: **Robert O. Morgan, PhD**

Source: National Institutes of Health

Title: "Medicare + Choice and Minority Elderly"

Amount/Period: \$936,131; 9/02-9/05

Medicare is specifically mandated to provide health care services to elderly and/or disabled United States residents, as well as those with end stage renal disease. Although Medicare has been successful in dramatically improving both the access to care and the overall health of its constituents, studies have shown inequalities in care associated with the race/ethnicity of Medicare beneficiaries. On the surface, Medicare health maintenance organizations (HMOs) appear to address some of the factors associated with these inequalities, however, the Medicare HMO program, now called Medicare+Choice (M+C), is itself undergoing substantial program changes as a result of the Balanced Budget Act (BBA) and subsequent revisions, e.g., the Balanced Budget Revision Act (BBRA) and the Benefits Improvement and Protection Act (BIPA). This study has two broad objectives. First, we will determine individual level characteristics related to M+C plan enrollment among elderly White, Black, and Hispanic Medicare beneficiaries, whether the factors which elderly Black and Hispanic beneficia-

ries report as influencing their enrollment in HMOs differ from those that influence elderly White Medicare beneficiaries, and whether elderly Black and Hispanic beneficiaries enrolled in HMOs differ from HMO enrolled elderly White beneficiaries in terms of their self-reported health, use of health care, and perceived access to care. Second, we will examine the availability of Medicare HMOs and benefit packages for beneficiaries of differing race/ethnic classifications, how HMO enrollment rates are related to race/ethnic classification and range of plan benefits, and how the availability of HMOs and HMO enrollment by different race/ethnic groups changed subsequent to implementation of BBA provisions. We will use both survey and population-based (using Medicare administrative data and other population-based data) methodologies to examine individual and system level factors affecting access to and use of medical care, the availability of plans and services, and plan selection by enrollees. This study will provide the first comprehensive examination of both individual and system level factors affecting minority use of the Medicare HMOs, and will provide needed information on how the evolving Medicare system is affecting health care for Black and Hispanic Medicare beneficiaries.

PI: **Maria Suarez-Almazor, MD, PhD**
Source: National Institutes of Health
Title: "Impact of Patient-Provider Interaction on the Response to Acupuncture"
Amount/Period: \$2,037,975; 10/02-9/07

The association of positive patient expectations with placebo responses is well recognized. However, the potential role of health care providers' behavior in modeling these expectations has not been adequately established. The overall goal of this proposal is to describe and quantify placebo effects in a trial of acupuncture for osteoarthritis (OA) of the knee. No previous studies have scientifically evaluated the effects of communicative style in providers of alternative and complementary medicine, and the placebo response that may result. This proposal will examine placebo responses in the context of practitioner-patient interactions at the time of the acupuncture treatment. The study will have three phases:

Phase 1 will include a qualitative component to determine potential patient-related determinants of

placebo response, such as beliefs and expectations towards treatment of knee OA with acupuncture; In phase 2 we will develop and test an instrument to measure evaluate outcome and self-efficacy expectations; and Phase 3 will be a nested RCT to evaluate practitioner-patient interactions and placebo responses. The experimental design will include two stages or randomization. Patients will initially be randomized to one of two different structures of practitioner-patient interaction. Acupuncture practitioners will be trained to behave following semi-structured communicative styles, including traditional approaches in Chinese Medicine, and techniques previously described in patient-doctor communication studies. Within each of these groups patients will be further randomized to receive acupuncture or sham acupuncture. In addition there will be a natural control group (waiting list group), in which patients will be offered acupuncture three months after study entry.

PI: Nancy Keitel; **Nancy J. Petersen, PhD** (Co-Inv)
Source: National Institutes of Health
Title: "Vaccine and Treatment Evaluation Unit"
Amount/Period: \$98,153; 6/02-5/07

PI: **Rebecca J. Beyth, MD, MS**
Source: National Heart, Lung, and Blood Institute
Title: "Improving Anti-Thrombotic Use in Stroke Prevention"
Amount/Period: \$2,526,642; 9/02-9/07

Atrial fibrillation is a common disorder and an important risk factor for stroke. Evidence from controlled clinical trials shows that adjusted-dose warfarin decreases the risk of stroke by two-thirds. Clinical practice guidelines recommend that most atrial fibrillation patients receive lifelong anticoagulation; only about one-third of atrial fibrillation patients receive it. This study is a randomized controlled trial of an intervention (the RBC) to increase the appropriate use of anti-thrombotic therapy (warfarin and aspirin) for stroke prevention in patients with chronic atrial fibrillation. The intervention is a tailored patient-specific risk-benefit consult (RBC) that incorporates the risks and benefits of anti-thrombotic therapy for stroke prevention using the American College of Chest Physicians guidelines and the Outpatient Bleeding Risk Index, a validated risk assessment for major bleeding. The

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intervention is aimed at primary care providers practicing in different clinical settings. Evidence-based specific recommendations about the use of anti-thrombotic therapy, as well as the quality of anti-thrombotic management will be formulated for each atrial fibrillation patient in the intervention physician's panel. The control and the intervention physicians will also receive performance feedback in the form of an Achievable Benchmark of Care (ABC) that informs them of the percentage of their patient panel with atrial fibrillation that is receiving anti-thrombotic therapy in relation to the other physicians (intervention or control) in their group. The primary outcome is the change, pre-to post-intervention, in the proportion of eligible patients with chronic atrial fibrillation who are prescribed anti-thrombotics. This will be measured by the proportion of the eligible patients in each physician's panel for whom anti-thrombotics are currently prescribed at baseline, 6-months, and 12-months. Secondary safety outcomes are the proportion of individuals in the physician's panel with stroke, the proportion of anticoagulated patients with major bleeds, and the proportion of total treatment time during which the International Normalized Ratio is below, above and within therapeutic range. This study will test a novel and generalizable approach to increasing the appropriate use of anti-thrombotic therapy in patients with atrial fibrillation in a community setting and the findings will provide valuable insight into stroke prevention.

PI: **Thomas Giordano, MD**

Source: National Institutes of Health

Title: "HIV, Race and Survival in the Highly Active Therapy Era"

Amount/Period: \$612,500; 12/02-11/08

Highly active antiretroviral therapy (HAART) has reduced mortality in patients with HIV. Crude CDC data demonstrate that, though they had the same mortality in the pre-HAART era, mortality in 2000 was >15% higher for Hispanics with AIDS and >50% higher for African Americans with AIDS, compared to whites. The effectiveness of HAART has not been assessed in a nationally distributed population with HIV, and the factors contributing the mortality discrepancy are not well known. The goals of this proposal are to assess the magnitude of the HAART-era mortality discrepancy

by race/ethnicity, and identify potentially modifiable factors responsible for that discrepancy. The research is based on a model of care that outlines crucial Steps of HIV Care, which in turn determine the overall effectiveness of HAART in clinical practice. These steps are: a) access outpatient care; b) utilize care services; and c) adhere to care. Past studies and preliminary data indicate that minorities may have difficulty with all 3 steps, but the relative influence that patient and process of care factors have on these Steps and the effect that the Steps have on survival are unknown. The four specific aims for this proposal are:

Aim 1: To determine if the mortality rates of patients with HIV in routine clinical practice differed by race/ethnicity in the pre-HAART and HAART eras;

Aim 2: To evaluate the relationship between the Steps of HIV Care, patient factors, and mortality;

Aim 3: To develop an instrument to assess newly diagnosed HIV-infected patients' attitudes and beliefs about HIV disease and care; and

Aim 4: To evaluate the relationship between patients' attitudes and beliefs about HIV disease and care and patients' success in following the Steps of HIV Care.

The first 2 Aims will be accomplished with retrospective cohort studies using a unique, national, Veteran's Health Administration HIV registry; the 3rd Aim with focus group and pilot studies of persons with HIV; and the last Aim with a prospective cohort study of patients newly diagnosed with HIV during hospitalization. This research will expand upon the principle investigator's current skills and past work by taking advantage of an outstanding research and mentoring environment, allowing him to acquire new and refine existing skills in the design and performance of patient-oriented clinical research, so that he will be an independent researcher improving the health of people with HIV.

PI: **Laura A. Petersen, MD, MPH**

Source: Robert Wood Johnson Foundation

Title: "Structuring Payment Systems to Promote Healthcare Quality"

Amount/Period: \$291,439; 7/02-6/06

This grant will fund Dr. Petersen's participation in the Foundation's Generalist Physician Faculty

Scholars Program. The program awards four-year career development grants to outstanding junior faculty at U.S. medical schools in family practice, general internal medicine, and general pediatrics. Petersen is the first Baylor faculty member to receive the award since the program's inception, and the second award recipient in Houston. The Foundation awards up to 15 grants annually to sponsoring institutions to help cover the scholars' salary and research costs. Petersen is focusing her research on how to restructure payment systems to reward the health care system for high quality care. "The way we currently pay for health care does not have the explicit goal of improving quality," Petersen said. "While our current healthcare system is good, it could be better. My goal is to work with colleagues from all disciplines to investigate and remove the barriers preventing us from providing the best care possible."

PI: **Laura A. Petersen, MD, MPH**

Source: VA VISN 9 (Contract)

Title: "Using DCGs to Profile and Forecast Facility Budgets in VISN 9"

Amount/Period: \$28,214; 6/02-1/03

PI: **Laura A. Petersen, MD, MPH**

Source: VA VISN 20 (Contract)

Title: "Using DCGs to Profile and Forecast Facility Budgets in VISN 20"

Amount/Period: \$30,138; 6/02-1/03

PI: **Laura A. Petersen, MD, MPH**

Source: VA VISN 22 (Contract)

Title: "Using DCGs to Profile and Forecast Facility Budgets in VISN 22"

Amount/Period: \$29,271; 6/02-3/03

PI: **Laura A. Petersen, MD, MPH**

Source: VA VISN (Contract)

Title: "Phase V - Patient Classification Work Group: Assessing the Impact of Using DCGs for Budget Allocation in VHA"

Amount/Period: \$187,471; 10/02-9/03

PI: **Maria Suarez-Almazor, MD, PhD**

Source: Scleroderma Foundation

Title: "Outcome Assessment in Scleroderma"

Amount/Period: \$149,719; 1/03-12/04

The treatment of scleroderma has been very disappointing. However, there is great optimism

that newly developed therapies will be effective. To determine if therapies are efficacious, it is necessary to measure the impact of scleroderma on patients' well-being. Yet, very few instruments have been developed specifically for scleroderma, and we do not know which are the best methods to evaluate if patients are getting better or worse. The purpose of this study, is to evaluate the measures that are most commonly used in scleroderma, and to modify, develop and test new measures as needed. We will evaluate several aspects of importance to patients with scleroderma and their physicians, including disease progression, disease damage, functioning and quality of life. We will conduct focus groups of patients to determine their concerns and we will survey physicians to establish those areas they feel are most related to prognosis. We will also analyze the information that is collected yearly in an ongoing study of over 200 patients with scleroderma in Texas. The newly developed measures will be tested in a pilot study of 70 patients with scleroderma seen on 2 occasions 6 months apart. We expect that the study will provide crucial information for clinicians and investigators who are in need of good measures to evaluate and treat patients with scleroderma. We are confident that the development and testing of scales that measure aspects of concern to patients, will improve the long-term outcome of this disease.

PI: **Tracie C. Collins, MD, MPH**

Source: VA Investigator-Initiated Research

Title: "Process of Care in Peripheral Arterial Disease"

Amount/Period: \$338,815; 10/02-9/05

Peripheral arterial disease (PAD) is a prevalent illness that most commonly affects patients over the age of 60 years. The management of PAD includes atherosclerotic risk factor control to reduce the risk of poor outcomes. Poor outcomes in PAD are either systemic (i.e., cardiovascular events such as myocardial infarctions or strokes) or localized to the legs (i.e., bypass surgery or amputation). While much research has focused on adverse systemic outcomes in patients with PAD, less has been done to determine those factors that are related to adverse limb events. The Centers for Disease Control and Prevention estimate that over 100,000 amputations are performed in the United States each year. What remains to be determined is the association of current standards of care [i.e., process of care] and actual risk factor control with adverse limb

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outcomes in patients with PAD. The purpose of this study is to examine the association of process of care and the level of risk factor control with adverse limb outcomes in patients with PAD. We will perform a retrospective cohort study of patients who have undergone diagnostic testing within the Houston VA Medical Center vascular laboratory from 1995 to 1998. We will review the vascular laboratory results for the ankle-brachial index (ABI; the ratio of the systolic blood pressure in the ankle to the systolic blood pressure in the arm) for each patient. For those patients who screened positive for PAD based on an ABI result of < 0.9 , we will then perform a chart review. We will define time zero as three years prior to the vascular laboratory visit and we will follow patients from this point forward until the first adverse limb event (i.e., lower extremity bypass surgery or amputation), death, or the end of the study (i.e., December 31, 2001). We will review each chart for information on the process of care for patients with PAD, including physicians' efforts to manage atherosclerotic risk factors (i.e., smoking, diabetes mellitus, hypertension, and dyslipidemia). We will also abstract information on the actual level of risk factor control (i.e., smoking cessation, adequate blood glucose control in diabetes mellitus, control of dyslipidemia, and control of hypertension) that is relevant for each patient (e.g., not all patients will have hypertension). Through chi-square analyses and multivariate modeling, we will then determine the association of process of care and the level of risk factor control with an adverse limb event. The results of this study will help to clarify the association of physicians' efforts and actual risk factor control with poor limb outcomes in PAD. This information will be disseminated to clinicians, researchers, and policy-makers. We will also translate the results for patients and family members so that our veterans can be informed about PAD.

PI: **A. Lynn Snow, PhD**

Source: VA Career Development Award

Title: "Improvement in Quality of Care of Demented Nursing Home Residents: Pain Management Approaches"

Amount/Period: \$217,571; 7/02-6/05

Nursing homes are an integral part of the health care network for demented individuals, who account for up to 67% of all nursing home

residents. However, improving quality of care for this vulnerable population is a challenging endeavor given the complex environment of the nursing home, particularly given well-documented staffing and training problems. As a clinical psychologist with expertise in dementia and geropsychology and a strong interest in nursing home quality of care, I am pursuing a long-term career agenda that focuses on the improvement of quality of care of demented nursing home residents. The quality of care area in which I have chosen to direct my efforts is pain management. High pain prevalence rates have been consistently reported in studies of nursing home patients. Further, there are strong indications that pain is under-recognized and under-treated in the nursing home setting. Demented nursing home residents are particularly at risk for under-diagnosis. One important reason for this high risk is the decreased self-report capacity of demented individuals due to the language, memory, and abstract thinking deficits inherent in the disease. The projects I propose for the Research Career Development Award are:

- (1) Validation of a nursing assistant-administered pain rating scale;
- (2) A qualitative study of the pain management barriers and facilitators in the nursing home;
- (3) Development of an integrated pain assessment model and tool;
- (4) Randomized controlled trial of a nursing home pain management system; and
- (5) Producing manuscripts investigating health service utilization in demented individuals and their caregivers from a dataset collected in 2000-2001.

These projects have been planned with the purpose of building the necessary components for a successful nursing home pain management and tracking system: (1) appropriate assessment tools, (2) an understanding of the potential barriers to a pain management and tracking system, and valid responses to these potential barriers, and (3) an understanding of how best to utilize all the different sources of pain assessment and treatment information available in the nursing home system. I then propose to develop and evaluate such a pain management and tracking system. My research agenda will strongly impact VHA patient care because: long term care is a significant VHA cost, the

prevalence of dementia in long term care facilities is high, the prevalence of dementia in the veteran population is high and is increasing, and the VHA has identified pain control as a priority clinical and research area. This award would allow me to pursue the planned training and research experiences under the guidance of my present mentors that will allow for the success of my research agenda.

PI: **Rebecca J. Beyth, MD, MS**

Source: VA Advanced Career Development Award

Title: "Improving Decision-Making in Stroke Prevention"

Amount/Period: \$456,036; 1/03-12/05

High quality epidemiological studies have demonstrated that atrial fibrillation is the most potent common risk factor for stroke and five randomized trials of anti-thrombotics in atrial fibrillation consistently have demonstrated a risk reduction of stroke by approximately two-thirds. Nonetheless anti-thrombotics remain underused in clinical practice. My prior studies have (1) developed and validated the Outpatient Bleeding Risk Index (OBRI) to prospectively classify patients according to their risk of major bleeding, and (2) shown that tailored consultation can prevent major bleeding during long-term warfarin therapy. Physicians may worry mistakenly about a patient's quality of life and how it will be affected by anti-thrombotic therapy. Physicians may mistakenly assume that patients will refuse therapy. However, in a study at a large staff model health maintenance organization, 93% of patients accepted warfarin therapy when offered. Physicians may fear committing an error of commission more than an error of omission; the fear of a hemorrhage from therapy may loom larger than prevention of a stroke that is considered more an "act of nature". In addition, the role of the macro- and micro- environment in which physicians and patients reach clinic decisions regarding stroke prevention in atrial fibrillation is not known. In order to improve stroke prevention for atrial fibrillation, a new approach is needed to explore these barriers and then develop target interventions to overcome these barriers. My long-term goal is to improve the care of patients with chronic illnesses. I plan to begin working toward that goal by using the *Crossing the Quality Chasm* report for implementing the interventions of the Chronic Care Model to improve stroke prevention for patients with chronic atrial fibrillation. Then, using chronic

atrial fibrillation and stroke prevention as a template, I will be able to develop, adapt, and test this work to improve the care of other chronic illnesses in future research projects. The Institute of Medicine report, *Crossing the Quality Chasm*, calls for improvements in six dimensions of health care performance; safety, effectiveness, patient-centeredness, timeliness, efficiency and equity. It provides a framework that comprises four levels (A - D) of interest: Level A is the experience of patients; Level B is the functioning of small units of care delivery (or "microsystems"); Level C is the functioning of the organizations that house or otherwise support the Microsystems; and Level D is the environment of policy, payment, regulation, accreditation and other factors that shape behavior, interests and opportunities of the organization at Level C. The VA's integrated health care system is ideal for using the Quality Chasm Report's framework to affect a change in a chronic health problem such as stroke and atrial fibrillation. My planned health services research in stroke prevention and chronic atrial fibrillation will lead to improved health care for veterans who are at risk for stroke, as well as provide a template for future research in improving the care of veterans with chronic illnesses. It will also provide me with the necessary leadership, organizational and health services research skills to become a fully independent health services researcher in an area that is of importance to the VA, improving the quality of care of veterans with chronic illnesses. My research will develop the information needed to ensure that the VA provides quality care for patients at risk for stroke, or who have already suffered a stroke. In addition, I will gain the skills and tools to be able to effectively translate the findings from clinical trials in to real world settings. Furthermore, the methodologies and framework used to improve stroke prevention for atrial fibrillation patients will generalize to other chronic diseases and can serve as a useful model for investigating and improving the health care and outcomes of other veterans.

PI: **Michael L. Johnson, PhD**

Source: VA Merit Review Entry Program

Title: "Epidemiology and Economics of Pharmaceutical Use in the VA"

Amount/Period: \$319,751; 1/03-12/05

The epidemiology and economics of pharmaceutical use in the Department of Veterans Affairs (VA)

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is a critical and under-studied area of health services research. Pharmaceutical costs continue to rise and outpace the growth of hospital and physician health care costs, while physicians and administrators struggle to provide the best quality of care under pressures of cost containment. In the VA, pharmaceutical costs have risen over 160% since the mid-1990's, while enrollment has increased 25%. The VA is the largest single purchaser of pharmaceuticals in the United States. A recent Institute of Medicine (IOM) report, Description and Analysis of the VA National Formulary (2000), cited the national formulary design of the VA as an example for a potential Medicare prescription drug benefit, and noted the "dearth of information" to evaluate the effects of pharmacy benefit design and delivery on the structure, processes and outcomes of care received by VA patients. My long-term goal is to become a serious leader of needed change, to help us cross the quality chasm of pharmaceutical services in the VA and the US healthcare system. This career award continues my professional development as a health services researcher with biostatistical training into the content areas of epidemiology and economics of pharmacy use. In the short term, I will work toward this goal by applying principles of redesign from the landmark IOM report, Crossing the Quality Chasm (2001), drawing upon the disciplines of pharmacoepidemiology and pharmacoconomics in specific studies to establish funding for my research agenda at the end of the three-year award.

PI: **Anita Deswal, MD**

Source: VA Investigator-Initiated Research

Title: "Impact of Diastolic Heart Failure on Healthcare Utilization and Outcomes"

Amount/Period: \$319,100; 4/03-3/06

Heart failure (HF) is a substantial public health problem in the US and within the VA. Nearly 5 million Americans have HF and 550,000 new cases are diagnosed each year. Heart failure may occur in the setting of either reduced ejection fraction (systolic heart failure or SHF) or preserved ejection fraction (diastolic heart failure or DHF). DHF may constitute 30-50% of the patients with HF. Although extensive data are available concerning the natural history, health care burden and treatment strategies for SHF, the estimated burden of DHF, especially in African American (AA)

patients and in veterans with CHF, as well treatment strategies for DHF are still not well characterized. The proposed study will address these gaps in knowledge in VA beneficiaries with DHF. The aims of this study are to determine the:

- 1) Prevalence, baseline characteristics and racial variation of DHF in veterans with HF;
- 2) Health care utilization (as measured by hospitalizations, bed-days of care, emergency room/urgent care visits and outpatient clinic use) in patients with DHF as compared to patients with SHF, and its variation according to race;
- 3) Short-term (six-month and one-year) and long-term (two-year) mortality in patients with DHF as compared to patients with SHF, and its variation according to race; and
- 4) Use of two classes of medications (ACEI and b-blockers) is associated with a reduction in hospitalizations and mortality in patients with DHF, and whether this effect varies by race.

We will perform a retrospective study of a national cohort of approximately 36,000 patients with HF treated at VA facilities between 10/99 and 06/02. Patients will be identified in the national External Peer Review Program (EPRP) database that utilizes chart abstraction data and is maintained by the VHA Office of Quality Performance (OQP). Patients will be classified as DHF and SHF based on the left ventricular ejection fraction. The study cohort will be linked to other VA databases including the patient treatment file (PTF), outpatient clinic (OPC) files, VA death files (BIRLS) and pharmacy data (PBM). Risk-adjusted measures of mortality, health care utilization and effect of medications (angiotensin converting enzyme inhibitors or ACE inhibitors and b-blockers) on mortality and hospitalizations will be compared between patients with DHF vs. SHF, and by race within patients with DHF, using hierarchical regression modeling. In the short-term this study will help to clarify the burden of DHF in veterans as well as in the VA health care system. It will help policy makers and researchers in deciding on the allocation of research resources to study the management and best practices for this condition and in the planning of multicenter studies of drug therapies for DHF within the VA. The proposed study is part of an incremental research agenda that aims to increase the awareness of the entity of DHF and to improve the process of

care and outcomes for all patients with DHF, with a special emphasis on African American patients.

PI: **Mark Kunik, MD, MPH**

Source: VA Investigator-Initiated Research

Title: "Causes and Consequences of Aggressive Behavior in Patients with Dementia"

Amount/Period: \$1,097,600; 4/03-3/08

Currently, 4 million Americans, including 600,000 veterans, have dementia. Dementia is often accompanied by aggressive behavior, including pushing, shoving, kicking, pinching, hitting, or verbal threats. These aggressive behaviors are frightening and dangerous to families and professional caregivers. Aggression has been documented to be highly prevalent in convenience samples of patients with dementia (25% to 50%); however, the true prevalence of aggression in community-residing residents is unknown, and no literature exists on the incidence of new aggression in patients with dementia. Without an accurate estimate of incidence, it is not possible to quantify the absolute risk of aggression. Aggressive behavior has been shown to result in several negative consequences that are both costly and distressing to caregivers and patients, including institutionalization, injuries to others and self, and a decrease in quality of care. Cross-sectional studies have associated aggression with several potentially treatable conditions, including delirium, pain, caregiver burden, depression and psychosis, and environmental stimuli. Although several risk factors and consequences of aggressive behavior have been identified, the causal relationship between aggression and either its putative precipitants or consequences has not been determined. Unfortunately, many practitioners accept aggression as an inevitable part of the dementia process and consequently make no effort to prevent it, choosing instead to treat it with physical and chemical restraints. If we can identify modifiable causal factors, it will be possible to prevent the onset of aggressive behavior or immediately intervene with the precipitant at aggression's initial onset. Such a primary or secondary prevention strategy would thus fundamentally change the current approach to the treatment of aggression. Such a prevention strategy is the long-term goal of this research. Our specific aims are:

Aim 1. To determine the incidence rate of aggressive behavior in an inception cohort of adults

recently diagnosed with dementia.

Aim 2. To determine the antecedents of aggressive behavior in an inception cohort of adults recently diagnosed with dementia.

Aim 3. To determine the effects and consequences of aggressive behavior on patients, caregivers, and the health care system.

This 4-year prospective cohort study aims to empirically validate risk factors and consequences in an inception cohort of 334 newly diagnosed community-dwelling dementia patients. Subjects will be recruited over 2 years through case identification using 2001 VA OPC files and direct recruitment at the primary care and geriatric clinics at the Houston VAMC. All consenting patients will have their diagnosis of dementia confirmed (DSM-IV) and will be assessed for presence of aggression at baseline. Patients and caregivers will be assessed at baseline and every 4 months thereafter in their home. Between home visits, caregivers will be called monthly to test for the development of aggression. This 4-month cycle will be repeated 6 times over 24 months. Home assessments will include assessments to detect the development of aggression and assessments of putative risk factors, including patient factors (e.g., depression, psychosis, pain, and delirium) and factors external to the patient (e.g., social stimulation, caregiver burden, and quality of caregiver-patient relationship). Telephone assessments will test for the development of aggression. In addition, each follow-up home and telephone assessment will track adverse outcomes, including nursing home placement, injury to caregiver or self, and use of physical restraints or anxiolytic/antipsychotics. The longitudinal cohort study proposed here will determine the extent to which mutable determinants cause aggression and will be used as a foundation to develop aggression-prevention strategies and interventions to be tested in future studies. Developing tools for family caregivers and practitioners may foster more effective responses to persons with dementia at high-risk for aggressive behavior and the associated use of acute and long-term care. Findings from this investigation could fundamentally change the approach to aggression in dementia patients from that of tertiary prevention, primarily using restraints and tranquilizing medications, to an innovative secondary prevention strategy associated with lower health care costs and higher quality of care.

Funding Update

Recent Publications

Mark E. Kunik, MD, MPH; Dianna Densmore, MS. "Depression and COPD," *Journal of COPD Management*. 2002;3:4-9.

Abstract

Depression is of significant concern in the population with chronic obstructive pulmonary disease (COPD). Depression in COPD is a determinant of patient quality of life and physical functioning as well as the ability to cope with chronic illness. Studies have placed the prevalence of depression symptoms in COPD patients at higher than 40%, and depression is also associated with other psychiatric illnesses, including anxiety disorders. All COPD patients should be assessed for the presence of depression using one of the currently available structured depression inventories. Management options include exercise/pulmonary rehabilitation, brief psychotherapy, and pharmacologic interventions.

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Marvella E. Ford, PhD; Deanna D. Hill, MPH; David Nerenz, PhD; Mark Hornbrook, PhD; Jane Zapka, PhD; Richard Meenan, PhD; Sarah Greene, MPH; Christine Cole Johnson, PhD. "Categorizing Race and Ethnicity in the HMO Cancer Research Network," *Ethnicity & Disease*. 2002;12:135-140.

Abstract

The Center Research Network (CRN) was formed in 1999 with funding from the National Cancer Institute. The CRN represents a collaboration of 10 health plans across the United States, with a combined total of approximately 9 million enrollees. The goal of the CRN is to promote collaborative research, which will ultimately increase the effectiveness of preventative, curative, and supportive interventions for major cancers. Special emphasis is placed upon diverse populations, and racial and ethnic differences in outcomes, costs, and cost effectiveness.

Purpose. There is increasing awareness in the research literature of the relationship between race and ethnicity and health outcomes. However, the majority of the health maintenance organizations represented in the CRN, similar to other health plans and organizations, do not routinely collect race and ethnicity data on their members. In order to compare data and outcomes across the CRN sites, consensus is needed in the measurement of race and ethnicity.

Methods. This review discusses terminology used in the research literature to describe race and ethnicity and the manner in which these constructs have been measured in previous studies.

Conclusions. This review concludes with suggestions for standardized measures of race and ethnicity.

Implications. It is hoped that shared conceptualizations of race and ethnicity will lead to improved data quality and precision in measurement.

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J. Bruce Moseley, MD; **Kimberly O'Malley, PhD; Nancy J. Petersen, PhD;** Terri J. Menke, PhD; Baruch A. Brody, PhD; David H. Kuykendall, PhD; John C. Hollingsworth, DrPH, **Carol M. Ashton, MD, MPH;** and Nelda P. Wray, MD, MPH. "A Controlled Trial of Arthroscopic Surgery for Osteoarthritis of the Knee," *New England Journal of Medicine*. 2002;347:81-88.

Abstract

Background. Many patients report symptomatic relief after undergoing arthroscopy of the knee for osteoarthritis, but it is unclear how the procedure achieves this result. We conducted a randomized, placebo-controlled trial to evaluate the efficacy of arthroscopy for osteoarthritis of the knee.

Methods. A total of 180 patients with osteoarthritis of the knee were randomly assigned to receive arthroscopic debridement, arthroscopic lavage, or placebo surgery. Patients in the placebo group received skin incisions and underwent a simulated debridement without insertion of the arthroscope. Patients and assessors of outcome were blinded to the treatment-group assignment. Outcomes were assessed at multiple points over a 24-month period with the use of five self-reported scores - three on scales for pain and two on scales for function - and one objective test of walking and stair climbing. A total of 165 patients completed the trial.

Results. At no point did either of the intervention groups report less pain or better function than the placebo group. For example, mean (\pm SD) scores on the Knee-Specific Pain Scale (range, 0 to 100, with higher scores indicating more severe pain) were similar in the placebo, lavage and debridement groups: 48.9 ± 21.9 , 54.8 ± 19.8 , and 51.7 ± 22.4 , respectively, at one year ($P=0.14$ for the comparison between placebo and lavage; $P=0.51$ for the

comparison between placebo and debridement) and 51.6 ± 23.7 , 53.7 ± 23.7 , and 51.4 ± 23.2 , respectively, at two years ($P=0.64$ and $P=0.96$, respectively). Furthermore, the 95 percent confidence intervals for the differences between the placebo group and the intervention groups exclude any clinically meaningful difference.

Conclusions. In this controlled trial involving patients with osteoarthritis of the knee, the outcomes after arthroscopic lavage or arthroscopic debridement were no better than those after a placebo procedure.

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Lemuel A. Moye, MD PhD; Anita Deswal, MD. "The Fragility of Cardiovascular Clinical Trial Results," *Journal of Cardiac Failure*. 2002;8:247-253.

Abstract

Background. Clinical trials that have their prospective analysis plan altered are difficult to interpret.

Methods & Results. After providing 4 examples of problematic trial results that have had their findings reversed, the necessity of a fixed research protocol is developed. Investigators generally wish to extend the results from their research sample to the larger population; however, this delicate extension is complicated by the presence of sampling error. No computational or statistical tools can remove sampling error - the most that researchers can do is to provide to the medical and regulatory communities a measure of the distorting effect that sampling error can produce. Investigators accomplish this by providing an estimate of how likely it is that the population produced a misleading sample for them to study. However, studies in which the data determine the analysis plan damage these estimators. When they are damaged, these estimators produce untrustworthy assessments of the degree to which the study results reflect the population findings.

Conclusions. The way to avoid these complications is to design the experiment carefully, then carefully execute the experiment as it was designed.

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Jessica A Davila, PhD; Hashem B. El-Serag, MD, MPH; Linda Rabeneck. "Is There a True 'Shift' to the Right in the Incidence of Colorectal Cancer?" *Annals of Epidemiology*. 2002;7:515.

Abstract

Purpose. A recent "shift" in the incidence of colorectal cancer (CRC) to right-sided colon cancers has been reported. Whether this "shift" resulted from a true increase in the incidence of right colon cancers or decline in left colon cancers is unknown. To disentangle these potential explanations, we examined temporal trends in proportion of right colon, left colon, and rectal cancers as well as incidence rates.

Methods. Using data from the NCI SEER program, proportions and age-adjusted incidence rates were calculated for right colon, left colon, and rectal cancers by race over three-year time periods from 1978-1998. Proportion of cases by age at diagnosis was also calculated.

Results. Although the proportion of individuals diagnosed with right colon cancer increased for whites (1978-1980=34%;1996-1998=40%) and blacks (1978-1980=37%; 1996-1998=44%), the proportions with left colon and rectal cancers decreased. Between 1978-1998, age-adjusted incidence rates of left colon cancer declined in whites (1978-1980=16/100,000; 1996-1998= 13/100,000) and blacks (1978-1980=18/100,000; 1996-1998 = 12/100,000, while the incidence rates of right colon cancer (1978-1980 = 14/100,000; 1996-1998 = 15/100,000) did not change significantly. Age-adjusted incidence rates of rectal cancer remained stable for blacks (10/100,000) and declined for whites (1978-1980 = 15/100,000; 1996-1998=12/100,000). Overall, 43% of individuals >60 years diagnosed with CRC had right colon cancer. Smaller proportions were diagnosed with left colon (31%) or rectal cancer (26%). Conversely, among individuals <60 years, 28% had right colon, 34% left colon, and 38% rectal.

Conclusions. 1) The "shift" to right colon cancer is due to a decline in the incidence of left colon and rectal cancers, while the incidence of right colon cancers remains unchanged. 2) In the elderly, the majority of colon cancers are found in the right colon. This has important implications for choice of screening methods used in the elderly.

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Publications

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Hashem B. El-Serag, MD, MPH. "Hepatocellular Carcinoma and Hepatitis C in the United States," *Hepatology*. 2002;36:574-583.

Abstract

Chronic infection with hepatitis C virus (HCV) is a major risk factor for development of hepatocellular carcinoma (HCC). In general, HCC develops only after 2 or more decades of HCV infection and the increased risk is restricted largely to patients with cirrhosis or advanced fibrosis. Factors that predispose to HCC among HCV-infected persons include male sex, older age, hepatitis B virus (HBV) coinfection, heavy alcohol intake, and possibly diabetes and a transfusion-related source of HCV infection. Viral factors play a minor role. The likelihood of development of HCC among HCV-infected persons is difficult to determine because of the paucity of adequate long-term cohort studies; the best estimate is 1% to 3% after 30 years. Once cirrhosis is established, however, HCC develops at an annual rate of 1% to 4%. Successful antiviral therapy of patients with HCV-related cirrhosis may reduce the future risk for HCC. The incidence of and mortality caused by all HCC has doubled in the United States over the past 25 years, an increase that has affected all ethnic groups, both sexes, and younger age groups. Given the current prevalence of HCV infection among persons 30 to 50 years of age, the incidence and mortality rates of HCC are likely to double in the United States over the next 10 to 20 years. Future research should focus on improving understanding of the incidence and risk factors for HCC, causes of HCV-related carcinogenesis, means of early detection, and better treatment for HCC.

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Linda Rabeneck, MD, MPH; Karon F. Cook, PhD; **Kimberly O'Malley, PhD; Julianne Soucek, PhD;** Terri Menke, PhD; Nelda P. Wray, MD, MPH. "SODA (Severity of Dyspepsia Assessment) A New Effective Outcome Measure for Dyspepsia-related Health," *Journal of Clinical Epidemiology*. 2002;97(1):32-39.

Abstract

The aim of this research was to develop and evaluate an instrument for measuring dyspepsia-

related health to serve as the primary outcome measure for randomized clinical trials. Building on our previous work we developed SODA (Severity of Dyspepsia Assessment), a multidimensional dyspepsia measure. We evaluated SODA by administering it at enrollment and seven follow-up visits to 98 patients with dyspepsia who were randomized followed over 1 year. The mean age was 53 years, and six patients (6%) were women. Median Cronbach's alpha reliability estimates over the eight visits for the SODA Pain Intensity, Non-Pain Symptoms, and Satisfaction scales were 0.97, 0.90, and 0.92 respectively. The mean change scores for all three scales discriminated between patients who reported they were improved versus those who were unchanged, providing evidence of validity. The effect sizes for the Pain Intensity (.98) and Satisfaction (.87) scales were large, providing evidence for responsiveness. The effect size for the Non-Pain Symptoms scale was small (.24) indicating lower responsiveness in this study sample. SODA is a new, effective instrument for measuring dyspepsia-related health. SODA is multidimensional and responsive to clinically meaningful change with demonstrated reliability and validity.

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Hashem B. El-Serag, MD, MPH; Howard Hampel; Christine Yeh; Linda Rabeneck, MD, MPH. "Extrahepatic Manifestations of Hepatitis C Among United States Male Veterans," *Hepatology*. 2002;36:1439-1445.

Abstract

Hepatitis C Virus (HCV) has been associated with several extrahepatic conditions. To date, most studies assessing these associations involved small numbers of patients and lacked a control group. Using the computerized databases of the Department of Veterans Affairs, we carried out a hospital-based case-control study that examined all cases of HCV-infected patients hospitalized during 1996 to 1999 (n=34,204) and randomly chosen control subjects without HCV (n=136,816) matched with cases on the year of admission. The inpatient and outpatient files were searched for several disorders involving the skin (porphyria cutanea tarda [PCT] vitiligo, and lichen planus); renal (membranous glomerulonephritis [GN] and membranoproliferative glomerulonephritis; hematologic (cryoglobulin, Hodgkin's and non-Hodgkin's lymphoma [NHL]); endocrine (diabetes, thyroiditis); and rheumatologic (Sjogren's syndrome). The association between HCV

and these disorders was examined in multivariate analyses that controlled for age, gender, ethnicity, and period of military service. Patients in the case group were younger in age (45 vs. 57 years), were more frequently nonwhite (39.6% vs. 26.3%), and were more frequently male (98.1% vs. 97.0%). A significantly greater proportion of HCV-infected patients had PCT, vitiligo, lichen planus, and cryoglobulinemia. There was a greater prevalence of membranoproliferative GN among patients with HCV but not membranous GN. There was no significant difference in the prevalence of thyroiditis, Sjogren's syndrome, or Hodgkin's or NHL. However, HNL became significant after age adjustment. Diabetes was more prevalent in controls than cases, but no statistically significant association was found after adjustment for age. In conclusion, we found a significant association between HCV infection and PCT, lichen planus, vitiligo, cryoglobulinemia, membranoproliferative GN, and NHL. Patients presenting with these disorders should be tested for HCV infection.

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Hashem B. El-Serag, MD, MPH. "Hepatocellular Carcinoma," *J Clin Gastroenterol.* 2002;35 (Suppl. 2):S72-S78.

Abstract

Hepatocellular carcinoma (GCC) is the fifth most common malignancy in the world and is estimated to cause approximately half a million deaths annually. Because of its high fatality rates, the factors for HCC are chronic hepatitis B virus infection, chronic hepatitis C virus (HCV) infection, and alcoholic cirrhosis. The epidemiology of HCC is characterized by marked demographic (age, gender, race/ethnicity) and geographic variations. Hepatitis B Virus infection, with and without aflatoxin exposure, is responsible for most cases in developing countries; better control of these risk factors has resulted in a recent decline in HCC in some places like Taiwan and China. Recently, however, a trend of rising rates of HCC has been reported from several developed countries in Europe and North America. These new trends are associated with "new" risk factors such as HCV and, possibly, diabetes. In the United States, the incidence of HCC has approximately doubled over the past 3 decades. White individuals are two to three times less often affected than African Americans, who in turn are two to three times less often affected than Asians,

Pacific Islanders, or Native Americans. Men are two to three times more often affected than women. Concomitant with the rising rates of HCC, there has been a shift of incidence from typically elderly patients to relatively younger patients between ages of 40 to 60 years. An increase in HCV-related HCC accounts for at least half of the witnessed increase in HCC in the United States.

Hepatocellular carcinoma continues to carry an overall dismal survival rate (close to 5%); very few patients qualify for and receive potentially curative therapy. The future incidence trends of HCC will be determined to a large extent by the clinical course of HCV-infected people.

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Hashem B. El-Serag, MD, MPH; David Y. Graham, MD; **Peter Richardson, PhD;** John M. Inadomi, MD. "Prevention of Complicated Ulcer Disease Among Persons Using Nonsteroidal Anti-inflammatory Drugs: A Cost-Effectiveness Analysis," *Arch Intern Med.* 2002;162:2105-2110.

Abstract

Background. Nonsteroidal anti-inflammatory drugs (NSAIDs) are associated with an increased risk of clinical upper gastrointestinal tract (UGI) events, namely, symptomatic ulcer, perforation, bleeding, and obstruction. Our objective in this study was to compare the cost-effectiveness of several strategies aimed at reducing the risk of clinical UGI events in NSAID users.

Methods. A decision tree model was used for patients requiring long-term treatment with NSAIDs to compare conventional NSAID therapy alone with 7 other treatment strategies to reduce the risk of NSAID-related clinical UGI events (cotherapy with proton-pump inhibitor, cotherapy with misoprostol, cyclooxygenase [COX]-2-selective NSAID therapy, or *Helicobacter pylori* treatment followed by each of the previous strategies, including conventional NSAID treatment, respectively). The outcome measure is the incremental cost per clinical UGI event prevented compared with conventional NSAID treatment over 1 year.

Results. The use of a COX-2-selective NSAID and cotherapy with proton-pump inhibitors were the 2 most cost-effective strategies. However, the incremental cost associated with these strategies was high (>\$35 000) in persons with a low risk of clinical UGI event with conventional NSAIDs (e.g., 2.5% per year). If the baseline risk of clinical UGI events is moderately high (e.g., 6.5%), using a

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Publications

Staff News

Nelda P. Wray, MD, MPH Appointed Chief of Research and Development

Secretary of Veterans Affairs Anthony J. Principi announced on December 4, the appointment of two senior health care leaders — the chief of research and development and the chief consultant for geriatrics and extended care for the Department of Veterans Affairs. **Nelda P. Wray, MD, MPH** is the VA's new chief of research and development. Dr. James F. Burris is the department's new chief consultant for geriatrics and extended care. Wray previously served as chief of general medicine at the Houston VA Medical Center and as a professor and the chief of health services research at the Baylor College of Medicine in Houston. She will assume the position from Dr. John R. Feussner, who retired.

“Dr. Wray is an internationally recognized leader in health research,” said Principi. “She will use her considerable skills as a researcher and administrator to improve health care for our veterans.” Wray received her medical degree from the Baylor College of Medicine. She created the Houston Center for Quality of Care and Utilization Studies, a VA Health Services Research and Development Center of Excellence, in 1990. She is a member of several national and state advisory committees on research. In 1999, she became the second person to receive the VA Under Secretary Award for Outstanding Achievement in Health Service Research. Wray is board certified in internal medicine and pulmonary medicine. Wray's recent research showed that patients with osteoarthritis of the knee who underwent placebo arthroscopic surgery were just as likely to report pain relief as those who received the real procedure. The results challenged the usefulness of one of the most common surgical procedures performed for osteoarthritis of the knee. As chief of research and development, Wray will oversee more than 15,000 research programs at 115 VA medical centers.

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Nelda P. Wray, MD, MPH, Bruce Moseley, MD and Baruch Brody, PhD will share the 2002 Michael E. DeBakey, MD Excellence in Research Award for their groundbreaking work published in the July 2002 edition of *The New England Journal of Medicine*. The journal reported the results of their milestone study, a randomized, placebo-controlled surgical trial of arthroscopic surgery for osteoarthritis of the knee.

The results of the study are exerting major influence on three paradigms: one, a practice paradigm in orthopedics; two, an important and lasting research paradigm in the evaluation of the efficacy of new surgical procedures; and three, a health care policy paradigm that potentially will have far-reaching effects.

The study, only the second placebo-controlled surgical trial in the United States within the past several decades, concluded that the outcomes after arthroscopic lavage or arthroscopic debridement were no better than those after a placebo procedure, and at times better for the relief of subjective symptoms. Dr. Wray and her colleagues have set a new standard for the ethical evaluation of new surgical procedures before their dissemination. Less than 6 months following the publication of the study's results, the Department of Veterans Affairs issued an advisory recommending that physicians not perform arthroscopic surgery to relieve pain for osteoarthritis of the knee until the procedure is reviewed by an expert panel. Similarly, Medicare has convened an expert panel to review whether they will continue to pay for this procedure in light of the study's findings. Over \$3 billion dollars are spent annually on this procedure, and the policy impact of these advisories is rather profound and speaks highly of the study, its scientific rigor, and especially the work of these esteemed health services researchers. The awards were presented on November 21 at the DeBakey Symposium.

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Paul M. Haidet, MD, MPH, a health services researcher at the Houston Center for Quality of Care and Utilization Studies at the Houston Veterans Affairs Medical Center and an assistant professor at Baylor College of Medicine has received the 2003 Society of General Internal Medicine's Clinician Educator of the Year Award for the Southern region. Carlos Estrada, president of the Southern region, will present this prestigious award that recognizes excellence in medical education scholarship to Haidet at the Southern region SGIM meeting in February in New Orleans. The Southern region comprises 13 states, including Texas. Further, Estrada emphasized that the competition for this year's award was quite intense and the panel that selected the award included esteemed leaders in the field of medical education within the Southern region. “We are all extremely proud of Dr. Haidet and no one deserves it more,”

said Carol Ashton, director of the Houston Center. Haidet is a graduate of Penn State, Hershey and Harvard School of Public Health. He is a general internist and a clinician researcher and educator. His research interests focus on the patient-doctor relationship, communication, and educational dynamics in medical education.

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Carol M. Ashton, MD, MPH was appointed to serve on the Veterans Health Administration National Finance Committee. In addition, Dr. Ashton was an invited guest and speaker in December at the San Francisco VA medical center as a part of their HSR&D Research Award Program, where she presented, “Racial Disparities in Health Care: Bias, Preferences or Poor Communication?”

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HCQCUS investigators: **Laura A. Petersen, MD, MPH**; **Hashem B. El-Serag, MD, MPH**; **Mark E. Kunik, MD, MPH**; **A. Lynn Snow, PhD**; **Tracie C. Collins, MD, MPH**; **Paul M. Haidet, MD, MPH**; **Howard S. Gordon, MD**; and **Carol M. Ashton, MD, MPH** have recently been interviewed by local and national print and broadcast media. Dissemination and translation of our research findings and their impact on health and health care is fundamental to our Center and we hold as a high priority, communicating our research to our internal and external communities.

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Former HCQCUS physician investigator, **Herminia Palacio, MD, MPH**, is the newly appointed executive director of Public Health and Environment for Houston’s Harris County. In a recently published article in the *Houston Chronicle*, Dr. Palacio’s intelligence and compassion were highlighted as unique traits that she will bring to her position as public health director. The Center will miss Herminia, and congratulates her!

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Siddharta G. Reddy, MPH, HCQCUS project staff, received 2nd prize for his research poster, “Achieving Maximum Effectiveness in Determining Health Services Researchers’ Areas of Measurement,” at the Kelsey Research Foundation 3rd Annual Health Services and Outcomes Conference in Houston.

New Staff

Jamie Baker, BS Project Staff
 Angelo Blanco Project Staff
 Amanda Borham Project Staff
 Jennifer Campbell, MS Research Economist
 Karen Carl, MA Project Staff
 Angela Davis Administrative Staff
 Shawna Davis Project Staff
 Vivian Driskell Project Staff
 Faten El-Zeky, PhD Programming Staff
 Virgie Fowler, BBA Administrative Staff
 Christine Hartman, PhD Programming Staff
 Barbara Kimmel, MS Project Staff
 Monique King Project Staff
 Tricia Krueger, MS Project Staff
 Tamara Levin, BA Administrative Staff
 Aimee Pinales Project Staff
 Kimberly Ramsey, BS Administrative Staff
 Paul Rowan, PhD Post-Doctoral Fellow
 Jasmeet Singh Tagore, BS Project Staff
 Raji Sundaravaradan, BS Programming Staff

Promotions

Rebecca J. Beyth, MD, MS Associate Director
 Marvella E. Ford, PhD Associate Director
 Mark E. Kunik, MD, MPH Associate Director
 Maria Suarez-Almazor, MD, PhD Associate Director

Welcome and
 Congratulations!

Staff News

Executive Team:

Carol M. Ashton, MD, MPH
Director, HCQCUS
Chief, Baylor HSR Section

Rebecca J. Beyth, MD, MS
Associate Director, HCQCUS

Marvella E. Ford, PhD
Associate Director, HCQCUS

Mark E. Kunik, MD, MPH
Associate Director, HCQCUS

Maria Suarez-Almazor, MD, PhD
Associate Director, HCQCUS



Management Team:

W. Keith Neeley, MBA
Chief Operating Officer

Dianna Densmore, MS
Chief of Project Staff

Shannon E. Dwyer, BA
Chief of Business Development

Theresa L. Foss, BS
Chief of Human Resources

Paul J. Gregor, PhD
Chief Information Officer

Nancy J. Petersen, PhD
Chief of Statistical Analysis and
Data Processing

Matt D. Price, MS
Chief Communications Officer

Angelita H. Vinluan, CPA
Chief Financial Officer



Post-Doctoral Fellows:

Serena Chu, PhD
Maria Garcia Popa-Lisseanu, MD
Karen Garibaldi, MD
Paul Rowan, PhD
LeChauncy Woodard, MD

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with New Leadership

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Suarez-Almazor

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health services utilization and population health at large. There are several areas in decision-making that members of HCQCUS have expertise and interest in. These cover three major areas of decision-making: a) determinants; b) processes; and c) outcomes. Some of the work currently performed at the Center includes:

- Patient preferences and values
- Evaluation of risks, benefits, and costs in choices about health care policies, programs, or interventions
- Impact of decision-making by patients and physicians in screening, preventive, diagnostic and treatment interventions, clinical trial entry, and end-of-life situations
- Utility of interventions and quality of life
- Patient-doctor communication
- Decision-making as a determinant of health disparities
- Development of patient-centered outcomes
- Use of decision support interventions designed to foster informed, preference-based patient choice
- Clinical practice guidelines

Dr. Suarez-Almazor believes there is a tremendous opportunity for growth in this field. Grouping these common interest themes under the shared umbrella of health decision-making, will enhance opportunities for funding and development. She sees this as an exciting and timely opportunity which will allow the Center to move ahead with a creative, forward-thinking and patient-relevant research agenda.



Publications

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COX-2-selective NSAID becomes the most effective and least costly (dominant) treatment strategy, followed closely by cotherapy with a daily proton-pump inhibitor. Because small changes in costs or assumed efficacy of these drugs could change the conclusions, the incremental cost-effectiveness ratios between any 2 strategies were presented in a nomogram that allows the flexible use of a wide range of values for costs and rates of clinical UGI events.

Conclusions. The risk of clinical UGI events in NSAID users depends on their baseline risk, the added risk associated with the individual NSAID, and the protection conferred by cotherapy. A nomogram can be used to incorporate these factors and derive estimates regarding cost-effectiveness of competing strategies aimed at reducing the risk of clinical UGI events.



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