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VA RESEARCH & DEVELOPMENT

VA Research & Development New Initiatives: *Meeting Veterans Needs*

1999

Department of Veterans Affairs

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VA Research & Development
New Initiatives:
Meeting Veterans Needs

September, 1999

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Veterans Health Administration



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The pursuit of excellence in many ways boils down to the pursuit of new knowledge. That is why research is so important to the VA's mission of improving the health of America's veterans. Without the continued breakthroughs and innovations of our Research and Development Program, VA's efforts to deliver excellence in health care service and value would be limited.

Because the veterans health care system is so large – consisting of more than 1,100 care delivery sites across the 50 states, the District of Columbia, Puerto Rico, the US Virgin Islands, Guam, and the Philippines – our research needs are many, varied and complex. And, due to the breadth, capacity and quality of our research enterprise, VA's R&D Program benefits not only veterans but all Americans. The scope of the VA research portfolio extends from basic laboratory research on the cause, treatment and cure of a variety of diseases, disorders and disabilities to clinical research on patient care management. Many modern medical technologies – including the cardiac pacemaker, the CT scan, magnetic resonance imaging, and drug therapy for the mentally ill – have their roots in VA research. Without question, VA's R&D Program is a world leader in medical science and health care research.

This document has been compiled to enhance understanding of VA's many and diverse research assets, offering the latest information on new and ongoing research initiatives, career development programs, and research partnerships. It is my hope that the information here will shed new light on the exciting cutting edge work of VA's Research and Development Program.

Thomas L. Garthwaite, M.D.
Acting Under Secretary for Health



It has been two years since our document, *Refining Research Priorities: New Initiatives Meeting Veterans Needs*, was published. Since then, so much has happened in VA Research that I felt it was time for an update. Even a cursory review of this new edition shows the breadth of new and ongoing research aimed at improving health care not only for veterans but for all people.

As the VA health system continues its rapidly unfolding transformation, the role of research in providing high-quality scientific evidence to support decisions is more important than ever. VA is the largest integrated health care system in the country, providing care to nearly 3.5 million veterans. Once a disease-oriented, hospital-based system, VA has redefined itself into a patient-centered, prevention-oriented system with primary care as its central focus. But change is far from over at VA – indeed, it will be a continuous process, and VA Research will continue to be a major contributor to that process.

Our four research services work to meet the mission of the VA Research enterprise: “to discover knowledge and create innovations that advance the health and care of veterans and the nation.” Those four services are:

- the Cooperative Studies Program, one of the most important large-scale clinical trial programs in the world, providing evidence on the effectiveness of new or unproved therapies;
- the Health Services Research and Development Service, which examines the organization, financing and management of health care and their effects on health care delivery, quality, cost, access and outcomes;
- the Medical Research Service, which provides knowledge of fundamental biological processes to expand our understanding of disease pathology; and
- the Rehabilitation Research and Development Service, whose goal is to minimize disability and restore function in veterans disabled by trauma or disease.

This document provides descriptive information on all new initiatives under way in each of the four VA Research services. A section on each service contains overview information on new initiatives and planned initiatives, as well as planned funding for these initiatives. For some of the services there is also a special section describing important partnerships with other public and private organizations. Information about VA Research Awards and the Research and Development Career Development program and their many opportunities for investigators is also provided.

The information provided here reflects the tremendous intellectual capital that VA Research brings to meeting the many and complex needs of our veteran patients. It also reflects our ongoing quest to develop new scientific information that supports VA in its mission of providing excellent, cost-effective health care. I am delighted to provide you with this research update, and I hope that it is a useful resource.

John R. Feussner, M.D.
Chief Research and Development Officer

COOPERATIVE STUDIES PROGRAM



*John R. Feussner, M.D.,
Director*

The Cooperative Studies Program (CSP) is a major clinical research program that conducts randomized controlled clinical trials across selected Veterans Affairs Medical Centers (VAMCs) and non-VA research facilities. Since the first cooperative trial in the 1940's, VA's CSP has grown into one of the world's premiere programs for large scale clinical trials. CSP's mission is to: conduct clinical research on health issues that are vital to our nation's veterans; define research results that establish new standards of care and improve veterans' health; improve the efficiency of the VA health care system; and improve the health of the population as a whole.

CSP utilizes rigorous scientific clinical trial methodology to establish definitive findings to clinical questions whose results will have a direct impact on veterans' clinical care. For example, recently published results of CSP trials described better treatment for refractory schizophrenia with clozapine, established the optimal medical management for benign prostatic enlargement, and established definitively the effectiveness of urologic surgery for prostate enlargement. The size and scope of the Veterans Health Administration and the VA CSP infrastructure that includes four Coordinating Centers, a Clinical Research Pharmacy and three Epidemiological Research and Information Centers (ERICs), make it an exceptional laboratory for conducting such large scale clinical trials. CSP can organize research involving multiple medical centers within VHA and obtain greater benefits than can be achieved from a single site study. CSP's multi-center study efforts provide a natural resource to the VA health care community and beyond.

Described below are our newly initiated clinical trials, trials in planning, epidemiology studies, new program announcements, training, and partnerships. To highlight a few items:

- We have recently funded three studies that will look at the impact on practice of important findings published in journals and presented at national meetings.
- We are working to find answers for Gulf War veterans. While there were few casualties associated with the Gulf War, many individuals returned from this conflict with unexplained symptoms and illnesses such as chronic fatigue syndrome, generalized body pain of unknown origin, post-traumatic stress syndrome, neurological abnormalities, and other generalized health impairments. It has been further suggested that service in the Gulf War may have impacted upon the health of the spouses and biological children of veterans. This constellation of symptoms has been termed Gulf War Veterans' Illnesses (GWI) and is the subject of three CSP studies.
- We also have three national scope epidemiology studies planned or under way, as well as many more smaller scale epidemiology studies in process through the three Epidemiology Research Information Centers.

The Clinical and Economic Impact of Olanzapine in the Treatment of Schizophrenia

Project Dates	1998-2001
Funding (provided by Eli Lilly & Co.):	\$6,734,072

Currently marketed antipsychotic drugs are useful in the treatment of psychotic disturbances, but opportunities exist to improve upon their efficacy and/or safety profiles. With respect to efficacy, 40% to 80% of patients either fail to respond or only respond partially to conventional antipsychotic agents. Olanzapine is a novel antipsychotic agent for the treatment of psychotic disorders, including schizophrenia, and is associated with only few, mild and often transient side effects.

The primary objective of the study is to assess the cost effectiveness of olanzapine (5mg to 20mg/day) compared with that of a standard antipsychotic medication, haloperidol (5mg to 20mg/day), in the treatment of schizophrenia as measured by clinical outcome. Secondary objectives of the study will compare olanzapine with haloperidol in the treatment of schizophrenia to assess the efficacy and the safety of olanzapine, and assess the improvement in social and vocational functioning in schizophrenic patients treated with olanzapine in comparison to those treated with haloperidol. This study is a randomized double-blind, parallel study of 600 inpatients and outpatients being conducted at 19 VAMCs with patients being randomized over a 20-month recruitment period and then followed for 12 months. (CSP 451)

Influenza Virus Infection in Patients with Chronic Obstructive Pulmonary Disease

Project Dates	1998-2000
Funding:	\$5,000,000

Influenza infections are a source of significant morbidity among patients with underlying respiratory illnesses such as chronic obstructive pulmonary disease (COPD). COPD is a common health problem among patients in the VA health care system. The primary question which this study is designed to answer is whether or not, in patients with COPD, co-administration of live, cold-adapted influenza virus vaccine (CAIV-T) with intra-muscular inactivated influenza virus vaccine (TVV) is more efficacious in preventing natural, wild-type influenza virus infection than intra-muscular TVV alone. The study is a prospective, randomized, one-year, multi-center, double blind trial. Participants are male and female veterans attending VA outpatient clinics or residing in VA nursing homes and domiciliaries who are at least 50 years of age and have pre-existing, clinically stable COPD. (CSP 448)

Enhancing the Quality of Informed Consent (EQUIC)

Project Dates	1999-2002
Funding:	\$248,953

Informed consent is the keystone of the protection of human rights in medical research, along with careful review of proposed projects. EQUIC is a CSP program-wide project aimed at systematically improving the quality of informed consent, by testing and measuring the results of innovative approaches to informed consent. Practitioners of clinical trials must ensure that patients' participation in research is informed and voluntary. This responsibility implies that we should strive continuously to improve the effectiveness of methods for informing prospective research volunteers about experimental studies, thereby enhancing the protection of their interests. We should test innovations in informed consent in realistic contexts such as clinical trials, and with the strongest scientific designs.

EQUIC will field and test: a method to assess the capacity of a research volunteer to understand and consent to a study; a method for "tailoring" an informed consent encounter to the vulnerabilities uncovered by that assessment; and a direct assessment of the success of an informed consent process at producing a good result, defined in terms of the successful protection of the patient's rights. Once these are fielded and tested, it will be possible to study a wide range of innovations in informed consent in the full variety of patients studied in the CSP. An important side benefit will be the ability to assess the true results of current practice in the VA CSP, and, potentially, other systems. (CSP 476)

DNA Bank Demonstration Project

Project Dates: 1999-2001
Project Funding: \$773,737

The “DNA bank” is a program-wide genetic tissue databank for the Department of Veterans Affairs Cooperative Studies Program (CSP). The aim of the DNA Bank is to ensure the protection of individual patient rights while enabling VA investigators to take advantage of exciting advances in human genetics that promise dramatic progress toward medical research and treatment goals. It will serve a wide range of studies in several disease areas.

The DNA bank is a collaboration among three institutions. The Palo Alto CSP Coordinating Center administers the tissue bank, coordinates the scientific and ethics oversight committees, maintains central access to clinical study data linked to the tissue bank, and provides statistical analysis. The Massachusetts VA Epidemiologic Research and Information Center (MAVERIC) provides a central repository for DNA and other genetic tissue specimens. The Human Genetics Center at Stanford University provides key scientific, legal, and ethical expertise to the DNA bank. The DNA bank will begin with a demonstration study, partnered with CSP 410, “The Iron (Fe) and Atherosclerosis Study (FeAST),” in patients with peripheral vascular disease. (CSP 478)

Positron Emission Tomography (PET) to Detect Solitary Lung Nodules

Project Dates: 1998-2003
Project Funding: \$2,684,132

Accurate non-invasive identification of cancerous lung tumors should expedite the removal of potentially surgically curable cancerous lesions and minimize the number of benign masses and surgically incurable lung cancers for which chest surgery is done. This study is evaluating the utility of FDG-PET in differentiating benign from cancerous process in patients with solitary lung nodules. It is anticipated that FDG-PET will be more accurate than chest x-ray and CAT scan in differentiating benign from cancerous lung nodules and that FDG-PET will be useful as a non-invasive technique for accurate differentiation of benign and cancerous lung nodules. (CSP 27)

Randomized Clinical Trial of Surgical Hernia Repair

Project Dates: 1998-2003
Project Funding: \$5,345,201

Inguinal hernia is one of the most common worldwide afflictions of men. An estimated 500,000 groin hernia repairs are performed annually in the US and as many as 800,000 Americans have groin hernias potentially in need of repair. This study is comparing the use of an open surgical procedure for repairing hernias with laparoscopic hernia repair to determine whether the open technique can achieve equal or better outcomes at a lower cost. (CSP 456)

Anti-Thrombotic Agents for Prevention of Hemodialysis Access Thrombosis

Project Dates: 1998-2001
Project Funding: \$3,467,000

Maintenance of blood vessel access has been termed the “Achilles heel” of hemodialysis of patients with kidney disease. Thrombosis (blood clotting) of hemodialysis grafts is a major cause of complications and hospitalization in hemodialysis patients. Effective therapy to decrease the rate of blood clotting would have significant impact on VA patient morbidity as well as providing cost savings of up to \$12 million. This study is examining the effectiveness and economic benefit of a combination therapy (aspirin + clopidogrel) in reducing thrombosis for hemodialysis patients. (CSP 440)

Prophylaxis of Medical Patients for Thromboembolism (PROMPT)

Project Dates: 1998-2002
Project Funding: \$13,969,919

Pulmonary embolism is thought to be the most common preventable cause of hospital deaths, accounting for about 15% of all deaths during hospitalization. This study will determine whether prophylactic treatment with heparin reduces the death rate for hospitalized patients. (CSP 438)

Treatment of Advanced Laryngeal Cancer

Project Dates: 1998-1999
Project Funding: \$60,000

Treatment for advanced stage laryngeal cancer most often results in the surgical removal of the larynx and necessitates a prosthetic voice synthesizer to allow the patient to talk. A VA Cooperative Study (CSP 268) conducted between 1985 and 1991 entitled “A New Strategy to Preserve the Larynx in the Treatment of Advanced Laryngeal Cancer” demonstrated that surgical removal of the larynx could be avoided in a majority of the patients by using a combination of chemotherapy and radiation therapy. These findings were published in *The New England Journal of Medicine*, *Cancer*, *Laryngoscope*, and the *Journal of Clinical Oncology*, and have been presented at numerous national meetings.

This impact study will compare the initial treatment regimen of patients with advanced stage laryngeal cancer before and after publication of the study results. Researchers expect to find increased use of the non-surgical strategy following publication. The follow-up study will provide means to measure how well the results of this important study have been disseminated to the general medical community, and a method to monitor the time from publication of a new effective treatment regimen to the actual implementation of the regimen in clinical practice. (CSP 268I)

Administration of Recombinant Human Erythropoietin in Dialysis Patients

Project Dates: 1999-2000
Project Funding: \$100,000

More than 90% of hemodialysis patients experience severe anemia. A new drug, recombinant human erythropoietin (epoetin), is very effective at combating this anemia, but it is very expensive, costing \$5,000 to \$10,000 per patient annually. A landmark CSP trial “A Comparison of Subcutaneous and Intravenous Administration of Recombinant Human Erythropoietin in Dialysis Patients,” demonstrated that the amount of epoetin required may be substantially reduced (as much as 32%) when the dose is administered subcutaneously rather than intravenously. Results from this study were published in *The New England Journal of Medicine* in August, 1998.

CSP is now conducting a follow-up study to evaluate the impact of these results. The follow-up study will assess changes in clinical practice and will evaluate the potential economic impact of subcutaneous epoetin administration compared to intravenous administration among HCFA Medicare reimbursement expenditures. This study will provide important information for health care managers and policy makers within VA and in the larger health care community. The potential economic impact of this study is enormous — VA CSP estimates that as much as \$450 million could be saved annually in the United States through Medicare reimbursements, if this drug were administered subcutaneously to all hemodialysis patients. (CSP 392I)

VA Non Q-wave Infarction Strategies in Hospital (VANQWISH)

Project Dates: 1998-1999
Projected Cost of Study: \$78,000

Some 600,000 patients are admitted to US hospitals each year with a non Q-wave myocardial infarction. Care involves routine diagnostic cardiac catheterization and treatment with angioplasty or bypass surgery, at a cost that exceeds \$20 billion a year.

The VA Non Q-wave Infarction Strategies in Hospital (VANQWISH) trial determined that a conservative strategy is better than an invasive approach in treating this type of heart attack. A cost-effectiveness study is now under way.

VANQWISH patients treated with a conservative strategy were less likely to have surgery or angioplasty, so their initial hospitalization should be less costly. The economic study will determine the effect of strategy on the cost of the initial stay and follow-up care, determine which strategy is the most cost-effective, estimate the impact of adopting VANQWISH recommendations on US health care costs and pioneer VA cost determination methods. (CSP368I)

Antibiotic Treatment of Gulf War Veterans' Illnesses

Project Dates: 1999-2001
 Projected
 Cost of Study: \$7,801,122

Although several explanations have been offered as to the cause of GWI, none of the putative etiologic agents or conditions is currently supported by sufficient evidence. One explanation that has received fairly widespread attention is systemic *Mycoplasma fermentans* infection. It is the purpose of this study to determine if antibiotic treatment directed against *Mycoplasma* species (i.e., doxycycline) will improve functioning and symptoms in deployed Gulf War veterans with GWI.

This clinical trial will follow 450 GWI patients who test positive for *Mycoplasma* species to determine if a 12-month course of antibiotic treatment directed against *Mycoplasma* species will improve functional status. (CSP 475)

A Randomized, Multi-Center, Controlled Trial of Multi-Modal Therapy in Veterans with Gulf War Illnesses

Project Dates: 1999-2001
 Projected
 Cost of Study: \$9,272,410

This trial will study Gulf War era veterans who have unexplained chronic medical symptoms such as pain, fatigue and/or cognitive difficulties. The treatments to be studied, cognitive behavioral therapy (CBT) and aerobic exercise, have been shown to be effective in alleviating symptoms in individuals with other similar types of illnesses, such as chronic fatigue syndrome and fibromyalgia. The primary hypothesis of this study is that both aerobic exercise and CBT will significantly improve physical function and that the combination of CBT and aerobic exercise will be more beneficial than either therapy alone. (CSP 470)

National Health Survey of Gulf War Era Veterans and Their Families

Project Dates: 1998-2002
 Projected Funding: \$11,657,833

In this study, a random sample of 1,000 veterans who were deployed in the Gulf War will undergo clinical examinations. Additionally, the spouses and children of these veterans will be examined. This group will be compared to a random sample of 1,000 Gulf War Era veterans and their families who were not deployed in the Gulf. These non-deployed patients and their families will undergo the same examinations as the deployed veterans. Veterans, their spouses and children will be examined at 17 participating VA medical centers. Findings should help determine if there is a higher level of health problems among Gulf War veterans and their families compared to non-deployed veterans. (CSP 458)

Warfarin and Antiplatelet Therapy Study in Heart Failure (WATCH)

Project Dates: 1999-2004
 Projected
 Cost of Study: \$23,000,000
 Projected
 VA Funding: \$10,000,000

Congestive heart failure (CHF) remains an important clinical and societal problem. In the United States alone, it is estimated that more than 4 million patients suffer from CHF, with an annual incidence of more than 400,000 new cases, resulting in 40,000 deaths and 875,000 hospitalizations. Although there have been important advances in the pharmacologic treatment of CHF over the past two decades, CHF remains a very lethal condition.

The use of anticoagulant therapy to prevent thromboembolic complications in patients with dilated cardiomyopathy has long been advocated, but little is known about the efficacy of this therapy, the optimal therapy, and for whom the therapy will be effective. Current practice guidelines reflect this uncertainty. Only a rigorous clinical trial can determine the appropriate use of anticoagulant and antithrombotic therapy. This study will compare the effect of three antithrombotic therapies in patients with congestive heart failure. Eligible patients will be randomized to treatment with aspirin, warfarin or clopidogrel. This international study will enroll 4,500 patients. This will require participation of up to 150 centers for a three-year enrollment period with all patients followed for a minimum of two years. Non-VA centers in the US as well as centers in Canada and the United Kingdom will participate. (CSP 442)

Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE)

Project Dates: 1999-2005
Project Funding: \$33,000,000

Heart disease affects more than 7 million people in the US and is the leading cause of death among Americans. The COURAGE study is a large-scale, multi-center, randomized controlled trial comparing the effectiveness of angioplasty with medical therapy to medical therapy alone in treating patients with coronary heart disease. CSP investigators are testing the hypothesis that angioplasty with intensive medical therapy is superior to intensive medical therapy alone, using the combined endpoint of all-cause mortality or non-fatal myocardial infarction. This international 6.5-year study involves more than 3,000 patients in VA and non-VA sites throughout the US and Canada. (CSP 424)

Planned Clinical Trials

Strict Monitoring and Regulation of Blood Sugar in Type II Diabetes

Estimates indicate that one-quarter of the patients who are treated in VA medical centers have adult onset diabetes. The cost of treating these patients for their diabetes and secondary diseases of the eyes, kidney, nervous system, and cardiovascular system is extremely high. While most patients can be initially treated with oral medications, most will eventually be treated with insulin as their disease progresses.

This clinical trial will examine whether very close monitoring of blood sugar levels, and maintaining these levels as close to normal as possible, might prevent or delay the onset of the secondary effects of diabetes, particularly cardiovascular outcomes. A cost-benefit analysis will also be performed to determine whether the high cost of monitoring and regulating blood sugar levels translates into savings with regard to the treatment of secondary diseases. (CSP 465)

Deep Brain Stimulation in the Treatment of Parkinson's Disease

Parkinson's disease affects from 750,000 to one million people in the United States. This disease is characterized by difficulty performing purposeful movements in a smooth manner, rigidity in the limbs and tremors. In a five-year survey of in-patients conducted by the VA, it was found that over 41,000 veterans had come to their medical centers with a primary or secondary diagnosis of Parkinson's disease. The number of out-patients treated for Parkinson's disease is expected to be significantly larger. Many patients with Parkinson's disease have persistent disabling symptoms even after receiving the most effective drug treatments available. For these patients, surgical therapy may be the most effective way of relieving their symptoms. Since 1900, a surgical procedure performed on the brain called pallidotomy has been effective in relieving symptoms on the opposite side of the body. It was discovered that performing this procedure on both sides of the brain to relieve symptoms had an unacceptable complication rate. This has prompted researchers to discover new methods of alleviating symptoms. Deep electrical stimulation of the brain is being suggested as an alternative to pallidotomy, since it is non-destructive and can be performed on both sides of the brain without the side effects of pallidotomy.

This study is designed to compare the effectiveness of bilateral electrical stimulation of the subthalamic nucleus with unilateral pallidotomy followed by contralateral globus pallidus interna stimulation. Patients included in this trial are those with persistent symptoms that severely limit their ability to perform activities of daily living for whom drug therapies have proven to be ineffective in the treatment of their symptoms. Patients will be followed for two years after treatment to determine the effectiveness of the two treatment strategies. (CSP 468)

**Radial Artery
versus Saphenous Vein
Grafts in Coronary
Artery Bypass Surgery**

Blockage in one or more of the vessels that provide the blood supply to the heart necessitates coronary bypass surgery. Historically, bypass surgery was performed using veins. It was the belief among surgeons that the use of arteries would be preferred over veins because they would remain open for a longer period of time. The use of radial arteries often was accompanied by a condition known as vascular spasm that would present itself after surgery (making bypass using radial arteries more speculative). The recent emergence of drugs to prevent vascular spasm has again made use of radial arteries more attractive for bypass surgeries.

This trial is designed to determine the long-term effectiveness of radial artery grafts for bypass surgery when compared with saphenous vein and internal mammary grafts. Both the immediate (one-week post-surgery) and the long-term (three years post-surgery) effects will be examined. It is estimated that 1,080 consenting patients will be recruited over a three-year period. Patients will be followed for another three years to determine the long-term condition of the grafts. (CSP 474)

**Homocystinemia in
Kidney and End-Stage
Renal Disease**

This randomized, controlled trial will investigate the effect of high doses of vitamin B (folate, B6, and B12) on mortality in patients with chronic renal failure and end-stage renal disease. Forty VA Medical Centers will enroll 2,000 patients over a 1 year period with a minimum follow-up of 3 months at each medical center. After this, patients will be followed by phone from a central location and have their drugs mailed from the research pharmacy for another 4¼ years. Homocysteine and vitamin levels will be measured at screening and again at 3 months. (CSP 453)

**Heart Failure in
Patients with Preserved
Systolic Function**

Although heart failure in patients with preserved systolic function causes significant morbidity and mortality among veterans and the general population, it has seldom been studied. CSP is conducting a multi-center, randomized, double-blind, controlled trial to determine the effectiveness of a beta-blocker and a renin-angiotensin system inhibitor in treating these patients. This four-year study involves more than 2,000 heart failure patients. (CSP 484)

**Cost and Outcome of
Varying Primary Care
Revisit Intervals**

“How often should the patients be seen in routine follow-up?” is one of the fundamental issues of day-to-day clinical operations. Does seeing patients more frequently result in better care? This study will serve as the start of a process to test the validity of this generally accepted clinical doctrine. The goal of this study is to provide data on the outcomes from lengthening and shortening primary care revisit intervals. By randomizing patients to one of three revisit intervals, the study will examine the effects of revisit intervals on patient health status and health care costs. A five-year study is proposed, with a one-year pilot followed by four years for the full study. (CSP 473)

**Trials of Home-based
PT-INR Monitoring**

The Home Monitoring Study will test whether patients who require anti-clotting therapy to survive can use a home monitor of anticoagulation status to reduce the rate of major complications. The method involves a simple-to-use take-home machine that measures the clotting time of the patient's blood, together with a careful training program to make sure that the patient knows what to do with the results. The use of anti-clotting therapies is currently limited by the chance of serious side effects, such as bleeding and stroke, if the clotting time is reduced too much, and by the chance of serious blood clots in the lungs, heart, and brain, if the clotting time is too long. The full

potential of anti-clotting therapy will be realized only if patients can be kept in a rather narrow “therapeutic window,” not too little and not too much, over the long term. Home monitoring is an exciting promise, made possible by new advances in micro-miniaturization, together with new approaches providing the patient the tools to help manage his or her treatment. (CSP 481)

Effects of Treatment of Sleep Apnea with Oxygen on Hospitalization and Survival of Patients with Stable Heart Failure

Heart failure and sleep apnea are prevalent in veterans. Pioneering VA studies have demonstrated the positive effects of vasodilators in patients with heart failure, but the mortality rate remains high, as does the rate of re-hospitalization. This CSP study tests the hypothesis that treatment of sleep apnea with oxygen will improve the survival and quality of life of veterans with heart failure and reduce the number of hospitalizations. The study will also identify risk factors associated with sleep apnea in patients with optimally treated, stable heart failure. (CSP 455)

Testosterone Treatment to Prevent Fractures in Aging Hypogonadal Men

Skeletal fractures are significant problems among older men. Medical knowledge of the role of testosterone replacement therapy for men with low serum testosterone levels to prevent fractures needs to be studied further. This study, in collaboration with the National Institutes of Health, and the National Institute on Aging (NIA), will assess the effects of testosterone replacement therapy compared to placebo on the incidence of bone fractures among veterans and non-veterans over 65 years old. Secondary analyses will study the effects of testosterone on markers of bone marrow, metabolism, and bone mineral density, and on the effects on the prostate and cardiovascular system. (CSP 490)

Planned Areas for New Clinical Trials

Persian Gulf War Veterans' Illness Research

Through CSP, VA seeks to investigate the efficacy and safety of treatments for a number of disorders experienced by Gulf War veterans, including chronic fatigue syndrome, fibromyalgia, post-traumatic stress disorder, somatoform disorder and other conditions. Using rigorous scientific trial methods, VA hopes to gain better understanding of the disorders that are afflicting these veterans and establish effective methods for treating them.

Aging Research

As the post-World War II veteran population enters retirement, the ranks of VA's senior veterans are growing faster than the overall senior population. By the year 2000, three of every five American men age 65 or older will be veterans, accounting for more than half of VA's patient population. Thus, it is more important than ever for VA to expand its knowledge of the diseases and conditions that affect elderly veterans.

In collaboration with the National Institute on Aging, CSP seeks to conduct a series of multi-site, randomized clinical trials that will enhance VA's efforts to effectively treat its rapidly growing population of elderly veteran patients. These studies include investigations of osteoporosis in men, focusing on fracture prevention; androgen replacement therapy in men; perioperative interventions for older patients undergoing non-cardiac surgery; approaches to cardiovascular surgery in older patients; and treatment for diastolic dysfunction for patients with coronary heart failure and normal systolic function. CSP also may conduct studies in long-term care settings, including ways to prevent lower respiratory infections and catheter-related urinary tract infections in nursing home units.

Other research projects may focus on ways to improve chronic disease management; the use of alternative treatment approaches for patients with potentially terminal illnesses; and the management of behavioral disturbances among patients institutionalized with Alzheimer's disease. CSP also will study the impact of nutritional interventions in vulnerable geriatric populations; the effectiveness of a variety of interventions in treating fall-related fractures; and the appropriateness, cost-effectiveness, and incidence of adverse effects of prescription drugs for geriatric patients.

Post-Traumatic Stress Disorder Research

More than 15% of male Vietnam War veterans, or almost 480,000 men, suffer from post-traumatic stress disorder (PTSD). In addition, a number of Gulf War veterans have complained of PTSD symptoms. This disorder consumes a substantial amount of VA resources. Future CSP research may explore innovative treatment intervention approaches including: psychosocial interventions and psychotropic medications; the effects of specific treatments on special subpopulations of patients with PTSD (like women veterans and Gulf War veterans) specialized management treatments for comorbid disorders, which are especially prevalent in PTSD patients; and treatment effects on pre-clinical markers that might be used as screens for treatment strategies.

Diabetes Mellitus (Type II) Research

Diabetes, the third most common diagnosis among VA patients, affects about 30 percent of the veteran population. Kidney failure, blindness, blood pressure problems, foot ulcers, and other serious conditions often complicate the diabetic veterans' quality of life. More than half of lower extremity amputations performed by VA are on diabetic patients. A series of future multi-site, randomized clinical trials by CSP will investigate a number of strategies for improving the effectiveness of treatment for diabetic patients, including issues related to insulin therapy and other approaches for regulating blood-sugar levels, and treatment of foot ulcers in diabetic patients. Other studies may investigate innovative models of care for diabetic patients, such as multi-disciplinary team care, collaboration between generalists and specialists, the use of non-physician providers; and the implementation of practice guidelines for diabetes care, as well as their impact on health outcomes.

Prostate Cancer Research

Prostate cancer is the most common cancer among men and the second leading cause of death in men. An estimated 30% to 50% of men over 50 have histologic prostate cancer. Critical insight into effective therapies and health care services for prostate cancer patients can be obtained from large, randomized trials. Accordingly, CSP is seeking to conduct a series of trials in a number of important areas. They include: chemoprevention therapy, using drugs that are well-tolerated by the general public; comparisons of brachytherapy, beam therapy, radical prostatectomy, and observation for early-stage cancer; androgen blockade with oral or parenteral estrogen; the use of adjuvant hormonal therapy in high-risk patients following surgery; phase II and phase III agents in hormone refractory prostate cancer; the effects of androgen suppressive therapy in patients with evidence of treatment failure following radiation or surgical therapy; supportive care in prostate cancer; and the predictive values of diagnostic tests.

***Parkinson's Disease
and Related
Neurodegenerative
Disorders Research***

Parkinson's disease and related neuronal degenerations, such as Alzheimer's disease and motor neuron disease, are sources of significant morbidity and mortality in the veteran population. These disorders impose severe challenges to patients, their families and the health care system. As part of a joint initiative between VA and the National Center for Human Genome Research, CSP is seeking to conduct several large, multi-site trials of medical and surgical approaches to treating these often devastating illnesses.

Epidemiology Studies

Epidemiology – the study of the incidence, distribution and control of disease in human populations – is well suited to exploring chronic diseases among various sub-groups of veterans. CSP focuses on epidemiology through three national studies and its three Epidemiology Research Information Centers (ERICs). ERICs work to link the epidemiology of disease with actual clinical practice. The ERIC centers enhance VA health care by promoting VA-based population research results and by converting these results into a format that VHA providers and administrators can apply to improve patient care. The three ERICs are located in Boston, Massachusetts, Durham, North Carolina and Seattle, Washington.

***Hepatitis C
Virus Study***

Hepatitis C virus (HCV) is the most common cause of post-transfusion and community-acquired non-A, non-B hepatitis. It is estimated that approximately 4 million Americans are infected with HCV, and that 8,000 to 10,000 deaths from HCV-associated chronic liver disease occur annually. There are data that suggest that the prevalence in the VA is higher than in the general US population. Data on the natural history of HCV infection suggest that there is a long interval between onset of infection and development of complications of chronic liver disease and a highly variable natural history. Currently, there is limited knowledge of risk factors for disease progression.

Two of the key questions facing the VA today are how many veterans suffer from Hepatitis-C infection, and how can we predict who will progress and develop serious liver disease. The first question must be answered in order to plan for the future needs of the patients, and the second is critical to the decision of when and in whom to begin antiviral treatment. This study will get a precise answer to the first question, and begin the process of answering the second. Since the current generation of treatments has not been proven to affect outcomes in patients who have side effects, it is crucial to avoid unnecessary treatment. This study is the beginning of a systematic approach to this potentially immense problem. (CSP 488)

***Selenium and
Vitamin E Cancer
Prevention Trial
(SELECT)***

Prostate cancer is the most common malignant tumor (excluding non-melanoma skin cancer) in US men. Until now, emphasis has been on screening for early detection and intervention after diagnosis. However, the ideal method to reduce mortality and morbidity of prostate carcinoma is likely to be through primary prevention. Studies have suggested that dietary factors may be the most important modifiable risk factors for prostate cancer. Although rates of prostate cancer are greater in African American men compared to white men, with mortality rates twice as great, data from large cohorts of African American men assessing risk factors for the etiology of prostate cancer are limited. The VA is collaborating with Southwest Oncology Group and the NCI to design a trial of Vitamin E and Selenium in the primary prevention of prostate can-

cer. SELECT is a randomized, double-blind, placebo-control, factorial design trial to assess the effect of selenium and vitamin E alone, and in combination, on the reduction of prostate cancer incidence as detected by annual visits and routine care. (CSP 499)

Amyotrophic Lateral Sclerosis (Lou Gehrig's Disease) Among Veterans of the Gulf War

The Durham ERIC is planning an epidemiological investigation of the incidence of ALS among veterans of the Gulf War with a particular focus on three areas: to define the natural history of ALS; to determine whether there is a higher than expected occurrence of ALS among Gulf War veterans; and to ascertain the possible or probable etiology of ALS (if above normal event rates are determined).

The study will be aimed at understanding the natural history of ALS through descriptive epidemiology of cases among Gulf War veterans nation-wide; to determine if there is a higher than expected occurrence of ALS among Gulf war veterans compared to non-deployed controls; and to ascertain possible etiologic factors (with focus on environmental factors) in the Persian Gulf area of deployment in conjunction with a genetic-based susceptibility to neurodegenerative disorders. (CSP 500)

Colorectal Cancer Risk Factors for Advanced Disease

Project Dates: 1998-2001
Project Funding: \$397,606

The relative five-year survival with colorectal cancer was estimated at approximately 40% among veterans, substantially lower than Surveillance Epidemiology and End Results (SEER) estimates in the general population of 61.7% (colon) and 59.3% (rectum). Colorectal cancer is preventable through screening, however and, if diagnosed in an early stage, is curable.

This is the first study to examine factors that might explain the worse prognosis for veterans with colorectal cancer. If modifiable factors such as physician and patient delay in diagnosis, or poverty, explain the increased mortality among veterans, educational programs and interventions that improve the process of care associated with screening and diagnosis can be instituted. This study will involve 750 veterans with advanced colorectal cancer. (CSP 707D)

Racial Differences in the Incidence and Mortality of Prostate Cancer

Project Dates: 1998-2000
Project Funding: \$450,891

Prostate cancer is the most commonly diagnosed cancer in American men. Among African Americans the incidence and mortality from prostate cancer is even greater. This study hypothesizes that racial differences in the incidence and mortality of prostate cancer may be a result of multiple factors including those that are socioeconomic, environmental, dietary and genetic. This research will provide insight into genetic-environmental interactions that initiate and promote prostatic neoplasia, as well as address whether there are differences in patterns of care which impact morbidity and survival. The results of this study will also be compared to findings in non-veterans that are being generated through a National Cancer Institute funded sister study. (CSP 708D)

Identifying Genetic Markers of High Risk for Prostate Cancer

Project Dates: 1998-2000
Project Funding: \$217,402

This study will consist of a large cohort of prostate cancer patients who are well characterized with respect to histology, stage of diagnosis, and (over time) mortality. With a projected enrollment of 500 patients (225 African-American cases and 275 white cases), this is one of the largest biomarker-based epidemiologic studies of prostate cancer in African-American men to-date. The ultimate goal of this research is to devise a method to identify men at high risk that may benefit from early detection and counseling. (CSP 709D)

Prospective Cohort of Early-Stage Prostate Cancer

Project Dates: 1999-2002
Project Funding: \$716,340

Counseling patients with early-stage prostate cancer about treatment options is extremely difficult since the relative benefit of different approaches is not known and little is known about risk factors which predict the transformation of early-stage prostate cancer to clinically aggressive disease. This study will observe a cohort of patients with early-stage prostate cancer who elect not to undergo radical prostatectomy or radiation therapy, to evaluate risk factors which predict the transformation of early-stage to clinically aggressive disease. The knowledge gained in this study will help allay the anxiety of those with indolent disease and potentially reduce the morbidity and mortality of those with disease likely to become clinically aggressive. (CSP 719B)

Screening for Diabetes Mellitus in Veterans

Project Dates: 1998-2002
Project Funding: \$511,286

The annual incidence of diabetes among veterans is unknown. The goal of this study is to provide insight into several general problems, including the short-term consequences of screening for diabetes. Measurement of the change in HbA1c, a blood-based indicator of blood sugar level, in screened patients will identify whether or not usual practice improves glycemic control in patients diagnosed early in the course of their type II diabetes. This will allow health care systems to determine whether mass screening must be coupled with efforts to improve usual care for these patients. As a supplement to this study, a new instrument (developed by Roche Diagnostics) for diagnosing diabetes by the fluorescent scatter of the eye lens is being evaluated. This diagnostic tool, if proven effective, represents a significant advance over current diagnostic techniques because it is non-invasive as well as rapid. (CSP 705D)

HIV Seroprevalence and Risks in Veterans with Severe Mental Illness

Project Dates: 1998-2001
Project Funding: \$425,346

This study supplements the National Institute of Mental Health's HIV/Severe Mental Illness study with a four-year longitudinal cohort study of 300 severe mentally ill veterans in order to estimate the prevalence of HIV risk behaviors and HIV infection, as well as to measure utilization of health services over time. (CSP 706D)

Excess Influenza Morbidity and Health Care Utilization in Veterans with HIV Infection

Project Dates: 2000-2001
Project Funding: \$150,000

Influenza vaccine is routinely recommended for people at high risk for serious complications associated with influenza. Although the Advisory Committee for Immunization Practices has recommended influenza vaccine for HIV-infected individuals, there is limited information on the frequency and severity of influenza illness among such patients. This four-year, retrospective cohort study would measure the impact of influenza on HIV-infected patients, testing the theory that these patients in fact suffer greater morbidity from influenza, as reflected by the number of outpatient visits and inpatient stays for influenza, pneumonia, and other acute cardiopulmonary conditions during influenza season. The main goal of this study is to calculate the attributable incidence of influenza-associated morbidity among HIV-infected patients. (CSP 722S)

Cholesterol Reduction in the Elderly

Project Dates: 1998-1999
Project Funding: \$30,614

The objective of this study is to determine the extent to which various lipid parameters, including total, HDL and LCL cholesterol, triglycerides, total/HDL ratio, LCL/HDL ratio, HDL subfractions, and apolipoproteins, predict the risk of coronary heart disease among those 65 years or older, compared with younger individuals. Screening of and treatment for hyperlipidemia in the elderly for the primary prevention of heart disease remains controversial due to insufficient data. Better estimates of risk associated with lipid abnormalities, as well as the risks, benefits, and costs of cholesterol reduction in

the elderly, will aid in the refinement of guidelines targeted for the aging US population. Given the aging veteran population and the prevalence of hyperlipidemia and heart disease, the role hyperlipidemia plays in atherogenesis in the elderly, as well as the impact of treatment, are timely and important questions for the VA health care system. (CSP 718B)

Myocardial Infarction and CABG Long-Term Follow-up Study

Project Dates: 1998-2002
Project Funding: \$286,027

Cardiovascular disease is the leading cause of death for both veterans and non-veterans. This study will identify strategies to improve outcome in all patients with acute myocardial infarction (AMI). This study will determine the long-term outcome and clinical risk factors for AMI in three groups of VA patients: those with AMI, those with AMI during surgery and those who underwent coronary artery bypass graft surgery (CABG). (CSP 720B)

Could Abdominal Aortic Aneurysm be an Infectious Disease?

Project Dates: 1998-1999
Project Funding: \$169,383

Abdominal aortic aneurysm (AAA) is a potentially catastrophic condition that is relatively common in older men. Past studies have suggested that several infectious agents may be causally associated with atherosclerosis, which contributes to development of AAA. This study will use banked serum samples on 161 AAA cases, and 483 controls, from the Cardiovascular Health Study, a cohort study of over 5,000 persons aged 65 years and older, to determine whether exposure to these and other infectious agents is associated with AAA. Because some of these infections are readily treatable with antibiotics, the study may lead to ways to prevent or retard the progression of AAA. (CSP 704S)

Researchers Study Genetic Susceptibility to Carotid Atherosclerosis

Project Dates: 1998-2001
Project Funding: \$769,900

Atherosclerosis of the carotid arteries is a common cause of stroke. The prevalence and progression of carotid atherosclerosis are believed to be influenced by genetically inherited variations in lipoprotein metabolism. This study investigates the specific role of paraoxonase, an enzyme thought to detoxify atherogenic oxidized low-density lipoprotein. This study compares veterans who have significant carotid atherosclerosis on ultrasound examination with controls without carotid atherosclerosis. Both paraoxonase activity and genotype will be determined and compared between groups. The results may eventually make it possible to screen for a paraoxonase allele that confers high risk of atherosclerosis, and to diminish the risk by early treatment. (CSP 701S)

A Prospective Cohort Study of Respiratory Function and Illness in Chronic SCI

Project Dates: 1998-2002
Project Funding: \$579,169

This study assesses respiratory function in patients with spinal cord injury (SCI) in order to determine the association between level of SCI and chronic respiratory symptoms, measures of pulmonary function, and respiratory illness, both cross-sectionally and longitudinally, to identify possible interventions. (CSP 717B)

Mental Health Outcomes Associated with Peacekeeping Duty for US Military Personnel

Project Dates: 1999-2002
Project Funding: \$453,463

US military personnel deployed to peacekeeping missions are at risk for post-traumatic stress disorder (PTSD) and other mental health disturbances. This study examines mental health consequences of peacekeeping missions on US military personnel and factors that hinder treatment-seeking in this population. Other research has shown early education and treatment can prevent acute problems, such as PTSD, from becoming chronic. The results of this study will help VA to prepare special educational and treatment programs addressing mental health needs of veterans of peacekeeping operations. (CSP 712B)

Comorbidity of PTSD and Antisocial Personality Disorder

Project Dates: 1998-1999
Project Funding: \$105,918

Research has documented a high rate of comorbidity between PTSD and Antisocial Personality Disorder (APD) among Vietnam veterans. Comorbidity is associated with a more severe course of illness, poorer treatment outcome, and greater impairment for the suffering individual. However, the nature of the relationship between these disorders remains unclear. The purpose of this study is to clarify the relationship between PTSD and other psychopathology, particularly APD, in order to impact prevention and treatment efforts. (CSP 713B)

General Life Adjustment in a National Sample of Vietnam Veterans

Project Dates: 1999-2000
Project Funding: \$94,380

The overall objective of this project is to gain a better understanding of general life adjustment among Vietnam veterans and to document pre-military, military and post-military factors that contribute to positive or negative adaptation. This project is intended to go beyond the traditional emphasis on psychopathological outcomes and focus on outcomes that represent personal competence, accomplishment and well-being following possible exposure to highly stressful events in the Vietnam war zone. (CSP 715B)

Prevalence and Determinants of Osteoporosis in Male Veterans

Project Dates: 1998-2001
Project Funding: \$476,120

Osteoporosis in men has historically been understudied. This project will describe associations between potential risk factors and baseline bone mineral density (BMD), as well as rates of BMD loss. Subjects are drawn from two existing VA cohorts, the Normative Aging Study (NAS) and the Veterans Health Study (VHS). When completed, this study will be one of the largest in the US to study risk factors for osteoporosis in men. Several of the hypothesized risk factors (smoking, alcohol, caffeine, for example) are amenable to change and represent potential areas of intervention. Thus, not only can the VA make a valuable contribution to furthering our understanding of osteoporosis in men in general, but strategies may be identified to reduce morbidity as well as reduce health care costs associated with fracture in the elderly. (CSP 714B)

Study to Identify Risk Factors for Bacteremia in VA Patients with Urinary Tract Infections

Project Dates: 1998-1999
Project Funding: \$61,994

Urinary tract infection (UTI) is the most common form of hospital-acquired infection and causes an estimated 17-40% of hospital-acquired bacteremias. Yet risk factors for development of bacteremia among UTI patients are largely unknown. This study seeks to identify correlates of bacteremia among 625 patients with UTI who were hospitalized at the VA Puget Sound Health Care System, Seattle Division, between 1984 and 1996. Factors considered will include comorbid conditions (such as diabetes) and use of systemic antibiotics. Results of this study will help identify opportunities for prevention of bacteremia and the increased morbidity, mortality and economic costs associated with it. (CSP 703S)

Study Evaluates the Prognostic Importance of MRI Findings for Low Back Pain

Project Dates: 1998-1999
Project Funding: \$239,948

Low back pain is a frequent cause of disability and a common reason for outpatient care in veterans. Magnetic resonance imaging (MRI) of the lower back often reveals abnormalities, which may be used to justify expensive and invasive therapy, such as surgery. Yet the link between MRI abnormalities and the risk of developing clinically significant back pain is far from clear. This longitudinal study will determine the prevalence and incidence of MRI abnormalities among veterans and determine the extent to which specific MRI abnormalities predict future development of back pain. The results should help clinicians use MRI more efficiently, and they may ultimately help reduce the frequency of unnecessary back surgery. (CSP 702S)

**VA Cooperative Studies
Annual Clinical Research
Methods Course**

Project Dates: 1999-2002
Project Funding: \$260,000

Since 1998, CSP senior staff has offered a five-day Clinical Research Methods Course. The course covers most designs used in clinical research/cohort studies, case-control studies, randomized trials and meta analyses. Specific components of the research design will include defining hypotheses, selection of subjects, planning of measurements, stratification and randomization, data management, statistical inference, sample size determination, data analysis, and ethical considerations.

The course includes a mixture of lecture and discussion sessions, interspersed with breakout sessions in which groups of students and faculty mentors serve as planning committees to plan a research proposal which is later evaluated in class.

**VA Epidemiology
Summer Session**

Project Dates: 1999-2002
Project Funding: \$240,000

Epidemiologic Research and Information Centers (ERICs) provide opportunities for training in epidemiology to professionals throughout the VA system in order to help improve clinical care delivery, inform administrative decision-making, and generate top-quality research proposals. The first VA Epidemiology Summer Session was held in June, 1999 in Seattle on the University of Washington campus. Seven short courses were offered, including Evidence-Based Medicine and Critical Reading of the Medical Literature, Outcomes and Effectiveness Research, Epidemiologic Methods for Planning and Evaluating Health Services, General Biostatistics, Clinical Epidemiology and Clinical Decision-Making, use of National VA Data in Research, and VA Quality Improvement.

**VA Cooperative Studies
Program Career
Development
Enhancement Award**

The VA Cooperative Studies Program has established a sabbatical program for clinician investigators to train at one of the Cooperative Studies Program centers. The purpose of the program is to support established investigators who wish to secure training time to learn about the conduct of cooperative studies and epidemiological research. Currently participating VA CSP centers are the Coordinating Center at West Haven, CT and the Epidemiological Research and Information Centers at Durham, NC and Boston, MA. The application process for this program follows policies established for the VA Career Development Enhancement Award. This program provides a mechanism for educating clinical investigators to participate in CSP as trained investigators.

**Research Consortia
and Partnerships**

**Alzheimer's Disease
VA Consortium**

Project Dates: 1999-2001
Projected
Cost of Consortium: \$299,760

Alzheimer's Disease (AD) is the third most expensive chronic disease to treat following cancer and heart disease. It is estimated that by the year 2000, there will be 600,000 veterans with severe dementia.

The principal goal of this consortium is to take advantage of existing VA resources to address important issues in the management of AD and other progressive dementias. The main objectives of the consortium are: to identify VA medical facilities with substantial numbers of patients suffering from AD and related progressive dementias that possess the infrastructure, interest and expertise to conduct informative clinical trials; to identify and prioritize areas of investigation that should be pursued in consultation with other research organizations (e.g., NIH Consortium, Reagan Institute, Harmonization Group); to implement a restricted number of clinical trails in VA facilities which are prepared to embark on these studies in an expeditious manner; to develop promising clinical trials in collaboration with pharmaceutical and biotech industries; to analyze and publish these studies; and to integrate the results of these studies into the practice of VA physicians. (CSP 606)

**Cardiology Clinical
Trials Initiative**

Project Dates: 1999-2000
Project Funding: \$147,000

The pharmaceutical industry and the National Institutes of Health are major initiators and supporters of research in cardiology. The VA Cooperative Studies Program has considerable experience with clinical trials, and capacity for conducting them in a scientifically and ethically valid manner. VA investigators in cardiology are at the forefront of the field, but are spread throughout the nation at individual VA medical centers. The distributed nature of the clinical scientific expertise in the VA is at once an advantage and a barrier to involvement with this important area of research. To ensure that VA patients have access to the latest innovations in care and that study design is responsive to the needs of the VA, it is desirable to facilitate the collaboration between VA cardiologists and the principal sponsors of cardiology research.

This initiative will work to develop a process for expediting the involvement of VAMCs in such cardiology trials. The initiative has already begun to attract interest and it is expected that several large studies will emerge from this initiative. (CSP 605)

**VA Clinical
Oncology Network**

Project Dates: 1999-2002
Project Funding: \$295,069

The VA Clinical Oncology Network (VACORNET) is a group of VA clinician investigators interested in oncology research and multi-site trials with the pharmaceutical industry. It is a virtual organization of approximately 125 clinicians representing 98 VA facilities in the system. The mission of the VA CORNET is to:

- promote oncology research relevant to the health of veterans;
- promote oncology research with pharmaceutical companies, especially multi-site trials, and promote investigator-initiated research;
- foster communication among oncology researchers;
- develop an infrastructure to support national studies;
- encourage supportive care trials; and
- offer assistance to VA investigators who need multiple sites to answer a clinical research question.

(CSP 608)

**VA CSP AIDS
Consortium**

Project Dates: 1998-2001
Project Funding: \$327,000

The AIDS Clinical Trials Research Consortium was formed to identify VA Medical Centers with a substantial number of HIV/AIDS patients that possess the infrastructure, interest and expertise to conduct informative clinical trials. The consortium will identify and prioritize areas of investigation that should be pursued through discussions with other HIV clinical and research organizations and the HIV pharmaceutical and biotech industries. Results of these studies would inform the practice of VA physicians and are targeted for integration with the VA health care system and nation's health care at large.

**National Institute on
Drug Abuse/VA
Collaborative Study**

Project Dates: 1999-2001
Projected Funding: \$5,910,032

Although many compounds have been evaluated for the treatment of opiate dependence, only three medications have been approved by the Food and Drug Administration for this indication: methadone, LAAM and naltrexone. These medications must be administered at traditional narcotic treatment programs. This study is designed to determine the safety patient acceptance and clinical efficacy of buprenorphine/naloxone in tablet form that can be administered in an office-based setting. Approval for the use of this product in normal office-based practices would, hopefully, encourage some opiate dependent patients to seek treatment sooner, since it would not involve the stigma attached to seeking treatment at traditional narcotic treatment programs. (CSP 1018)

***NIDA/VA
Substance Abuse
Medications Development
Research Units***

Project Dates: 1999-2004
Projected
Cost of Project: \$40,000,000

The development of new pharmacotherapeutic approaches to the treatment of drug addiction was specifically provided for in appropriations to implement the Omnibus Anti-Drug Abuse Act of 1988. This program will enable NIDA to provide a mechanism by which compounds can be rapidly evaluated for their utility as novel and effective pharmacotherapeutic medications. This interagency agreement provides for the establishment and support of a clinical trial research organization to test by scientifically sound methods, the benefits, or lack thereof, of medications of potential use against addiction to controlled substances and alcohol. All clinical trials will be designed and conducted to strictly adhere to regulatory standards necessary to meet Investigational New Drug or New Drug Application regulations of the US FDA and FDA Good Clinical Practice Guidelines. The goal of the program is to provide support for the development and approval for marketing of new investigational compounds to treat addictive and certain psychiatric disorders. These areas are vastly under-represented in pharmaceutical development and for which a high national priority has been set by the US Congress.

***VA/National Institutes of
Health (NIH), National
Institute on Aging (NIA)***

The VA Cooperative Studies Program issued a Joint Program Announcement in collaboration with the NIH National Institute on Aging in June 1998. The Program Announcement identified aging research priority areas for VA multi-site, randomized, Phase III clinical trials. VA and NIA content experts in Aging Research will actively engage in this collaboration to address clinical questions important to the VA and non-VA aging populations and successful peer-reviewed trials will be considered for joint funding.

***VA/United Kingdom
and Canada Medical
Research Councils
(MRC)***

In 1998, the VA CSP initiated formal discussions with the national Medical Research Councils of the United Kingdom and Canada in an effort to develop a formal tri-national clinical trials collaboration. Although the VA CSP has previously collaborated on cooperative studies with the UK and Canada, this VA CSP initiative is designed to establish a formal process for systematically identifying clinical trials of high relevance to the clinical mission of all three countries' research entities.

The national triumvirate seeks to establish formal policies for submission, review, conduct, and management of multinational clinical trials while maximizing the efficiency of conducting clinical trials. The benefits of this formal collaboration include maximizing the feasibility and rate of patient recruitment for very large trials, enhancing marketability of clinical trial ideas to private industry, minimizing duplicative research activity, and increasing the generalizability of study findings globally.

***VA/Juvenile Diabetes
Foundation***

Project Dates: 1998-2003
Project Funding: \$2,500,000

The VA Cooperative Studies Program collaborated with the Juvenile Diabetes Foundation (JDF) to identify primary research areas for Phase III clinical trials on macrovascular complications of Type II diabetes mellitus. In the Spring of 1999, the VA CSP and the JDF convened a panel of experts from VA, JDF, NIH, and academia who identified priority research areas for innovative multi-center diabetes treatment trials. This collaboration with the CSP is in addition to the existing collaboration between VA Medical Research Service and the JDF, and the JDF's support of several VA/JDF Diabetes Biomedical Research Centers.

**VA and the National
Parkinson Foundation**

Parkinson's disease is a progressive, degenerative disorder with devastating consequences that affects more than 1 million Americans. About 50,000 new cases are diagnosed each year in the US. The VA treats more than 41,000 veterans who are diagnosed with Parkinson's.

VA and the National Parkinson Foundation, Inc. (NPF) have joined forces to find a cure and improve treatments for Parkinson's disease. The Alliance to Cure Parkinson's disease between VA and NPF has launched a variety of activities designed to enhance both organizations' work. They include: a series of symposia highlighting state-of-the-art research on Parkinson's for scientists and policy makers; educational programs for VA medical personnel that are focused on advances in the understanding and treatment of Parkinson's; information products for public dissemination on VA's research and treatment programs in Parkinson's; continuing medical education training for VA providers who treat patients with Parkinson's; and jointly funded research initiatives to expand the medical community's understanding of the causes, mechanisms, and treatment of this disease.

**National Institutes
of Health, National
Cancer Institute (NCI)**

The VA has entered collaborations with the NCI and the Southwest Oncology Group to study the effects of Vitamin E and Selenium in the primary prevention of prostate cancer. The proposed Selenium Vitamin E Cancer Prevention Trial (SELECT) is a randomized, double-blind, placebo controlled, factorial design trial of 30,000 healthy men without prostate cancer. The proposal is currently under review by the NCI.

**National Institutes of
Health, National Heart
Lung & Blood Institute
(NHLBI)**

The VA, in collaboration with the NHLBI and Intercardia Incorporation, is conducting a major study entitled, "Beta-blocker Evaluation of Survival Trial (BEST)," to determine whether beta blockers extend the lives of patients with chronic heart failure. The implications of this trial, involving 2,800 patients with moderate to severe congestive heart failure, are substantial. In addition to prolonging patients' lives, researchers conservatively predict that the successful use of these drugs will save the VA system approximately \$9.4 million annually.

Project Dates: 1995-1999
Project Funding: \$21,087,817

**VA/Pharmaceutical
Companies**

VA's Cooperative Studies Program has collaborated or formed partnerships with the following pharmaceutical companies, who provide study medications, devices or other support for some of the on-going cooperative studies:

Amgen, Inc.	Hybritech	Pfizer, Inc.
Astra Pharmaceuticals	Incara Pharmaceuticals	Reckitt & Colman
Aviron	Corporation (formerly	Pharmaceuticals, Inc.
Bayer Corporation	Intercardia)	Rhone-Poulenc Rorer
Berlex Laboratories	Interpore Corporation	Pharmaceuticals, Inc.
Boehringer Ingelheim	Johnson & Johnson	Sanofi Pharmaceuticals, Inc.
Pharmaceuticals, Inc.	Medical, Inc.	Sandoz Pharmaceuticals
Bristol-Myers Squibb	J.R. Carlson Laboratories	Schein Pharmaceutical, Inc.
Company	Key Pharmaceuticals, Inc.	Schering Laboratories
Chiron Therapeutics	KOS Pharmaceuticals, Inc.	Schwartz Pharma
Core-Vent	Merck & Co., Inc.	SmithKline Beecham
DuPont Pharmaceuticals	Marion-Merrell Dow	Pharmaceuticals
Eli Lilly and Company	Noblepharma	Somerset Pharmaceuticals
Fujisawa Healthcare, Inc.	Nycomed Amersham	Solvay Pharmaceuticals, Inc.
Glaxo Wellcome, Inc.	Ortho-McNeil	Wyeth-Ayerst Laboratories
Hoechst-Marion	Pharmaceutical Corporation	
Roussel, Inc.	Parke-Davis, Division of	
	Warner-Lambert Company	



John G. Demakis, M.D.,
Director

The Health Services Research and Development Service (HSR&D) pursues research at the interface of health care systems, patients and health care outcomes. HSR&D underscores all aspects of VA health care, specifically, quality, access, patient outcomes and health care costs. The need for high quality health services research continues to grow to keep pace with and respond to the rapid changes underway within the Veterans Health Administration, and in the health care community as a whole. Many HSR&D studies have been used within and outside VA to assess new technologies, explore strategies for improving health outcomes, and evaluate the cost-effectiveness of services and therapies.

The HSR&D mission is to advance knowledge and promote innovations that improve the health and care of veterans and the nation. HSR&D carries out this mission through peer reviewed research and through its key centers which include eleven Centers of Excellence, the Management Decision and Research Center, and the Veterans Affairs Information Resource Center. The newly funded VA Health Economics Resource Center will bring additional depth to HSR&D's expertise.

HSR&D also manages the Quality Enhancement Research Initiative (QUERI) for the Office of Research and Development. QUERI is a key part of VA's ongoing systematization of quality management efforts and represents VA's commitment to providing veterans with the best, most cost-effective health care possible.

Current Initiatives

Quality Enhancement Research Initiative (QUERI)

QUERI is a bold and innovative program seeking to translate research innovations into improved quality of health care for veterans. Eight conditions are the focus of QUERI based on their high volume and/or high risk in veteran patients. The conditions are: chronic heart failure, diabetes, HIV/AIDS, ischemic heart disease, mental health (including depression and schizophrenia), spinal cord injury, stroke, and substance abuse. A steering committee co-chaired by a prominent investigator and clinician has been formed for each condition, and strategic plans have been approved. Following is a summary of the mission and goals of each of the eight QUERI modules.

QUERI Chronic Heart Failure Module

Estimated Funding:

FY99	\$300,000
FY00	\$850,000
FY01	\$1,300,000
FY02	\$1,300,000
FY03	\$1,300,000

Chronic heart failure (CHF) is a syndrome that results from the heart's inability to pump sufficient blood to meet the body's metabolic needs. The prevalence is high and is increasing. CHF affects 2-3 out of every 100 adults aged 65-74. CHF also has a high mortality rate: one third of patients die within two years of diagnosis. Hospital and resource use associated with this serious condition is intense, yet effective therapies are often underused.

The goal of CHF QUERI is to create measurable, rapid and sustainable improvements in quality of care and in the health outcomes of veterans with heart failure. Specific goals are to:

- identify the gaps in science, practice and informatics that, if filled, would yield the best and most rapid improvements in the care of patients with CHF, and to recommend to VA how best to use existing resources to close these important gaps;
- foster a network, within VA, of professionals who are deeply committed to improving care for patients with CHF;
- monitor practice in heart failure from the patient's perspective, as well as the system's, in order to determine if the QUERI process is achieving its goals;
- create an information dissemination loop that ensures all stakeholders are kept up-to-date with best practices in CHF and with the most pressing research needs;

- inventory and advocate for improvement in ongoing data collection efforts pertaining to quality improvement in CHF throughout the VA system; and
- compare some VA and non-VA CHF data on processes and outcomes.

The CHF QUERI Executive Committee issued solicitations this year, and proposals were approved for topics related to guideline implementation, interventions which promote compliance, and other topics relevant to optimal outcomes.

QUERI Diabetes Module

Estimated Funding:

FY99	\$600,000
FY00	\$2,600,000
FY01	\$2,600,000
FY02	\$3,000,000
FY03	\$3,000,000

Diabetes Mellitus is a common disease affecting between 10 and 16 million people living in the United States. A leading cause of blindness, amputation and renal failure, diabetes contributes to serious and debilitating health complications among veterans. As a consequence, diabetes care is extremely expensive. In 1997, diabetes was responsible for almost 25% of all VA pharmacy costs and over 70,000 hospital admissions. The diabetes QUERI is focusing on those aspects of diabetes care that are highlighted within the VA guidelines regarding glycemic control, hyperlipidemia, hypertension, and screening and early intervention for nephropathy, retinopathy, and foot complications. These areas represent aspects of care for which the literature suggests that adherence to best practices will result in substantial improvements in quality and length of life. Five proposals that address the most significant aspects of diabetes self-management and care were recently approved in the diabetes area. For example, proposals were approved relevant to glycemic control and education.

QUERI HIV/AIDS Module

Estimated Funding:

FY99	\$500,000
FY00	\$2,000,000
FY01	\$2,600,000
FY02	\$2,600,000
FY03	\$2,600,000

HIV causes a chronic progressive disease characterized by immune depletion, chronic symptoms, and vulnerability to opportunistic infections. Between 650,000 and 900,000 adults living in the US are infected with HIV, which is also a significant cause of morbidity and mortality among veterans. It is estimated that VA provides care for 40% of all HIV-infected veterans thus the associated health care burden and costs are high.

The quality of HIV care is the ultimate concern of the HIV QUERI Module. This group focuses on preventing the spread of infection among the HIV-positive population and preventing illness among those already infected. For those who are known to be HIV positive, the HIV QUERI promotes high quality care by, for example, evaluating current practice patterns and by improving the existing Case Registry. Other concerns, such as patient self-care and medication adherence, were the focus of proposals received following solicitations from the HIV QUERI group. Several approved proposals addressed adherence to retroviral therapy.

QUERI Ischemic Heart Disease Module

Estimated Funding:

FY99	\$600,000
FY00	\$1,300,000
FY01	\$1,600,000
FY02	\$2,000,000
FY03	\$2,500,000

Ischemic Heart Disease (IHD) is the number one cause of death in the United States and is one of the most frequent indications for care in VA facilities, yet therapies such as hypertension control and smoking cessation are known to be underused.

The IHD QUERI has targeted specific disease states relevant to IHD, including a focus on the needs of patients undergoing coronary revascularization. The IHD QUERI is striving to improve the outcomes of veterans with ischemic heart disease by using health services research methods to identify, implement and evaluate interventions that promote improved compliance with national treatment guidelines.

The primary short-term objectives are to define baseline practice patterns and identify areas for improvement and then implement quality improvement initiatives. Long-term objectives are to disseminate and implement successful quality improvement strategies identified in the short-term objectives and to promote the development of a

national database that can be used when measuring process and outcome data. The IHD QUERI group will soon be releasing new solicitations relevant to all aspects of diagnosis and patient care.

QUERI Mental Health Module

Estimated Funding:

FY99	\$350,000
FY00	\$1,500,000
FY01	\$2,000,000
FY02	\$2,000,000
FY03	\$2,000,000

The Mental Health Quality Enhancement Research Initiative module (MHQ) targets two disorders: major depressive disorder (MDD) and schizophrenia. These two disorders are prevalent among VA service users. Each disorder has a devastating impact on affected veterans’ lives, and each imposes a substantial cost on the VA. Efficacious treatments are available for both disorders, as are evidence-based VA-specific guidelines to define best practices. Nevertheless, depression often goes undetected and treatment for veterans with depression and schizophrenia is often suboptimal. Some patients drop out of treatment altogether. These circumstances result in disability, high personal and systems costs, and a great burden of suffering.

The goal of the MHQ is to create a data-driven, outcomes-based national program to improve the quality of care for veterans with MDD or schizophrenia through the timely translation of research knowledge into clinical and organizational practice. Critical gaps in knowledge, such as the need for information about performance criteria and multi-site testing of an outcomes management system, have been identified and are being addressed. Solicitations will soon be issued by this group on a variety of topics relevant to mental illness among veterans.

QUERI Spinal Cord Module

Estimated Funding:

FY99	\$320,000
FY00	\$700,000
FY01	\$1,200,000
FY02	\$1,200,000
FY03	\$1,200,000

The ultimate goal of the Spinal Cord Injury QUERI is to enhance the quality of life of veterans with SCI. This is accomplished through a concerted effort to close knowledge gaps, identify best practices for the care of veterans with SCI, and put best practices into place within VA in order to improve health care outcomes.

The SCI QUERI links the VA SCI care system, the Spinal Cord Dysfunction Registry, the Chief Consultant Spinal Cord Injury & Disorders Strategic Health Care Group, VISN Directors and Clinical Managers, and health care providers and researchers with veteran input.

The SCI strategic plan has seven specific objectives:

- create a data-driven, outcomes-based national system of care management for SCI, making a strong link between process and outcomes of care;
- identify high priority areas for individuals with SCI across the lifespan, and identify health delivery issues including long-term care that are potential targets for intervention;
- prioritize and facilitate the implementation of interventions to improve health care practice for SCI based on provider and consumer input, as well as evidence from existing literature;
- evaluate the success of specific interventions using well-designed and formulated research studies;
- supply feedback to providers, managers and policy makers to encourage best practices;
- develop a risk-adjusted quality improvement program to generate data for comparison with other health care systems; and
- implement and test measurements and feedback to facilitate continuous improvement in the care provided to veterans with SCI.

QUERI Stroke Module

Estimated Funding:

FY99	\$260,000
FY00	\$150,000
FY01	\$1,200,000
FY02	\$1,500,000
FY03	\$1,500,000

Stroke is the third leading cause of death and a leading cause of adult disability in the United States. Both inside and outside the VA, the lack of a systematic approach to stroke prevention and treatment has contributed to reduced rates of compliance with recommended practices. Stroke QUERI will focus on areas where there are gaps in the knowledge base or a lack of a systematic approach to high quality care.

Priority objectives related to strategic improvements in prevention, treatment and rehabilitation are:

- identify core processes for anticoagulation clinic services and enhance veterans’ access;
- develop risk-adjusted models for the surgical preventive procedure carotid endarterectomy to understand facility variation in outcomes so practices can be improved;
- define a systematic acute stroke management system so that high quality stroke-related care can be generalizable to a variety of VA settings; and
- assess the impact of post-stroke rehabilitation on risk-adjustment and the location of outcomes so as to facilitate the implementation of the best rehabilitation practice.

QUERI Substance Abuse Module

Estimated Funding:

FY99	\$450,000
FY00	\$2,500,000
FY01	\$2,500,000
FY02	\$2,500,000
FY03	\$2,500,000

The overall mission of the QUERI Substance Abuse Module (SAM) is to establish an evidence-based program which identifies best practices for the treatment of substance use disorders, disseminates information about best practices, implements changes in practice patterns that improve patients’ symptoms and quality of life, assesses clinicians’ reactions to guidelines and the forces that enhance or hinder their use, and develops new research in order to promote ongoing improvements in practice. Three factors compel efforts to improve the quality of VA treatment for patients with substance use disorders: 1) the high prevalence and cost of substance abuse disorders in the VA and in the nation as a whole; 2) the growing complexity of VA substance abuse patients’ disorders and a concomitant decline in resources for treatment; and 3) a growing body of knowledge about effective substance abuse treatment and the development of evidence-based, clinical practice guidelines. Six specific aims of the SAM module are to:

- improve identification and management of patients with substance use disorders seen in primary care and other medical settings;
- improve the current system for monitoring substance abuse patients’ outcomes and care;
- improve the information and methods needed to implement research-based efforts to enhance the quality of substance abuse care;
- improve specialized substance abuse treatment practices;
- improve treatment for patients with multiple comorbidities; and
- improve treatment for high-risk or underserved substance abuse patient subgroups.

The Substance Abuse QUERI recently issued solicitations to address their objectives. Proposals related to substance abuse were approved that address smoking cessation, interventions related to alcoholism, primary care needs related to substance abuse, and the effects of caring for dually diagnosed patients.

QUERI Patient-Centered Outcomes

Estimated Funding:

FY00	\$600,000
FY01	\$900,000
FY02	\$900,000
FY03	\$1,000,000

As the VA moves to a more cost-effective and efficient managed care model, managers are interested in ensuring that the VA does not lose sight of the patient, and issues important to the patient. Some of the most important questions in health services concern: the health beliefs and preferences of patients and clinicians; the nature of clinician-patient interactions; and the social organization of medical practice and other factors that affect patient outcomes including satisfaction with care.

This initiative focuses on the eight QUERI conditions and builds on an earlier HSR&D special solicitation on Patient-Centered Care. Studies that utilize rigorous qualitative methods, either exclusively or in ways that complement quantitative methods, are encouraged.

VA Information Resource Center (VIREC)

Estimated Funding:

FY99	\$350,000
FY00	\$350,000
FY01	\$350,000
FY02	\$350,000

Critical to VA's goal of becoming the nation's state-of-the-art health care system, it is essential to improve current information systems in order to enhance assessment of patient outcomes, reimbursement rates, quality of care and customer service. These challenges require that information systems service multiple purposes and multiple users.

The goal of VIREC is to assist VA HSR&D in making information about VA databases available to the research community for studies that ultimately improve VA health care. The VIREC was funded in July 1998, and the VIREC website became functional in September 1998. VIREC staff are presently available to answer researchers' questions on VA databases and are working to update available documentation on current databases.

VA Health Economics Resource Center

Estimated Funding:

FY99	\$90,000
FY00	\$350,000
FY01	\$350,000
FY02	\$260,000

The difficulties associated with the determination of VA costs represent the single greatest barrier to health economics research in the VA. VA does not have the detailed charge data that research in the rest of the US health care sector use to estimate patient-level costs. The goal of the newly funded VA Health Economics Research Support Center is to increase VA's capacity to conduct high-quality health economics research and cost-effectiveness studies.

The Center will provide leadership and an infrastructure to facilitate improvement in the quality, accessibility, utility and understanding of VA utilization and cost data. In addition, the Center will create an economic consulting and mentoring resource for VA investigators.

Cross-Cutting Issues in Telemedicine

Estimated Funding:

FY99	\$200,000
FY00	\$400,000
FY01	\$600,000
FY02	\$900,000

Telemedicine — using electronic information and communications technologies to provide health care when health care providers and patients are in different locations — has significant potential to improve both access to health care and the quality of care.

In VHA, telemedicine applications are many and varied. To maximize the potential benefits of telemedicine, careful evaluations are needed as to how telemedicine affects outcomes and whether these outcomes justify the associated costs. In FY99, HSR&D solicited proposals for systematic evaluations of telemedicine applications and theoretically-grounded research on cross-cutting principles. These projects may focus on issues related to health systems, providers, patients or methods.

Implementation of Evidence-Based Clinical Practice Guidelines

Estimated Funding:

FY99	\$200,000
FY00	\$1,300,000
FY01	\$1,150,000

Evidence-based clinical practice guidelines have been widely accepted as a means to increase the use of appropriate clinical practices and to reduce the use of inappropriate practices, thereby improving quality of care and reducing unnecessary health care costs. The effectiveness of practice guidelines, however, depends on their consistent and accurate implementation.

This initiative invites research to study alternative strategies for implementing evidence-based clinical practice guidelines in VHA and to identify implementation strategies that may be replicated systemwide. Only guidelines that were developed nationally and are based on scientific evidence are eligible for study. Investigators are to focus on general principles of guideline implementation, as these relate to particular guidelines that are relevant to veterans (depression, diabetes, pressure ulcers, etc.). The research will focus on alternative ways of introducing guidelines into practice, for example, incentives, computerized reminders, administrative rules, and penalties. These studies also will address the impact of guideline implementation on such outcomes as quality and cost of care, practitioner knowledge and practice patterns, and patient behavior.

VISN Collaborative Research (VCR)

Estimated Funding:

FY99	\$300,000
FY00	\$600,000
FY01	\$900,000
FY02	\$900,000

All Veterans Integrated Service Networks (VISNs) currently can obtain services of the national HSR&D Centers of Excellence for conducting research in areas of mutual interest. However, additional capacity is needed, particularly in those networks without an established core of experienced health services researchers. The purpose of this program is to enhance VA health services research capacity and expertise to address important health services research issues of broad interest to the VA and to the Networks. Mission critical questions may focus on such issues as: enhancing patient access to primary, emergency room, or specialty care; determining the optimal staffing level, panel size, or geographic location for specific treatment programs; and evaluation of innovative care delivery systems. Studies under this initiative will add generalizable knowledge to the health services literature and also inform key policy and programmatic decisions.

This initiative is limited to VISNs that do not currently have a national peer-reviewed and funded HSR&D Center of Excellence geographically located within their network. Studies under this initiative are funded collaboratively with the Network and HSR&D each providing half of the direct cost of the study.

Patient Safety and Prevention of Adverse Outcomes

Estimated Funding:

FY99	\$80,000
FY00	\$500,000
FY01	\$900,000
FY02	\$900,000

A key element of VA's efforts to improve the quality of health care provided to veterans is identifying factors related to adverse patient outcomes and strategies for reducing and eliminating them. A number of VA initiatives are addressing these critical issues including the Patient Safety Improvement Policy, which established an Adverse Events Registry and Patient Safety Improvement Oversight Committee, Patient Safety Improvement Awards Program, and the National Patient Safety Partnership. Building on these initiatives, HSR&D published a solicitation entitled "Patient Safety and the Prevention of Adverse Outcomes" in May 1998 and, in February 1999, announced that proposals will be accepted until further notice. Investigator-initiated research projects funded as a response to this solicitation will identify high-risk patients, providers, processes, and situations, and identify strategies for reducing and eliminating adverse events, thereby improving patient outcomes and the overall quality of care.

Tobacco Use Treatment Outcomes Research (TUTOR) Centers of Excellence

Estimated Funding:

FY00	\$500,000
FY01	\$500,000
FY02	\$500,000
FY03	\$500,000

Tobacco use is a potent cause of potentially preventable morbidity and mortality for the nation's veterans, and it accounts for a substantial portion of the nation's overall health care costs. Recognition is growing, however, that more favorable outcomes may be achievable for the treatment of tobacco at the primary care provider level. Establishment of a Tobacco Use Treatment Outcomes Research (TUTOR) Center of Excellence will enhance VA's capacity to conduct a broad spectrum of interdisciplinary research on health care problems pertaining to tobacco use (and related disorders) within VHA.

Across the span of its multiple year funding award, TUTOR is expected to develop interdisciplinary research expertise encompassing basic biomedical science, applied clinical research, applied health systems research, and rehabilitation outcomes research. TUTOR is intended to facilitate the translation of research findings into ongoing clinical practice for the purpose of enhancing the quality of life for the nation's veterans.

Pain Assessment and Management

Estimated Funding:

FY00	\$250,000
FY01	\$600,000
FY02	\$900,000
FY03	\$900,000

In FY 2000, HSR&D plans to initiate several new studies on the management of acute and chronic pain. This work will complement VHA's ongoing National Pain Management Strategy efforts. New research will emphasize pain related to conditions that are most prevalent among veterans and will address characteristics and/or circumstances of veterans that make pain assessment and management particularly challenging (e.g., comorbidities, substance abuse, homelessness). This work will add to VA's portfolio of research projects that emphasize quality of care and, in particular, patient-centered care. Products from these studies will include valid methods and measures for assessing pain and for evaluating the quality of pain management services.

End-of-Life Care

Estimated Funding:

FY00	\$500,000
FY01	\$600,000
FY02	\$900,000
FY03	\$900,000

VHA is committed to providing national leadership in systematically improving end-of-life care. As part of this effort in FY 2000, HSR&D plans to initiate several new studies on the quality of care at the end of life. This new initiative will emphasize patient-centered care and patient preferences, with explicit attention to ethnic and cultural variations, social support, and other pertinent patient characteristics. It will encompass studies of how patients, families, and health care professionals can collaborate to make appropriate decisions, and how to best utilize specialized services for improving the quality of dying.

Homelessness

Estimated Funding:

FY00	\$300,000
FY01	\$600,000
FY02	\$600,000
FY03	\$900,000

Veterans constitute about one-third of the adult homeless population. On any given day, as many as 250,000 veterans are living on the streets or in shelters. Many more veterans experience homelessness at some point during the year or are at-risk of becoming homeless as a result of poverty, overcrowded or substandard housing, or an unstable social support system.

VA provides substantial assistance directly to homeless persons through a wide spectrum of special programs targeted to help homeless veterans. Although limited to veterans and their dependents, VA's programs constitute the largest integrated network of treatment and assistance services for the homeless in the country.

Studies that target the special needs of this population, or evaluate one or more of the VA programs designed to address these needs, are encouraged.

**VA Costs,
Cost-Effectiveness and
Health Economics**

Estimated Funding:

FY00	\$750,000
FY01	\$1,500,000
FY02	\$2,000,000

This new Request for Applications is designed to support research on the cost and cost-effectiveness of health care interventions and the economic evaluation of VA providers and programs. A special focus is improvement, validation, and comparison of methods for determining VA health care costs, development of VA expertise in cost-effectiveness analysis, applied economics research, and comparison of the cost and cost-effectiveness of VA and non-VA providers.

**Establishment of a New
Health Services Research
Center of Excellence**

Estimated Funding:

FY00	\$500,000
FY01	\$500,000
FY02	\$500,000
FY03	\$500,000

HSR&D Centers of Excellence support the integration of research and practice, linking the clinical aspects of patient care and organizational/management needs. Each Center develops its own research agenda, is hosted by a collaborating VA Medical Center, and maintains affiliations with community institutes and schools of public health, university health administration programs, and research institutes to support its goals and objectives.

A nationwide solicitation is used to inform all VA medical facilities of the opportunity to compete for core support to establish a new Center. Typically, a formal application process that includes technical reviews, external panel reviews, and site visits follows this solicitation. Centers of Excellence are subject to periodic external peer review, with the continuation of core support funding being dependent on the results of those reviews.

Operating within general HSR&D Service guidelines, an individual Center of Excellence is expected to:

- develop and refine its own research agenda;
- maintain collaborative partnerships with affiliated community institutions;
- provide periodic support (if appropriate) for HSR&D management consultation activities;
- serve (if designated) as a training site for pre- and post-doctoral training programs in health services research and medical informatics (sponsored by VA's Office of Academic Affiliations);
- provide periodic support (if applicable) for VA's Office of Research and Development (e.g., VA's new Quality Enhancement Research Initiative); and
- sustain the HSR&D Center of Excellence tradition of vigorously leveraging each Center's provision of (limited) core support funding.

Partnerships

**Quality Interagency
Coordination Task
Force (QuIC)**

The Quality Interagency Coordination Task Force was established to enable all Federal agencies with health care responsibilities to coordinate their activities to measure and improve the quality of care, to provide beneficiaries with information to assist them in making choices about their care, and to develop the infrastructure needed to improve the health care system, including knowledgeable and empowered workers, well designed systems of care, and useful information systems. HSR&D is one of VA's representatives on QuIC.

National Advisory Council for the Agency for Health Care Policy and Research

HSR&D's collaboration with the Agency for Health Care Policy and Research (AHCPR) is formalized in the continuing role of HSR&D's Director as an ad hoc member of the National Advisory Council for Health Care Policy, Research and Evaluation. The Council's twice yearly meetings provide a forum for exchange of information and ideas between the Federal government's two largest health services research programs, and among a broad array of experts representing other Federal agencies and the private sector. In the past year, HSR&D and AHCPR have exchanged information on activities related to health care quality, aging, mental health, and peer review. The agencies' many shared goals and priorities make this a natural collaboration that benefits both.

Health Care Finance Agency Collaboration

HSR&D, with the support of the Office of Policy and Planning, has taken the initiative to develop a framework for prospectively merging VA and HCFA health utilization data. This will allow the VA and HCFA to:

- examine and predict the amount and patterns of health service use by veterans, especially by VA enrollees within and outside the VA health care system;
- set VA corporate deductible levels; and
- develop estimates of the total cost of health care services for VA users.

Cochrane Collaboration

The Cochrane Collaboration is an international effort by health care professionals to collect and disseminate high quality research evidence about the effects of health care practices. This unique effort is accomplished by a network of review groups/health care specialists who prepare, maintain and disseminate systematic reviews of research evidence on specific therapeutic interventions in order to provide patients high quality, evidence-based treatment. VA researchers are among the international experts participating in this cutting-edge effort to promote evidence-based medicine. VA supports a Cochrane Center within HSR&D's Veterans Evidence-Based Implementation and Dissemination Center in San Antonio, Texas and a Cochrane Review Group on Urologic Diseases through the HSR&D Center for Chronic Disease Outcomes Research in Minneapolis, Minnesota.

Association for Health Services Research

The Association for Health Services Research (AHSR) is the national membership organization for health services researchers. VA HSR&D has had a collaborative relationship with AHSR for over eight years, particularly focusing on broadly disseminating research results to policy makers, managers, clinicians and researchers to positively affect policy and decision making.

Scientific Forum on Heart Disease and Stroke

VA HSR&D along with the American College of Cardiologists, Robert Wood Johnson Foundation, and the American Heart Association are working together to improve the quality of care for heart disease and stroke. HSR&D investigators actively participated in the first scientific forum focused on current approaches to measuring and improving quality of care for cardiovascular disease and stroke. The goal of this effort is to improve cardiovascular health and health care through the dissemination of information about strategies and challenges in measuring quality of care, performance measures to evaluate quality of care, and successful strategies to improve care.

Study of Clinically Relevant Indicators for Pharmacologic Therapy (SCRIPT)

SCRIPT is a national coalition, organized by the Health Care Financing Administration and the Joint Commission on the Accreditation of Health Care Organizations, to define, test and recommend pharmacologic performance measures for a number of diseases including diabetes and heart disease. The SCRIPT coalition has 52 members, including VA and representatives from federal agencies such as the Agency for Health Care Policy and Research, the Centers for Disease Control and Prevention, Food and Drug Administration, Indian Health Service and the Department of Defense, as well as private sector health care organizations, professional associations and other relevant organizations. HSR&D managers and researchers from the Quality Enhancement Research Initiative (QUERI) are among the VA participants in this important national quality improvement effort.

Federal Collaboration on Health Care Quality

VA HSR&D is participating in a national collaboration with other federal agencies to explore the relationship between the quality of patient care and conditions of work in the health care industry. This group, which includes VA HSR&D, Occupational Safety and Health Administration, Health Resources and Services Administration, Department of Labor, Voluntary Protection Program, and the Agency for Health Care Policy and Research, is working to identify what we know and what we need to know about this important topic, and to identify opportunities for further research or collaboration.

MEDICAL RESEARCH SERVICE



Paul M. Hoffman, M.D.,
Director

Medical Research Service (MRS) is the most significant of VA programs reflecting medical science innovation. The biomedical arm of the Office of Research and Development, MRS funds and administers research focusing on the etiology, pathogenesis, diagnosis, and treatment of a wide range of diseases and disorders affecting veterans and the general population. The MRS portfolio includes research on such topics as cardiovascular disease, cancer, diabetes, AIDS, neurological disorders, mental illness, and spinal cord injury among others.

Approximately 1,100 projects – or 75% of all MRS-funded research – are funded through the Merit Review Program. Funded at over \$100 million annually, the Merit Review Program is considered the mainstay of MRS programs. More than 300 programs have been approved for funding in the last two review cycles at a success rate of 35% and 32% respectively. Other current and planned MRS programs are described in the following sections.

Current Initiatives

Merit Review Entry Program

Estimated Funding:

FY98	\$800,000
FY99	\$5,100,000
FY00	\$7,500,000

The Merit Review Entry Program (MREP) increases opportunities for beginning investigators to enter the VA Medical Research Program. New investigators are required to maintain a vibrant research program, but recently the success rate of first-time applicants in Merit Review has been significantly below that of more seasoned investigators. The number of first-time applicants was declining, so the MREP program was introduced in the summer of 1997. The first set of proposals was reviewed in the Spring 1998 cycle.

MREP support is for non-renewable, mentored, three-year awards limited to \$50,000 per year plus a maximum of \$15,000 for equipment. For non-clinician scientists, salary support is also available. Medical Research Service has made a major commitment to training new clinician and non-clinician investigators. The MREP is part of that commitment.

Research Enhancement Award Program

Estimated Funding:

FY99	\$6,400,000
FY00	\$4,900,000
FY01	\$4,900,000
FY02	\$4,900,000
FY03	\$4,900,000

Medical Research Service established the Research Enhancement Award Program (REAP) in 1998 to promote and support groups of VA investigators studying medical areas of importance to the veteran population. The REAP program enables researchers to integrate basic science and clinical research approaches to understanding and treating these conditions. The goals of REAP are to:

- train new investigators in research areas of importance to veterans health;
- develop new and innovative research approaches to medical problems; and
- foster collaboration among investigators working in common areas.

Twenty programs from 18 VA medical centers were selected for funding thus far. These REAPs focus on a wide variety of medical areas of particular importance to veterans including pulmonary disease, bone disease, Parkinson's disease, vascular disease, renal disease, disorders of the gastrointestinal system, wound healing, multiple sclerosis, Hepatitis C, depression, and prostate cancer.

Research Training Initiative for HBCU and HSI

The Research Training Initiative for Historically Black Colleges and Universities (HBCU) and Hispanic Serving Institutions (HSI), will expand through the new Research Experience Program. This is open to all students and faculty who are enrolled in or employed by HBCU's, HSI's or Native American colleges. The program will support the salary of undergraduate or graduate students, post-doctoral fellows or faculty members so they may conduct research at a VA medical center. This research must be related to

Estimated funding:

FY00	\$200,000
FY01	\$250,000
FY02	\$300,000
FY03	\$350,000

currently VA-supported research. Support will be through a supplement to ongoing VA sponsored research that is not a salary-only or mentored research program.

The research experience may be up to two years and will be overseen by the principal investigator of the research program supporting the participant. The purpose is to recruit more new investigators into the VA research programs, especially from underrepresented racial or ethnic groups. Applicants are the principal investigators, and proposals are reviewed for the suitability of the background and training of the proposed participant and the benefit to that person's career development. Applications will be reviewed within two or three months to allow for reasonable planning of the student's career development opportunities.

Epidemiologic Research Initiative

Estimated Funding:

FY99	\$949,000
FY00	\$1,200,000
FY01	\$1,200,000
FY02	\$1,100,000
FY03	\$622,000

In 1997, VA's Office of Research and Development announced the opportunity for investigators to submit research proposals for review under the Medical Research Merit Review program. The Office of Research and Development is especially interested in research on the epidemiology of chronic diseases, but epidemiological proposals may be submitted in any area of particular importance to veterans. Applications must show relevance to major veteran health-related problems, and they must also show the contribution the research project is expected to make to veteran health care. The investigator may request funds of up to \$150,000 per year for up to 5 years. Proposals are reviewed twice a year, in the spring and in the fall, in conjunction with the Medical Research Service Merit Review cycles. During the 1998 cycles 10 proposals were funded and four additional proposals were funded in the Spring of 1999.

Medical Research State-of-the-Art Equipment

Estimated Funding:

FY98	\$14,600,000
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A request for proposals for Medical Research state-of-the-art equipment was released in April 1998. Medical Research Service allocated \$14.6 million for this initiative in fiscal 1998. State-of-the-art equipment is defined as research laboratory equipment costing between \$200,000 and \$500,000 for common use by researchers. This initiative will modernize and upgrade equipment, providing research laboratories to access the latest technology and ensure that VA research is state-of-the-art.

Research Centers

Research Centers for Basic Science and Clinical Studies on Alcoholism or Substance Abuse

Estimated Funding:

FY99	\$800,000
FY00	\$600,000
FY01	\$600,000
FY02	\$600,000
FY03	\$600,000

A major problem facing many veterans is substance abuse (alcohol and/or drugs), which has wide-ranging, deleterious effects resulting from dependence and toxicity. In response to the need for research related to the cause, treatment and prevention of alcoholism, VA's Office of Research and Development solicited proposals to compete for Research Centers on Alcoholism or Substance Abuse. A committee of nationally recognized experts in the fields of alcoholism or substance abuse reviewed proposals and recommended two centers for funding beginning in January 1999.

The West Haven VA Alcoholism Research Center is working to better understand the biology and genetics of alcoholism and to translate those findings into improved care of alcoholic veterans. The Omaha VAMC Research Center for Basic and Clinical Studies of Alcoholism is researching the basic mechanisms of alcoholic liver disease. Both centers enhance the larger mission of VA research advancing the understanding and treatment of alcoholism.

Environmental Hazards Research Centers

Estimated Funding:

FY00	\$1,200,000
FY01	\$1,200,000
FY02	\$1,200,000
FY03	\$1,200,000
FY04	\$1,200,000

The VA recognizes the importance of basic science and clinical research studies of environmental hazards, particularly as such studies relate to veterans' potential exposure to chemical and biological hazards during active military duty. Consequently, VA's Office of Research and Development has been supporting research on environmental hazards since 1995 when the first of four Environmental Hazards Research Centers were funded. Research at these centers has identified even further need for studies of environmental exposures.

The Office of Research and Development's Medical Research Service has requested proposals for new environmental research centers for basic and clinical science studies of environmental hazards. As many as four centers will be funded following a review of the proposals by a panel of nationally recognized experts. Centers will receive up to \$300,000 annually for up to five years to conduct research related to environmental exposure of importance to the veteran or military population. These centers may focus on organ systems affected by environmental exposures, such as the reproductive, liver, pulmonary or nervous systems. They may also focus on specific classes of environmental hazards, for example, pesticides, solvents or biologic agents. Within these areas, researchers may concentrate on topics such as: carcinogenesis, autoimmune or allergic responses, neurobehavioral alterations, reproductive developmental outcomes, genotoxicity, or prevention or consequences of exposure.

AIDS Centers

Estimated Funding:

FY99:	\$1,000,000
FY00:	\$1,000,000
FY01:	\$1,000,000
FY02:	\$1,000,000
FY03:	\$1,000,000

VA recognizes the importance of basic science and clinical research studies of Human Immunodeficiency Virus (HIV) infection and Acquired Immunodeficiency Syndrome (AIDS), including relevant retroviruses and retroviral diseases. Consequently, VA's Office of Research and Development has been supporting research centers on HIV and AIDS since 1993. Four centers are currently funded under this initiative.

Although continuation of Centers focusing on HIV and AIDS is anticipated, the Medical Research Service has not yet announced the solicitation of proposals.

VA/JDF Diabetes Research Centers

Estimated Funding:

FY00	\$1,500,000
FY01	\$1,500,000
FY02	\$1,500,000

VA recognizes the importance of basic science and clinical research studies of diabetes, a disease which affects the veteran population with a high incidence. Because of the complications associated with the disease, the cost to patients in terms of disability and to the medical system in terms of expense is significant. Consequently, VA's Office of Research and Development has joined with the Juvenile Diabetes Foundation (JDF) to support research studies on diabetes through the establishment of Diabetes Research Centers. There are currently three centers funded through this initiative which began in 1997 and will expire in 2002.

VA's Office of Research and Development has formed a new alliance with JDF for Phase III clinical trials through the Cooperative Studies Program.

Research Centers for Schizophrenia

Schizophrenia is a complex mental disorder that affects patients and their families over a lifetime. The long-term care of schizophrenic patients exacts a tremendous cost to the VA and society in general. In order to enhance and expand the research into the etiology, pathogenesis and treatment of schizophrenia, VA's Office of Research and Development has been supporting research centers on schizophrenia since 1989. Three centers are currently funded under this initiative.

To underscore the importance of schizophrenia research to the VA, the Medical Research Service announced the solicitation for proposals for Research Centers on

Research Centers

Medical Research Service

Estimated Funding:

FY00	\$1,600,000
FY01	\$1,200,000
FY02	\$1,200,000
FY03	\$1,200,000
FY04	\$1,200,000

Schizophrenia in April 1999. The support (up to \$300,000 per year for five years) will be provided for the integration of exceptional multidisciplinary basic and clinical research focused on solving fundamental medical problems related to schizophrenia. One important goal of this initiative is to train new VA investigators in research related to schizophrenia.

A scientific committee, comprised of experts on schizophrenia, will review the proposals in November 1999. Funding of the selected projects will begin in January 2000.

Planned Initiatives

Parkinson's Disease

Estimated Funding:

FY99	\$1,100,000
FY00	\$1,200,000
FY01	\$1,200,000
FY02	\$1,000,000
FY03	\$900,000
FY04	\$400,000

Parkinson's disease is a progressive, degenerative disease that accounts for significant morbidity and mortality among veterans and the general population. In September 1997, the Office of Research and Development announced a new program combining basic studies with genetic, epidemiological, and clinical studies of the disease. This program allows VA investigators with a funded Merit Review Program to submit a second Merit Review Proposal in the area of Parkinson's disease and neurodegenerative disorders.

In March 1998, Medical Research Service included Parkinson's disease and neurodegenerative disorders as a potential focus for the newly announced Research Enhancement Award Program (REAP).

VA/DoD Collaborative Research

Physiological Foundations of Physical Performance and Combat Readiness

Estimated Funding:

FY99	\$1,500,000
FY00	\$1,500,000
FY01	\$1,500,000

Developing and maintaining high levels of physical fitness are of major importance for combat readiness and for general health in the veteran population. In contrast, physical fitness is a challenge for many veterans with chronic ailments, such as heart disease, type II diabetes, stroke or spinal cord injury. This initiative solicited proposals related to physical performance of active duty military personnel, optimizing and sustaining performance for combat readiness, and maintaining fitness and health following termination of active duty. Basic and applied physiology, biomechanics and epidemiology were appropriate approaches for the studies.

Topics submitted in response included: mechanistic studies relating cardiovascular function, muscle physiology and metabolism to exercise and performance; gene regulation and expression related to exercise and physical training; physiological correlates of body composition in relation to performance or health; biomechanical factors affecting human performance, including dynamic balance and its relationship to falls; exercise physiology in individuals with disabilities such as type II diabetes, spinal cord injury, congestive heart failure, or stroke; and epidemiology of long-term health impact of exercise and physical fitness.

Prostate Diseases Including Cancer

Estimated Funding:

FY99	\$975,000
FY00	\$975,000
FY01	\$980,000

Prostate diseases affect large numbers of current and former military personnel. In order to advance diagnostic and treatment capabilities for these diseases, fundamental information about the disease processes is essential. This initiative encouraged mechanistic studies on the etiology, pathogenesis and pathophysiology of prostate cancer, benign prostate hyperplasia (BPH), and prostatitis. Epidemiologic studies to identify occupational hazards and risk factors were also encouraged.

Among the topics submitted under this initiative were: the role of oncogenes and tumor suppressor genes in human prostate cancer; diagnostic distinctions between BPH and prostate cancer; biomarkers predicting prostate cancer progression; the cellular events involved in the development and progression of prostatic intraepithelial neoplasia (PIN); the role of microorganisms and inflammatory mediators in the development of prostate diseases; the physiologic role of growth factors, hormones, neuroendocrine peptides and their receptors in normal and abnormal prostate growth; the etiology and pathogenesis of chronic idiopathic prostatitis and autoimmune prostatitis; and epidemiologic studies to identify environmental factors which may be causative agents of prostate diseases.

Eight proposals were funded, seven from VA and one under a VA/DoD collaboration.

Military Operational Stress-Related Illnesses

<i>Estimated Funding:</i>	
FY99	\$1,600,000
FY00	\$1,400,000
FY01	\$1,100,000

Chronic stress-related illness may be a consequence of military operations in which current and former active duty and reserve personnel have served, such as the Gulf War. Reported symptoms in operationally exposed individuals have included fatigue, headache, joint pain, and psychological conditions. Stress-related disorders include, but are not limited to, post-traumatic stress disorder (PTSD) and fibromyalgia. An understanding of the biological and chemical basis of these disorders is essential to advancing the treatment and prevention of stress-related illnesses. Therefore, further research is needed on the etiology, pathogenesis and pathophysiology of traumatic and non-traumatic stress related disorders.

Topics of interest include: the role of neurotransmitter, immunologic, and neuroendocrine dysregulation in the development of stress-related illnesses; neurotransmitter, immunologic, and neuroendocrine receptor dysregulation; characterization of heritability or identification of polymorphic markers associated with the control of stress response and PTSD; psychological and biomedical measurements for early identification of individuals at risk for stress-related disorders; animal models to identify processes contributing to human chronic stress response disorders; and imaging studies to localize and quantify abnormal brain structure, function and neurochemistry associated with stress response and stress-related disorders.

Fourteen proposals were funded, 10 from VA, three from DoD, and one under a VA/DoD collaboration.

Traumatic Brain Injury

<i>Estimated Funding:</i>	
FY99	\$1,500,000
FY00	\$1,500,000
FY01	\$1,500,000

Traumatic Brain Injury (TBI) and its consequences affect both active duty military personnel and veterans. Penetrating head injury is a major concern during military operations, while closed head injury is more common in civilian life. Although the pathophysiology of penetrating and closed injury may differ, both types can result in long-term impairment of physical, cognitive and behavioral functioning. In order to advance treatment and rehabilitation following TBI, fundamental information about the acute and long-term processes is essential.

Topics submitted in response to the TBI initiative include: development of innovative, humane in vivo models for penetrating injury; primary and secondary therapeutic interventions following TBI; relationships between the neurobiology and neuropsychology of acute and chronic TBI; relationship between pathophysiology of TBI and the effectiveness of interventions; innovative approaches to late sequelae of TBI, such as post-traumatic epilepsy (including primary prevention strategies), cognitive deficits, and mood impairment; and impact of rehabilitation strategies on neural plasticity following TBI, using imaging, neurobiological and cognitive approaches.

REHABILITATION RESEARCH AND DEVELOPMENT



Mindy Aisen, M.D.,
Director

The ultimate goals of the VA Rehabilitation Research and Development (Rehab R&D) Service include achievement of actual functional return, compensatory therapies to maximize remaining function and to mitigate secondary conditions, corraling cutting edge technologies to compensate for lost function, and fostering better ways for living with disability. To this end, over 200 VA researchers have dedicated themselves in a comprehensive effort to advance the health care needs of veterans with disabilities.

Nine Rehabilitation R&D Centers located at VA facilities around the country function to attract the best and brightest minds from academia, industry, and medicine into VA to study specific aspects of disability research, as well as work together as a national network. Here, investigators renew half a century of commitment to seeking solutions to rehabilitation's most challenging research problems. Moreover, in looking toward a new generation of researchers, a research career development program has been initiated to mentor doctoral-level rehabilitation clinical professionals. These men and women will help guide the future of rehabilitation research and development.

In order to disseminate research results, the Rehab R & D Service has committed to publishing its efforts, through outlets such as a bi-monthly peer-reviewed journal, an annual reporting of progress in rehab research throughout the world, clinical monographs, and data sheets. Each of these activities stimulates new research ideas and keeps clinicians and consumers on the cutting edge of new ideas in disability management.

New Initiatives

VA Rehabilitation Research and Development Centers

Estimated Funding:

FY99:	\$375,000
FY00:	\$1,500,000
FY01:	\$1,500,000
FY02:	\$1,500,000
FY03:	\$1,500,000
FY04:	\$1,125,000

In July of 1999, the VA Rehabilitation Research and Development Service added three new R&D Centers to its portfolio. These three teams were funded after an extremely competitive review of 14 high quality proposals in important and relevant areas of disability. The newest of the now nine Centers focus on Restoration of Function in SCI and Multiple Sclerosis (West Haven, CT), Wheelchair and Related Technology (Pittsburgh, PA), and Cognitive and Motor Impairment Rehabilitation (Gainesville, FL). This group complements the six established Centers in Geriatric Rehabilitation (Atlanta, GA), Aural Rehabilitation (Portland, OR), Prosthetics and Consequences of Amputation (Seattle, WA), Mobility (Palo Alto, CA), and Aging with a Disability (Houston, TX). It is anticipated that these Centers will sponsor research and attract funding from many sources to advance knowledge in these important areas. In addition, Centers mentor young investigators thus, building capacity for future research.

Rehabilitation Outcomes

Estimated Funding:

FY99:	\$350,000
FY00:	\$500,000
FY01:	\$750,000
FY02:	\$1,000,000
FY03:	\$2,000,000

Current rehabilitation therapies are often based on anecdotal evidence or intuition, but few data are available to set reliable policy and protocol. There is a great deal of interest among VA rehab clinicians to document and quantify outcomes of care to be sure that veterans are receiving optimal therapies for their conditions. With strong research capacity in both Health Services Research and Rehabilitation Research, VA is positioned to provide strong evidence about best practices and lead the rehabilitation community in this effort.

Building on an initiative begun in 1997, a special solicitation was issued in summer of 1998, resulting in twelve proposals focused on Interdisciplinary Studies in Rehabilitation Outcomes. Two new studies were funded: one examining barriers to efficient performance in stroke rehab and one focused on low vision. This area will be a continuing priority area for Rehab R&D. Proposals will be received twice a year and scientifically reviewed in January and July of each year. In addition, a workshop designed for rehab clinicians interested in conducting outcomes research was presented at the Rehabilitation Clinical Symposium held in Houston, TX in June of 1999.

Elder Technology*Estimated Funding:*

FY00:	\$250,000
FY01:	\$250,000
FY02:	\$250,000
FY03:	\$250,000
FY04:	\$250,000

“Elder Technology” is a stated priority of the White House Office of Science and Technology Policy. The growing population of older adults will change many aspects of health care. One change will be an increase in the number of people who experience a disabling condition as a result of aging and consequently, need to use some form of assistive technology. During inpatient rehabilitation, an adult receives an average of eight devices to use at home for dressing, mobility, seating, bathing, grooming, and feeding. Safety monitoring devices for geriatric patients are helping to heal an industry beset by liability costs due to falls and accidents. These problems are not limited to just slipping on floors and tumbling-or sneaking-out of bed. Noncompliance is the number one reason for nursing home admittance.

In April of FY99, Rehab R&D issued an RFP calling for proposals to evaluate new and emerging “elder technologies.”

Telerehabilitation*Estimated Funding:*

FY00:	\$500,000
FY01:	\$500,000
FY02:	\$500,000
FY03:	\$500,000
FY04:	\$500,000

Telerehabilitation is an emerging health care delivery tool that uses electronic information and communications technologies to provide and support health care when distance separates the participants. Because of many unresolved questions, there is a need for specific evidence of therapeutic efficacy, diagnostic impact, cost analysis, and the development of baseline data in many areas of telerehabilitation. Issues of diagnostic/therapeutic efficacy, privacy and security of information transmission, clinical standards and guidelines for practice, technical interoperability of systems and technology, and human resource planning all must be addressed. Statistically significant outcome studies on the effectiveness of telerehabilitation as compared to conventional rehabilitation service delivery models are required.

In FY99 Rehab R&D issued a call for proposals to conduct studies which either 1) systematically and scientifically evaluate existing telerehabilitation applications; 2) are demonstration projects to obtain pilot data on new applications; or 3) propose to develop pilot data on new applications.

**Neuro-Rehabilitation
Robotic Systems***Estimated Funding:*

FY00:	\$500,000
FY01:	\$500,000
FY02:	\$500,000
FY03:	\$500,000
FY04:	\$500,000

Conventional rehabilitation for sensorimotor impairment includes physical and occupational therapy programs. These require labor intensive individualized exercises with a therapist. Typical exercise activities include manual manipulations of the patient's limb, either as the patient remains passive or actively assists with the movement. As an alternative clinical intervention, robotic technology may assist the therapist in the rehabilitation of neurologically impaired patients.

In April of FY99, Rehab R&D issued an RFP calling for proposals to evaluate and develop innovative robotic systems for therapeutic application after neurologic disorders such as multiple sclerosis, stroke, and traumatic brain injury. It is anticipated that these studies will be designed to use robotics as training aids, assisting patients to regain the ability to move.

Technology Transfer*Estimated Funding:*

FY99:	\$1,000,000
FY00:	\$1,500,000
FY01:	\$1,500,000
FY02:	\$1,500,000
FY03:	\$1,500,000

Technology Transfer efforts within Rehab R&D have traditionally been focused on evaluating prototypes of developed assistive technology. These evaluations are helpful in furthering the commercialization of developed devices, but not enough to assure that promising prototypes reach the commercial market. In addition, rehabilitation research results not only in new technology, but also in therapies, practices and new knowledge. These results must be translated into clinical care.

In FY 98 and FY 99 Rehab R&D expanded its scope of technology transfer activities

to include pursuing patents and developing the capacity for conducting clinical trials. A workshop was presented at the June VA Rehabilitation Clinical Symposium in Houston to introduce clinicians to opportunities for translating research findings into practice that results in improved patient care.

**Multiple Sclerosis:
A Step Forward**

Estimated Funding:

FY99:	\$250,000
FY00:	\$750,000
FY01:	\$1,000,000
FY02:	\$1,000,000
FY03:	\$1,000,000

Multiple sclerosis (MS) attacks the nervous system creating multiple disabilities, from paralysis to impaired vision, and sometimes blindness. Veterans with MS are predominantly male and older than the typical MS patient. Due to its patient population and its research capacity in the areas of disability prevalent in the MS patient community, VA is in a unique position to advance MS research. For example, ongoing research funded by Rehabilitation Research and Development will impact MS care. Rehab research in dysphagia, physical therapies, dementia, audiology and vision also applies to some or all of this patient population.

In February of 1999, Rehabilitation Research and Development, in collaboration with the National MS Society, Eastern Paralyzed Veterans of America, and Paralyzed Veterans of America, organized a research agenda setting symposium to usher in the beginning of a new focus on applying rehabilitation disciplines to treating and alleviating the symptoms of multiple sclerosis. The proceedings of the symposium are scheduled to be published in September, 1999. A collaborative effort to study the sensory impairments (speech, vision, and hearing) affected by MS is currently underway. Other issues to be addressed immediately include coordinating the several registries already in existence, encouraging more “cross talk” and collaboration between disciplines, and, ultimately, finding ways to translate research results into accepted clinical protocol.

**Journal of Rehabilitation
Research and
Development**

The *Journal of Rehabilitation Research and Development* has a long history of disseminating research results related to prosthetic and rehabilitative care. Although largely oriented towards engineering and assistive technology, the Journal has made an impact on the general rehabilitation research community. However, science has advanced and more possibilities exist in rehabilitative care than ever before. It is essential to create forums where research results can be disseminated, discussed and sometimes disputed amongst the scientific, clinical and consumer communities.

Rehabilitation Research and Development is in the process of expanding the scope of the Journal, while at the same time creating efficiencies in its production. For instance, it is now available on the internet. Additional plans include increasing the number of editions to six per year and adding clinical commentary on scientific abstracts.

Planned Initiatives

**Upper Extremity
Prosthetics**

Estimated Funding:

FY00:	\$500,000
FY01:	\$1,000,000
FY02:	\$1,000,000
FY03:	\$1,000,000
FY04:	\$1,000,000

Little research has been done in the area of upper extremity amputations and prosthetics, however, upper extremity amputation is a disabling consequence of combat and, therefore, a high research priority of Rehabilitation Research and Development. Advances in materials and range of motion must be sought and utilized.

In FY99, Rehabilitation Research and Development will issue a program announcement to guide the rehab field in submitting appropriate proposals in response to this need. Funding for these proposals will begin in FY2000.

NeuroRehabilitation

Estimated Funding:

FY00:	\$500,000
FY01:	\$1,000,000
FY02:	\$1,000,000
FY03:	\$1,000,000
FY04:	\$1,000,000

NeuroRehabilitation is a young and exciting science on the cusp of therapeutic breakthroughs which promise to return useful function. For instance, in stroke therapies, patients are often taught adaptive strategies to compensate for paralyzed muscles. However, it has been shown in rat models that forced use of affected areas can actually return useful function to those areas. Research in NeuroRehabilitation stands to benefit many veteran populations with neurologic disorders, including those with spinal cord injuries, multiple sclerosis, Parkinson’s disease, or consequences of stroke. Capitalizing on these opportunities requires coordinating the intersection of basic and applied sciences, a step already taken through the development of a NeuroRehabilitation scientific review panel with expertise from both areas.

To guide the field in developing proposals in this area, Rehab R&D will issue a program announcement in FY2000 stating priority areas for research in the field of NeuroRehabilitation. The aim of the announcement is to clarify the scope of neurorehabilitative research and to encourage “cross talk” between scientists and clinicians engaged in this area. In addition, NeuroRehabilitation will be a priority area in all announcements for Centers, Enhancement Awards, and special programs.

Community Reintegration

Estimated Funding:

FY00:	\$500,000
FY01:	\$1,000,000
FY02:	\$1,000,000
FY03:	\$1,000,000
FY04:	\$1,000,000

VA Rehabilitation Research currently focuses on therapies addressing post-acute phases of care immediately following trauma. However, the process through which one reintegrates from hospital to community setting with a chronic disability is overlooked in many health care settings. Successful community reintegration can be one of the single most preventive measures of secondary disabilities and is the ultimate goal of all rehabilitation.

VA Rehab R&D is planning to launch a “Quality of Life” initiative. This initiative will address necessary follow-up care, vocational rehabilitation, and long-term outcomes.

Special Disability Supplements

Estimated Funding:

FY00:	\$300,000
FY01:	\$300,000
FY02:	\$300,000
FY03:	\$300,000
FY04:	\$300,000

VA Rehab R&D joins other federal funding agencies, including the NIH, in encouraging scientists with disabilities in all research disciplines, but especially in rehabilitation research. To accommodate such persons, a program is being designed to provide mentored support for those wishing to pursue a research career. In addition, supplemental funding for required changes or adjustments in the academic or research environment that will allow access will be available.

AWARDS

There are many talented and exceptional researchers within VA who devote their careers to advancing the health and care of veterans. It is only fitting, therefore, that VA recognize outstanding achievements by its researchers. Following are descriptions of current R&D awards available to outstanding investigators.

The William S. Middleton Award

Estimated Funding:

FY00	\$155,000
FY01	\$155,000
FY02	\$155,000

The William S. Middleton award is presented annually to a VA researcher for outstanding achievement in biomedical or behavioral research. The Middleton award was established in 1960 in honor of William S. Middleton, M.D., a distinguished educator, physician-scientist and Chief Medical Director of the VA from 1955 to 1963. Medical centers may nominate candidates once per year, and a committee of senior VA investigators evaluates and selects the person who will be recommended to the Chief Research and Development Officer and the Under Secretary for Health as the recipient for that year.

Nominees are evaluated on originality of research, significance of the research to a field of science, evidence that the research has or will advance other scientific or clinical disciplines, recognition by peers through major research presentations or awards, leadership positions in national and international professional societies, and evidence that the research has been performed with VA support and relevance to the VA mission.

Earlier Middleton awardees received a plaque and \$5,000. The award now provides \$50,000 in research funds each year for three years. The Middleton Award is presented annually at a national meeting of a scientific organization, currently the American Federation for Medical Research.

Under Secretary's Award for Excellence in Health Services Research

Estimated Funding:

FY99	\$55,000
FY00	\$110,000
FY01	\$165,000
FY02	\$165,000

The Under Secretary's Award for Outstanding Achievement in Health Services Research was established in 1998 to recognize and honor the highest level of achievement in health services research. The award recognizes an individual who has: 1) conducted research that significantly enhances our understanding of factors affecting the health of veterans, or that has led to a major improvement in the quality of veterans' health care; 2) made a substantial contribution to the future by inspiring a new generation of investigators through excellence in training and mentorship; and 3) enhanced the visibility and reputation of VA research through national leadership.

The Paul B. Magnuson Award

Estimated Funding:

FY99:	\$5,000
FY00:	\$55,000
FY01:	\$105,000
FY02:	\$155,000
FY03	\$155,000

The Paul B. Magnuson Award is presented annually to a VA Rehabilitation Research and Development Investigator. The award is given to an investigator who exemplifies the entrepreneurship, humanitarianism and dedication to veterans displayed by Dr. Magnuson during his distinguished career as a bone and joint surgeon, and as the Chief Medical Director of VA from 1948-51. The Award was established in 1998, in recognition of the importance of rehabilitation research within the VA health care system. The first honorary award was given to Ernest M. Burgess, MD, orthopedic surgeon and prosthetic pioneer, who developed the Seattle Foot and who founded amputee care standards as we know them today. The Award confers a one-time cash award of \$5,000, plus \$50,000 for up to 3 years, to supplement ongoing peer-reviewed research and is presented each February at the VA RR&D Annual Meeting.

CAREERS IN VA RESEARCH

One of VA Research's greatest strengths is the high caliber of its investigators. Nurturing and supporting investigators in the early, mid and advanced stages of their careers is, therefore, a high priority for VA's Office of Research and Development. VA offers a wide array of career enhancement programs for clinicians and non-clinician scientists in Health Services, Medical and Rehabilitation Research Services. These awards provide salary support for investigators so that they have protected time to pursue important research or specific training to enhance their research skills. Current career enhancement programs include:

For physicians:

Research Career Development Award – provides three years of support at the beginning stage of a clinician's research career.

Advanced Research Career Development Award – provides three years of support for clinician scientists who have some research experience, but need additional guided experience to become independent investigators.

Career Development Enhancement Award – supports established clinician scientists who wish to secure time to enter a new area of research specialization, especially in areas of importance to VA's mission.

For non-physician Ph.D. scientists

Assistant Research Scientist – supports entry level non-clinician Ph.D. scientists seeking an independent career in VA.

Research Scientist – supports mid-career Ph.D. scientists who are principal investigators on non-mentored VA research projects.

Research Career Scientists – supports established independent investigators who have distinguished themselves through scientific achievement, and who are key contributors to the VA research program.

Senior Research Career Scientist – supports well established research career scientists who are recognized internationally as leaders in their fields.

Developing and enhancing the careers of VA investigators is critical to ensuring VA's capacity to conduct research in areas of high relevance to the veterans health care system. VA's Office of Research and Development demonstrates its commitment to VA investigators by allocating up to ten percent of the research budget to support career enhancement programs within the Office of Research and Development.

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