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Commentary

Comparative Effectiveness Research— The New Imperative

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Concern over accelerated health care costs in the United States has increased sharply in recent years. The per capita spending of gross domestic product (GDP) in the United States on health care is greater than any other developed country. In 2006, the United States spent \$2.1 trillion, or 16 percent of GDP, on health care. This figure translates to \$7,026 per person annually, but unlike other developed countries that provide near-universal coverage, 47 million Americans (15.8 percent) lacked health insurance in 2006.

One of the dominant drivers of rising health care costs is technology related changes in medical practice (38-62 percent). Technology is pushed out into the field at an alarming rate often before it is ready for national deployment. Other factors that are dramatically increasing health care costs include prices in the health care sector (11-22 percent), personal income growth (11-18 percent), changes in third party payments (10 percent), administrative costs (3-10 percent), and aging of the population (2 percent).¹

At its current rate of increase, the rising cost of health care will be unsustainable in the future. As a result of these driving forces, researchers are examining a variety of approaches to controlling or decreasing health care costs.

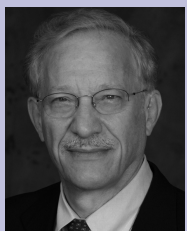
One of the hot new areas in research that is attempting to make an impact on improving health care and controlling cost is comparative effectiveness. While there is no standard definition of comparative effectiveness as of yet, several definitions have been proposed by the Center for Medical Technology Policy, Congressional Budget Office, and the Institute of Medicine. The VA Office of Research and Development is using the following working definition:

Comparative effectiveness studies are studies that provide information on the comparative benefits and/or harms of two or more alternative choices for a given clinical condition, patient population, or health care system. These choices can involve medications, invasive therapies, non-pharmacologic treatments, diagnostic tests and strategies, models of care, or implementation strategies.

Given this working definition, the minimum criteria for comparative effectiveness studies include:

- Comparison of two or more alternative approaches;
- Examination of patient outcomes (benefits and/or harms); and
- Comparison between interventions, modalities of care, or system attributes that can affect care, but not among patient factors, or time periods.

Director's Letter



This issue of FORUM focuses on the important topic of Comparative Effectiveness Research (CER). Both clinicians and patients appreciate the limited benchmarks available to inform clinical decisions and treatment options. Policymakers find themselves in a similar situation—making health care legislation in an evidence vacuum. For clinicians, patients, and policymakers alike, however, CER has the potential to provide much needed evidence-based criteria for health care decision-making.

Recently, CER activities have been expanding across the Federal Government. In March 2009, the U.S. Department of Health and Human Services (HHS) established a 15 member Federal Coordinating Council for Comparative Effectiveness Research (FCCER). Supported by funding of approximately \$1.1 billion, the FCCER will help guide, prioritize, and coordinate comparative effectiveness research across HHS and the Departments of Veterans Affairs and Defense. Joel Kupersmith, M.D., VA's Chief Research and Development Officer, represents VA on the council.

In other news, HSR&D gave a warm send off to Shirley Meehan who retired from VA service on May 1. Dr. David Atkins, QUERI Director, will also serve as Acting Deputy Director of HSR&D until a new Deputy is named.

And finally, I would like to note that we reviewed 124 proposals in the March review, of which we expect to fund 32 projects. In addition, we reviewed 30 Career Development Award applications and we expect to fund seven. Congratulations to all. Please keep your proposals coming.

*Seth A. Eisen, M.D., M.Sc.
Director, HSR&D*

Comparative Effectiveness – Research Methods

Different research methods are available for the study of comparing effectiveness of treatments. These methods include systematic reviews of existing research, analyses of claims records, analysis of medical registries, randomized controlled trials, and computer modeling. Each of these methods offers benefits and drawbacks.

Systematic reviews of research offer the easiest method by utilizing existing studies and synthesizing them to make additional comparisons. Analyses of claims records offer a more complex and time consuming method by utilizing existing sources of raw data. One advantage of this method is that it provides new information to resolve questions about treatments at a relatively low cost. One of the main difficulties with

analyses of claims records, however, is that such analyses do not account for patient health status differences. Medical registries are developed to track patients with a similar disease or similar specific treatment.

Randomized controlled trials are the most definitive way to compare different treatments but are generally very expensive to perform and take a long time to complete. Computer models are programs that simulate the effects of different treatments on various populations. This method has been suggested as an alternative or an addition to clinical trials. Each of these analytical methods offers advantages and disadvantages in studying comparative effectiveness; these techniques should be customized depending on the research question, or combined to answer specific questions.

Clinical Effectiveness or Cost Effectiveness?

There is current debate on whether federally-funded comparative effectiveness research should include consideration of cost effectiveness as well as clinical effectiveness. Some of the main arguments against including questions of cost effectiveness in comparative effectiveness studies are that cost structures vary across health care plans and, as a result, findings might not be generalizable to different plans or geographic areas. In addition, analysis of cost effectiveness might have a negative bias on the analysis of clinical effectiveness, leading to concerns that such analysis may result in restricted access to effective treatments. One advantage of considering cost effectiveness in federally-funded comparative effectiveness research is that it would encourage greater transparency and standardization in the methodologies used to determine cost.

The dominant driver of health care cost is the expanding medical technology arena where new modalities either fill a need for diagnosis and treatment, or replace older modalities that are cheaper. Newer technologies have a large impact on health care spending in the United States because there are few requirements that effectiveness be demonstrated before wide national implementation. Newer technologies also have the potential to increase applications where therapy might not even be effective.

The Veterans Health Administration research program offers an ideal home for studying comparative effectiveness. We are a large integrated health care system with an electronic medical record, Bar Code Medication Administration (BCMA) and provider order entry, strong pharmacy benefit, Technology Assessment Program (TAP) – and outstanding researchers.

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Response to Commentary

Comparative Effectiveness Research and Beyond

Paul G. Barnett, Ph.D., VA HSR&D's Health Economics Resource Center

Despite great advances in medical knowledge, the effectiveness of many health services is unknown. Comparative effectiveness research can close this gap and improve the quality of U.S. health care. The value of this research is widely appreciated. Effectiveness evaluations are almost universally employed by public and private health plans to determine what new technologies they will cover.¹

Comparative effectiveness research may not answer all decision makers' questions, however. An effectiveness study can determine both benefits and adverse effects of an intervention, but this does not reveal whether the health improvement outweighs the possible harm. Even with clear evidence that a new test can more effectively detect disease, other evidence is needed to know if early detection confers a net benefit. Data from many sources must be linked.

Using CEA to Extend Comparative Effectiveness

These types of limitations in comparative effectiveness research can be overcome by methods used in Cost-Effectiveness Analysis (CEA).²

CEA values health outcomes using a measure of morbidity adjusted survival called the Quality Adjusted Life Year (QALY). This measure can also be applied to comparative effectiveness research, to trade off benefits against harm. The medical decision modeling methods employed in CEA can be used in comparative effectiveness research, to link effectiveness findings to studies of long-term health outcomes.

Despite its versatility, CEA is not nearly as well regarded as comparative effectiveness

by U.S. decision makers. This may be because they do not understand the uses of CEA, because they feel that its methods are unreliable, or because findings have not been relevant to their particular setting or time-horizon.³

Other reasons why CEA may not be used include political opposition from drug and device developers, and unwillingness of Americans to concede that effective but expensive treatments cannot be provided if benefits are modest.

As Dr. Almenoff points out, new technology accounts for much of the increase in health care costs. CEA can help determine if innovations yield sufficient value to justify their cost. CEA methods have been standardized for more than a decade and applied to hun-

dreds of innovations. CEA is widely used in other countries, where it is among the criteria used to make coverage decisions.

VHA: The Challenge to Lead in Comparative Effectiveness Research

The Veterans Health Administration (VHA) is well positioned to be a U.S. leader in applying both comparative effectiveness and cost-effectiveness research. VHA is a globally budgeted, national system, with the long-term responsibility for the health of a well-defined population. Research is integrated with VHA care. VHA utilization and cost data are the envy of other health care plans.

Social value judgements about vulnerable or especially deserving plan members need to be incorporated into decisions based on CEA. This type of review has been important to the acceptance of CEA in other countries.⁴

Veterans are a well-organized constituency that deserves to participate in VHA coverage decisions.

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Recently, FORUM spoke with Al Perry, Director, VA Central California Health Care System regarding the challenges facing VHA Senior Leadership Teams in the field. Perry described five challenges:

1. Finding the most effective among constantly evolving treatment techniques, programs, equipment, and drugs.
2. Meeting the challenge of newly eligible Priority Group 8s, and of "victims" of the economic downturn.
3. Delivering health care services to returning OEF/OIF Veterans, particularly those with mental health care needs and those living in rural areas.
4. Delivering increasingly expensive services under tight budget constraints.
5. Addressing ever increasing expectations for measurable quality and outcomes.

HSR&D research topics of interest to leadership in the field include: provider behavior, comparative technology, inpatient vs. outpatient treatment particularly for mental health, settings and approaches to women's health, and solo vs. team or group treatment.

Research Highlights

Analysis of the Cost of an HIV Rapid Testing Initiative

Matthew Bidwell Goetz, M.D., Center of Excellence for the Study of Healthcare Provider Behavior, VA Greater Los Angeles Healthcare System

The benefits of identifying and treating asymptomatic Human Immunodeficiency Virus (HIV)-infected individuals substantially exceed those of early recognition of most medical conditions. Routine HIV testing is of particular importance to the VA, the largest provider of HIV services in the United States. Nevertheless, in the VA, as in many other health care systems, 50 percent of HIV-infected patients are diagnosed after they have developed severe immunological damage.

Among the deterrents to promoting early routine HIV testing is that reliance on standard blood tests requires that patients receive their test results at a later date; this can present a considerable barrier for homeless and transient patients. To address this barrier, QUERI-HIV/Hepatitis has undertaken a series of studies to evaluate the utility of same-day, oral fluid-based HIV rapid testing programs. One such study, which was conducted in a primary care clinic setting, demonstrated increased patient satisfaction and receipt of test results with nurse-based offer and performance of HIV rapid tests as opposed to traditional physician-ordered, blood-based HIV testing.

Economic Impact of HIV Rapid Testing

To assess the economic impacts of rapid testing, we conducted two separate complementary Cost-Effectiveness and Business Case Model (BCM, also referred to as Budget Impact Analysis) analyses. Whereas cost-effectiveness analyses consider the long-term (i.e., over a patient's lifetime) financial and health impacts of an intervention from a health care system or societal perspective, BCM analyses evaluate the

near-term financial costs of program implementation.¹

Even for programs that reduce costs (i.e., are cost saving), the savings are usually over a period of many years and the immediate implementation costs may overshadow short-term savings. This temporal financial mismatch is magnified for programs that are cost-effective rather than cost saving. Consequently, both Cost-Effectiveness and Business Case Models are necessary to appropriately estimate short-term and long-term financial impact.

Following this paradigm, we first conducted a cost-effectiveness analysis of the long-term financial and health impacts of nurse-based HIV rapid testing as opposed to physician-ordered traditional blood-based HIV testing. This evaluation built upon previous analyses that demonstrated that routine blood-based HIV testing is cost-effective on a societal basis at the \$50,000/QALY threshold for populations where the prevalence of undiagnosed HIV infection is greater than 0.05 percent. In analyses that considered the time spent for pre-test counseling, test performance and post-test counseling, laboratory supplies, and the care of persons found to be HIV-infected, we found that compared with the blood-based testing, the incremental cost of nurse-based rapid testing was \$10,689/QALY when societal benefits were considered.²

More recently, we developed a BCM to compare the financial impact of routinely offering rapid HIV tests during non-peak hours in a VA Emergency Department (ED) versus offering diagnostic testing only for patients presenting with symptoms sug-

gestive of HIV infection (as is usual ED practice). We estimated the number of people who would be identified as HIV-infected through routine rapid testing, the start-up and maintenance costs of the rapid test program, and diagnostic and treatment costs for HIV-infected patients identified by rapid testing. We then compared these costs to the expenses incurred by patients identified as being HIV-infected at later stages of disease through routine practice.

Using base case data from a single VA ED, we found that a rapid test program that makes use of ED capacity during non-peak hours was not more costly than usual ED practice. This result is likely due to the high costs of care of patients who present with late stage disease when current practice is followed. Given that early detection of HIV and linkage to treatment is associated with better health outcomes, and that the rapid test program does not cost more than current practice, this budget impact analysis provides support for the implementation of HIV rapid testing programs in VA EDs.³

Conclusion

Often, long-term cost-effectiveness assessments are used to establish the value of an initiative such as routine HIV testing. However, even when the long-term value of a program is clear, the realities of implementation in the near term can create significant barriers for acceptance. Effective BCM assesses the short-term costs and benefits to evaluate the consequences of implementing new initiatives.

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Research Highlights

Estimating Future Costs of Prosthetic Devices

David K. Blough, Ph.D., University of Washington, Seattle, Washington, Sharon Hubbard, M.S., Prosthetics Research Study, Seattle, Washington, Lynne V. McFarland, Ph.D., and Gayle E. Reiber, M.P.H., Ph.D., both with VA Puget Sound Health Care System, Seattle, Washington

Recently, the Department of Defense (DoD) issued a Rehabilitation Directive, the goal of which is to return service members with limb loss from Operation Enduring Freedom and Operation Iraqi Freedom (OEF/OIF) to pre-injury function and provide them the option of returning to active duty. To meet this goal, the DoD Amputee Patient Care Programs and VA Medical Centers offer state-of-the-art comprehensive rehabilitation care, including prosthetic care.

VA limb distribution practice allows any Veteran with limb loss to request and/or receive any prosthetic device if deemed medically appropriate, feasible and/or indicated according to their functional level. Prosthetic care is one component of a comprehensive rehabilitation care program for

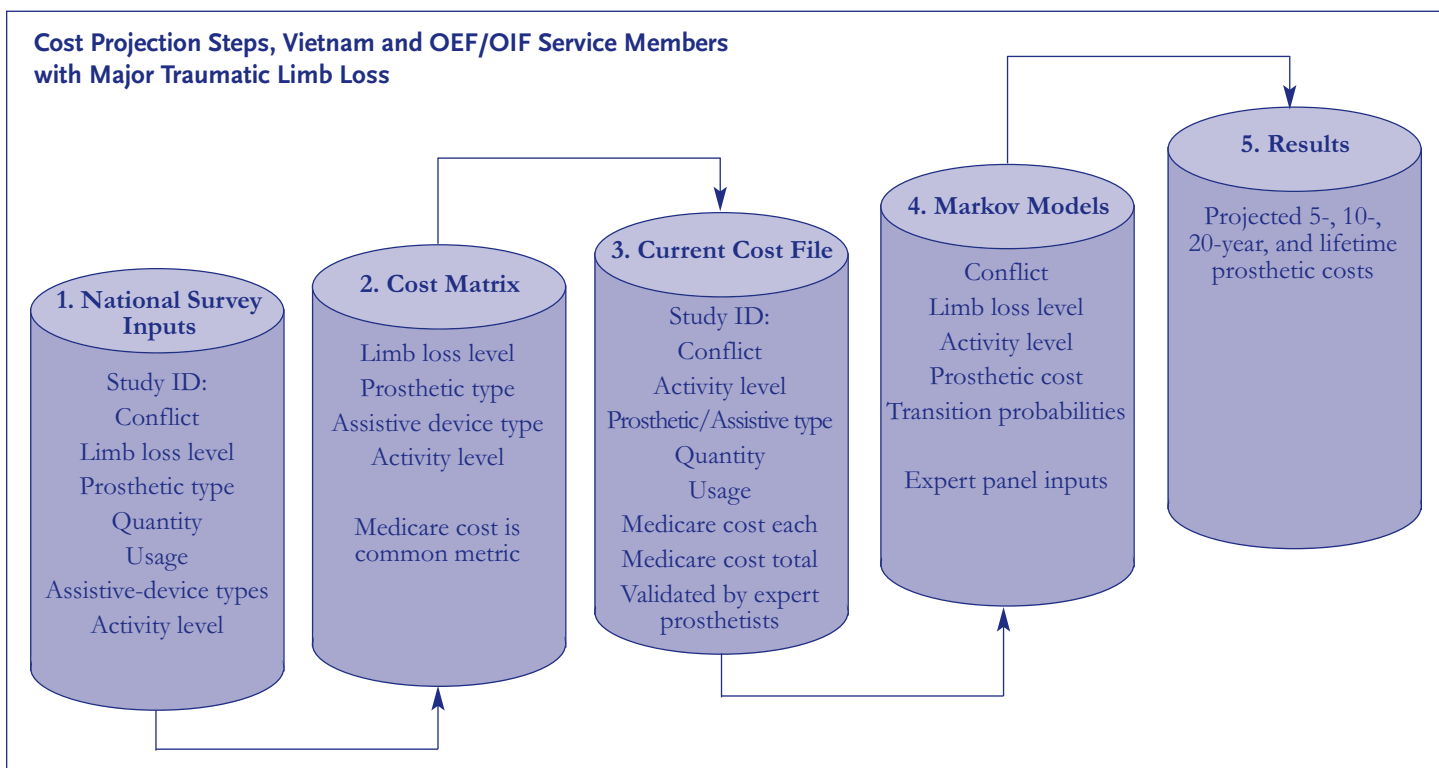
those with major limb loss. As such, it is crucial to estimate future costs of prosthetic devices in order to plan appropriately for effective resource allocation. We conducted a study of prosthetic costs as part of a larger research project involving service members with traumatic limb loss from Vietnam and OEF/OIF.

In step 1 of the study (see figure), researchers conducted a nationwide survey, which identified Vietnam and OEF/OIF service members' prosthetic history since limb loss and current assistive-device use. In step 2, researchers developed a cost matrix for all upper and lower limb prosthetic costs and assistive devices, and then categorized these by level of function using Medicare costs as the common metric.

In step 3, researchers linked each study participant's utilization and function to the cost matrix to compute individual total annual costs. In step 4, the study's expert panel of VA and DoD rehabilitation leadership, rehabilitation and prosthetic specialists, academic and private practice physicians, prosthetists, researchers, and service members with limb loss made recommendations on model parameters in areas where there is no published data. In step 5, researchers projected total cumulative prosthetic costs for 5-year, 10-year, 20-year, and lifetime time horizons. We did this separately for OEF/OIF service members and Vietnam Veterans suffering traumatic limb loss. Type of limb loss was categorized as isolated lower, isolated upper, bilateral upper, and multiple limb loss. For Vietnam and OEF/OIF cohorts, and each category of limb loss, we used separate cost-projection models.

The analysis results in cost distributions for projections over all time horizons and types of limb loss. Overall, our model indicates that for OEF/OIF service members with isolated lower limb loss, 5-year, 10-year, 20-year, and lifetime average per-person costs

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Research Highlights

Readmission for Heart Failure

Paul Heidenreich M.D., M.S., Chronic Heart Failure QUERI, VA Palo Alto Health Care System

Heart failure is a chronic syndrome associated with frequent exacerbations often resulting in hospitalization and death.¹ Readmission for heart failure occurs within 30 days following 20 percent of discharges from the VA system with similar rates in the Medicare health care system. The high rate of hospitalization has led to cost estimates of over \$37 billion for heart failure care in the United States for 2009.²

Given the high cost and morbidity associated with heart failure hospitalization, recent research has focused on preventing admissions and readmissions in particular. Accordingly, preventing readmissions is now a focus of heart failure studies including studies related to comparative effectiveness. The rate of heart failure readmission has been discussed as a possible performance measure by the VA, Joint Commission, and Centers for Medicare and Medicaid Services. The latter plans to release to the general public risk-adjusted 30-day heart failure readmission rates for all non-government hospitals in summer 2009.

A heart failure readmission may be defined in multiple ways. It can be the primary cause of admission (coded as a principal diagnosis), a contributing factor (coded as one of the secondary diagnoses), or it may be unrelated to heart failure but occurring within a certain time period following a heart failure discharge. Using the principal diagnosis criteria, readmission occurs in 10 percent of patients at 30 days following discharge compared to 20 percent if one defines heart failure as a primary or secondary diagnosis. An admission for any cause occurs in approximately 25 percent of heart failure patients at 30 days following discharge.

Readmission as a Measure of Health Outcome and Quality of Care

While a heart failure readmission clearly increases cost, its use as a measure of health outcome is less clear. One of the principles of care coordination is delivering the optimal care in the optimal setting. Occasionally this setting is in the hospital, and trying to keep some patients out of the hospital may result in inferior care.

If readmission is a valid measure of the quality of heart failure care, it should satisfy several criteria. First, a significant fraction of readmissions should be due to preventable causes. Unfortunately, heart failure as the primary diagnosis accounts for only about a third of readmissions. Half of all readmissions are due to non-cardiac causes (as the principal diagnosis), and the remainder of readmissions (one sixth) is due to non-heart failure cardiac causes.

Second, one should be able to distinguish elective from non-elective readmissions. Presumably the non-elective admissions are more indicative of quality of care. Patients may be readmitted for elective device placement (e.g. defibrillator or resynchronization therapy) and the diagnosis may be coded as heart failure.

Third, all relevant admissions should be captured. Often, readmissions for Veterans are not captured using VA records because many Veterans receive cardiology care for heart failure outside of the VA system. This dual use may bias results of comparative effectiveness and cost-effectiveness studies.

Finally, variation in case mix should be minimal or measurable so that appropriate ad-

justments can be made. VA hospitals show moderate differences (e.g. age, income) in the patient population they admit with heart failure and such differences are likely to impact readmission rates.

Heart Failure Readmissions and Cost-Effectiveness

Since heart failure admissions account for up to 80 percent of the cost of heart failure care, knowing the impact on heart failure admissions is important for all cost-effectiveness analyses of heart failure interventions. As a general rule, any treatment that reduces heart failure hospitalizations (or mortality) is likely to be cost-effective compared to other accepted health interventions. Many disease management programs have reduced heart failure readmissions, though recent trials have had difficulty showing significant reductions, perhaps due to the improvement in usual care for heart failure.

Data from VA, non-VA U.S., and non-U.S. countries have demonstrated that as recommended medication use has increased so has survival following a hospitalization for heart failure. Unfortunately, readmission rates have not similarly improved in the VA and data from the U.S. National Hospital Discharge Survey indicate a slight increase in hospitalization rates from 1995-2004. While a heart failure admission is a clear contributor to the cost of care, using it as an outcome or quality measure is challenging. Cost-effectiveness and comparative effectiveness studies should not limit their outcome assessments to readmission when evaluating heart failure treatments.

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Highlights of the 2009 HSR&D National Meeting

“Defining Optimal Care: Balancing Quality, Cost, and Patient Preferences” was the theme of the 27th VA Health Services Research and Development Service (HSR&D) National Meeting held February 11-13, 2009 in Baltimore. The Center for Clinical Management Research – HSR&D’s Center of Excellence in Ann Arbor, Mich. served as this year’s meeting host. More than 660 policymakers, clinicians, and researchers attended the meeting where 82 papers, 18 workshops, and 125 posters were presented on vital health care issues, such as chronic illness, vulnerable populations, mental health, economic analysis, and long-term care.

In addition to the exceptional peer-reviewed research presented over the course of the meeting, the meeting offered a day devoted to HSR&D’s Career Development Program. One of HSR&D’s greatest strengths is the high caliber of its investigators. Supporting the development of investigators in the early, mid- and advanced stages of their careers is a high priority. The meeting also offered several special interest group sessions and breakfast sessions on topics ranging from ways to improve health care for Veterans living in rural settings, to strategies for improving VA/DoD research collaborations, to genomics.

A special plenary paper session highlighted the five top scoring abstracts submitted to the meeting. The topics of these five presentations were as follows:

- Impact of Novel Patient Educational Booklet on Colonoscopy Preparation in Veterans by Brennan Spiegel, M.D., M.S.H.S., and
- Assessing VA Mental Health Intensive Case Management: Program Effects on Mental Health Services Use by Eric Slade, Ph.D.

Other meeting highlights included an address by then VA Under Secretary for Health Michael Kussman, M.D., M.S., MACP, who also presented two of VHA’s highest honors. H. Gilbert Welch, M.D., M.P.H. received the Under Secretary’s Award for Outstanding Achievement in Health Services Research. Part of the White River Junction VA Medical Center in Vermont, Dr. Welch has made significant contributions in the areas of technology assessment, health policy, and understanding the benefits and harms of early diagnosis. The other honor was presented to Dr. Shirley Meehan (see box).

VA’s Chief Research and Development Officer, Dr. Joel Kupersmith, and HSR&D Director, Dr. Seth Eisen, each spoke about current VA research priorities, such as the care of complex chronic conditions and post-deployment health. The keynote address was provided by Nicole Lurie, M.D., M.S.P.H., Director of Population Health and Health Disparities and Co-Director of the Center for Domestic and International Health Security at the RAND Corporation, who spoke about the rapidly changing health care environment. Dr. Lurie’s thoughts on the topic were of particular interest given her recent role as a member of the Obama Transition Project’s Agency Review Working Group, for which she assessed the U.S. Department of Health and Human Services.

Meeting abstracts are available at www.hsrd.research.va.gov/meetings/2009/abstracts.cfm. Slide presentations are available on the VA Intranet only at vawww.hsrd.research.va.gov/meetings/2009/presentations.cfm

Several new Special Interest Groups (SIG) have formed within HSR&D. See information about joining or starting a new SIG at www.hsrd.research.va.gov/for_researchers/sig/

Meehan Receives VA’s Exemplary Service Award



Dr. Kussman presented the highest honor bestowed by the Office of the Under Secretary – VA’s Exemplary Service Award – to Shirley Meehan, M.B.A., Ph.D., HSR&D Deputy Director. Dr. Meehan received the award at the 2009 HSR&D National Meeting.

During her 38-year tenure with VA, Dr. Meehan contributed in many ways to improving the health and health care of

Veterans. She began working within research in the 1970s, helping to build the infrastructure of the health services research program. Most of us know her best as Deputy Director of HSR&D, a position she has held since 1992. In the Deputy role, she helped to enhance the HSR&D program by strengthening the merit review process, contributing to the development of the HSR&D Centers of Excellence, shaping the Career Development Award Program and more recently, helping construct the Evidence Synthesis Program. In addition, she helped shape the HSR&D research portfolios and guided the hiring and training of the excellent Scientific Program Managers who currently oversee them. Dr. Meehan retired from VA on May 1, 2009.

- A Cost-Benefit Analysis of Higher Medication Copayments in Veterans with Schizophrenia by John Zeber, Ph.D.,

- Case/Self Management in COPD: A Randomized Trial by Kathryn Rice, M.D.,

- AUDIT-C Alcohol Misuse Screening and Post-operative Complications: A Cohort Study of Men Undergoing Major Surgery in VA by Katharine Bradley, M.D., M.P.H.,

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Researchers must do a better job of learning the needs of health care decision makers. (For an example, see the concerns of medical center director Alan Perry in the side bar). We must clearly articulate our methods. Our studies must be more relevant and timely. We can shorten our response time by developing models of care for major diseases in anticipation of future coverage decisions.

Every household understands that resources are limited and that choices must trade off value against cost. Comparative effectiveness is just the first step on a path to greater efficiency. Cost-effectiveness analysis can help us get the best possible outcomes from the available health care budget.

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are \$229,000, \$474,000, \$856,000 and \$1.5 million, respectively. The corresponding costs for the Vietnam group were estimated to be \$82,251, \$167,848, \$281,234, and \$342,716, respectively. The mean costs for the OEF/OIF group are 2.8 fold to 6.2 fold higher than the corresponding costs for the Vietnam group. This reflects higher costs for the more technologically advanced prostheses, use of multiple artificial limbs, and fewer service members abandoning prosthetic devices. The standard deviations of costs steadily increase as the length of the projected time horizon increases for both groups and all types of limb loss, thus estimating costs over longer periods has greater uncertainty.

Based on our findings we recommend a uniform standard of rehabilitation and prosthetic care for service members with limb loss cared for by VA directly or through VA contracts. A uniform standard for coverage of prosthetic and assistive devices as part of their overall rehabilitation care will assist veterans with major traumatic limb loss.

The study provided VA clinicians and policy makers with information on the health, combat injuries, function, quality of life, prosthetic-device utilization, replacement, abandonment,

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and satisfaction of these service members. The results of this study will assist VA clinicians and decision makers in planning for future care of service members with limb loss. Findings from the larger study include four editorials, 10 manuscripts and the expert panel's clinical and research recommendations for care of service members with limb loss. Complete study findings are slated for a special issue of the *Journal of Rehabilitation Research and Development* later this year.