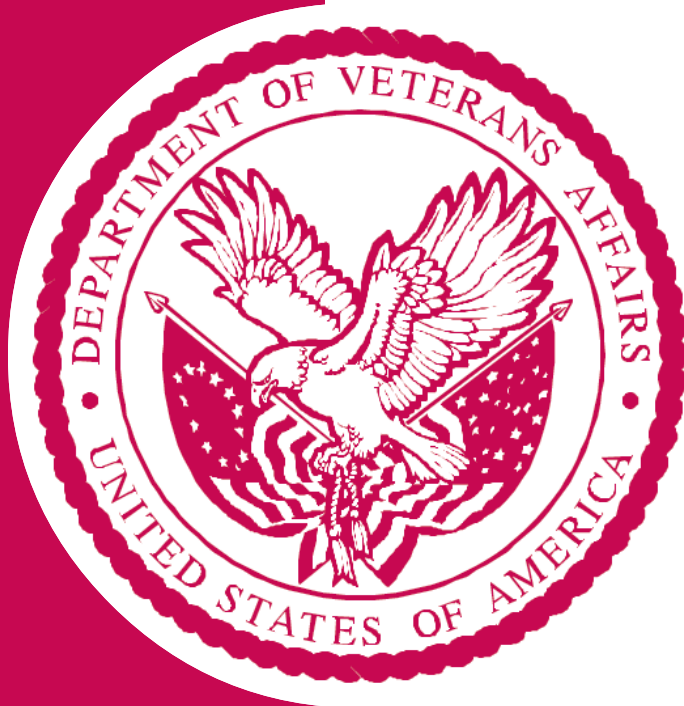


Refining Research Priorities:
New Initiatives Meeting
Veterans Needs

1997



Department of
Veterans Affairs

Veterans Health
Administration

Office of Research and Development

Refining Research Priorities: New Initiatives Meeting Veterans Needs

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John R. Feussner, M.D.
Chief Research and Development Officer (12)

Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420
202.273.8284

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Message from the Under Secretary for Health

The research and development program in the Department of Veterans Affairs has long been recognized as a key asset in efforts to improve the health of veterans. However, because of the evolution of health care, both within and outside of VA, and because of a need to more effectively marshal our research resources toward veteran health problems, I established the VA Research Realignment Advisory Committee (VARRAC) in 1995 to advise me on the overall appropriateness of the focus of VA's research program. In particular, among other things, I asked VARRAC to provide recommendations to me on the degree to which VA research:

- appropriately targets the needs of veterans;
- capitalizes on the unique resources and opportunities provided by the veterans health care system;
- has sufficient managerial flexibility to accommodate a rapid response to changing health care needs, while maintaining the stability of the research infrastructure;
- has an appropriate balance of basic, applied and outcomes research; and
- is targeted to projects that cover a spectrum of health care issues or disease conditions that increases the likelihood of multiplicative benefits of individual projects.

The Final Report of VARRAC contained many recommendations that, if implemented, would greatly enhance the impact of research on the health of veterans.

Since the release of the VARRAC's Final Report in October 1996, the Office of Research and Development has been actively engaged in implementing the recommendations.

Refining Research Priorities: New Initiatives Meeting Veterans Needs is an important step in implementing the VARRAC recommendations. The new initiatives outlined in this document cover all aspects of VA research and development, including health services delivery and quality of care, medical research, multi-center cooperative studies, and rehabilitation.

This strategic planning document represents one of many activities that will change the face of VA research. As these new initiatives are put into place, the VA Office of Research and Development continues to improve the relevance and effectiveness of VA research as it addresses the health care needs of veterans.

Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

Message from the Chief Research and Development Officer

In 1996 the Research Realignment Advisory Committee recommended that VA realign priorities to serve the needs of our Veteran population. This document reflects initial efforts to focus the VA research activities on areas of unique or special concern to Veterans, VA health care managers, and VA policy makers. This document presents only new initiatives and does not review the entire VA research portfolio. The focus of the new VA research priorities includes:

- expansion of Health Services Research
- creation of an Epidemiologic Research capacity
- Revitalization of Cooperative Studies
- Refocusing of Medical and Rehabilitation Research Services.

To start these new initiatives, the Research and Development Office redirected nearly 10% of FY 1997 research appropriations. To maintain this new direction, we assumed a stable, inflation-adjusted research appropriation in the future.

Health Services Research

The new initiatives expand Health Services Research priorities at the interface of clinical and operational activities. Health services research activities include:

- access to health care
- managed care strategies
- affect of facility integrations
- changes in clinical services organization with service line management
- ethnic, cultural, and gender issues as they relate to health services use
- rehabilitation patient outcomes research.

Epidemiologic Research and Information Centers

We initiated efforts to create Epidemiologic Research and Information Centers to focus on the epidemiology of medical care and management of chronic conditions and chronically ill Veterans. This epidemiologic capacity expands the expertise in our four Environmental Hazards Centers, whose focus is on toxic and other environmental health hazards.

Cooperative Studies

New studies initiated in Cooperative Studies in the first quarter of FY 1997 include:

- the investigation of new treatments for mental health and stress related diseases
- treatment of alcoholism
- diseases prevalent among aging veterans
- new therapies for cardiovascular diseases
- primary prevention of disease through immunization
- and other studies.

Medical Research

In fundamental biomedical research, new initiatives in diabetes, environmental hazards, emerging infections, and wound repair reflect current priorities.

Rehabilitation Research and Development Program

As we reevaluated our Rehabilitation Research and Development Program, we noted the lack of research training and career development pathways. Accordingly, we created predoctoral programs, and we have announced a Research Career Development opportunity for rehabilitation investigators from diverse backgrounds. These include:

- doctoral level applicants who are physicians, nurses, rehabilitation engineers, physical and occupational therapists
- professionals from prosthetics, orthotics, psychiatry, audiology, optometry, speech therapy, social work, and others.

We have released new Request for Applications (RFA) for research on the outcomes of rehabilitation services provided by the VA. The scope of this announcement encompasses rehabilitation for physical disabilities due to traumatic accidents and injuries, stroke, falls, and degenerative musculoskeletal or neurologic diseases. We may find new Rehabilitation Centers of Excellence in sensory loss, brain injury, aging with a disability, patient outcomes from rehabilitation care, and spinal cord regeneration.

The VA Research Program brings tremendous intellectual capital to the challenges posed by the diseases and disabilities that effect our Veteran patients. We know that our research can improve not only the duration of their lives, but also their quality of life. We agree that refocusing our research effort is an effective strategy to assure the relevance of our research results to the needs of the Veterans. Now that we have successfully realigned our research priorities, we intend to get on with the business of finding solutions for today's health care problems, so that diagnostic and treatment options available to our patients exceed currently available clinical practices.

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

Introduction

Background

This report provides an overview of major initiatives underway or in planning by the VHA Office of Research and Development since June 1996. In most cases the term “initiative” refers to formal Request for Applications (RFA) inviting VA investigators to submit research proposals for funding. All initiatives discussed in this document represent concrete expressions of centrally-defined priorities of the Office of Research and Development. The initiatives build on, but are distinct from, the VA’s ongoing research investments, especially the investigator-initiated programs in medical, health services, and rehabilitation research.

This report is targeted at a broad audience of officials in the Executive and Legislative branches of government, as well as for stakeholders such as Veterans Service Organizations, veterans and private institutions representing various academic, research and disease interests. It will lay out the current direction of VA research and what resources are being invested.

Organization

This report is divided into five major sections reflecting the current organizational structure of the Office of Research and Development:

- Health Services Research and Development
- Cooperative Studies
- Medical Research
- Rehabilitation Research and Development
- Career Development.

For each new and planned initiative the rationale, illustrations of potential research focus and projected five-year cost is provided.

Lastly, Career Development was identified by the VA Research Realignment Advisory Committee as a vital area of the Research and Development program in need of revitalization and expansion. A narrative description of actions to be taken in an effort to revitalize Career Development and the cost of this revitalization is provided.

Health Services Research and Development

New Initiatives

MANAGING ACCESS TO IMPROVE OUTCOMES

Access to VHA health care is affected by a variety of managerial and policy decisions, including eligibility criteria, clinical protocols, referral practices, staffing patterns, and service location and capacity.

This Request for Application invites proposals to address practical questions about the effects of efforts to improve veterans access to VHA services. The studies supported under this solicitation are to focus on the effects of interventions that intend to enhance access, restrict access (to unnecessary or ineffective services), or redistribute access across populations or places. Priority is given to studies of interventions at the Veterans Integration Service Network or system-wide level. Each study is to assess the intervention in terms of its effect on important patient outcomes (such as change in health status or functional capacity, satisfaction with care), population outcomes (incidence or prevalence of disease, complication rates), or system outcomes (quality, efficiency, cost, or cost effectiveness of care). All studies are expected to measure changes in costs and quality of care.

VISN directors were actively involved in developing this initiative and in helping to identify proposed studies that will address the information needs of VHA managers and service providers. Proposals to be reviewed in March 1997 address a wide range of timely issues, including: outsourcing of VHA cardiac surgery, hospital-linked care for homeless veterans, short versus long revisit intervals, and a computerized system for storage and retrieval of radiographic images.

Estimated Funds Required through FY01:	1997 - \$550 K
	1998 - \$1.9 M
	1999 - \$2.5 M
	2000 - \$2.5 M
	2001 - \$2.5 M

THE INTERFACE OF MANAGED CARE AND PRIMARY CARE

VHA's adoption of specific managed care principles and practices, such as the emphasis on primary care, coordination of care, emphasis on evidence-based practice, and attention to practice variation, reflects greater emphasis on accountability to patients and taxpayers as well as the need to be competitive in the health care marketplace. Significantly, the trends toward more managed care and more primary care are proceeding simultaneously in VHA. These dual movements raise many questions about new relationships among key components of the health care system and have potentially dramatic effects on the outcomes of care.

This RFA invites research that addresses timely questions about how VHA's movement toward managed care affects important patient and system outcomes. Investigators are expected to focus on questions whose answers will have immediate importance for guiding the continuing changes in the VA system or for providing baseline data that will be essential in continuing efforts to monitor and manage change. Examples of the questions that might be addressed include: Can the organizational structures or policies that enhance the effectiveness and efficiency of primary care within managed care also improve specialty care? What features of VHA health care organizations or VHA patient populations mediate the effectiveness of managed care principles? Where within VHA are the greatest potential cost savings attributable to managed care principles and/or practices?

Estimated Funds Required through FY01:	1997 - \$550 K
	1998 - \$1.1 M
	1999 - \$1.6 M
	2000 - \$2.2 M
	2001 - \$2.2 M

Health Services Research and Development

IMPLEMENTATION OF EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES

Evidence-based clinical practice guidelines are intended to facilitate and increase the use of clinical practices shown to be effective and to reduce the use of ineffective practices. Guidelines have enormous potential to improve the quality of care, reduce unnecessary costs, and reduce inappropriate variations in practice – if they are used correctly.

This RFA invites research to evaluate alternative strategies for implementing evidence-based clinical practice guidelines in VHA health care and to identify strategies that may be replicated system wide. Only guidelines that were developed nationally and that are based on scientific evidence are acceptable for study. Investigators may select guidelines on any clinical area relevant to veterans (depression, diabetes, pressure ulcers, cardiac rehabilitation, etc.). The evaluation should focus on alternative ways of introducing guidelines into practice, for example, incentives, computerized reminders, administrative rules, and penalties. Studies will also address the impact of guideline implementation on such outcomes as quality and cost of care, practitioner knowledge and practice patterns, and patient behavior.

Estimated Funds Required through FY01:	1997 - \$440 K
	1998 - \$1.6 M
	1999 - \$2.2 M
	2000 - \$2.7 M
	2001 - \$2.7 M

UNDERSTANDING ETHNIC AND CULTURAL VARIATIONS
IN THE DELIVERY OF VA HEALTH SERVICES

Ethnic and cultural variations in health care have been documented in Veteran, Medicare, and general populations, but few studies have gone beyond simple identification of such variations. While prior descriptive research has been useful, additional research is needed that focuses on more precise definitions of, underlying reasons for, and potential interventions for resolving issues that may result in the disparate treatment of patients.

This solicitation encourages proposals that employ innovative research methods and instruments for analyzing and evaluating ethnic and cultural variations in the delivery of health care, and that result in implementation of plans for effective interventions. This RFA invites proposals that go beyond the subjective grouping of individuals into arbitrary classifications and encourages research that incorporates self-identity and individual perceptions that may influence the delivery of health care.

Estimated Funds Required through FY01:	1997 - \$550 K
	1998 - \$1.9 M
	1999 - \$2.7 M
	2000 - \$2.7 M
	2001 - \$2.7 M

Health Services Research and Development

GENDER DIFFERENCES IN HEALTH CARE AND IMPROVING HEALTH SERVICES FOR WOMEN VETERANS

The Women Veterans Health Program Act of 1992, targets health issues specific to women veterans for research by the (VHA). HSR&D efforts to expand health services to women veterans have included: (1) Improving the VA's database for tracking women veterans and their health status; (2) Expanding physician intake guidelines to encompass early diagnosis and treatment; (3) Placing coordinators at VHA facilities to conduct outreach, patient care, education and research; and (4) Establishing comprehensive women's health centers for treating women veterans. HSR&D supports research to increase outreach and access to health care, and to explore health issues that affect many women veterans, such as breast cancer, reproductive health, post-traumatic stress disorder (PTSD), sexual abuse, mental illness, alcohol and substance abuse. Expansion of services to women veterans and improvements in tracking of utilization and outcomes provide new opportunities for researching women's health issues in the veteran population. This initiative seeks proposals that explore gender differences in veterans health care or investigate problems identified in non-veteran female populations that have not been studied among female veterans. Funded projects will build upon prior VHA research, explore new research areas, and recommend or evaluate interventions for improving women's health services.

Estimated Funds Required through FY01	1997 - \$330 K
	1998 - \$770 K
	1999 - \$1.1 M
	2000 - \$1.6 M
	2001 - \$1.6 M

EPIDEMIOLOGICAL RESEARCH AND INFORMATION CENTERS

As a research paradigm, epidemiology is well-suited for addressing the process and distribution of chronic diseases among various subgroups of veterans. However, the lack of established epidemiology research centers has hindered adoption of the *science* of epidemiology within VHA. Thus, a request for applications (RFA) was developed by VHA's Office of Research and Development to promote a greater interplay between clinical practice and the epidemiology of medical care. Studies are expected to address such issues as the use of risk assessment, surveillance and control techniques, and population-based epidemiological surveys that can be targeted toward selective health behaviors.

This RFA announced the opportunity for VHA medical facilities to compete for funding to establish one or more peer-reviewed Epidemiological Research and Information Centers (ERICs). Applicants will submit concurrently a proposal for an Epidemiology Research and Information Center, together with a complement of individual proposals to establish the Center's initial portfolio of scientifically approved epidemiologic research projects.

Each Center will have its own "core support" funding to accomplish a specific set of programmatic expectations, and each project will have its own "non-core" source of funding to accomplish a specific set of research objectives. Core support funds are intended to facilitate the recruitment of a stable "critical mass" of professional staff with skills sufficient to expand the science of epidemiology within VHA. In addition, Center staff will be fully responsible for managing the Center's research project budget.

Estimated Funds Required through FY01	1997 - \$550 K
	1998 - \$2.2 M
	1999 - \$2.2 M
	2000 - \$2.2 M
	2001 - \$2.2 M

Health Services Research and Development

DEVELOPMENTAL PROJECTS IN HEALTH SERVICES RESEARCH

This new program builds upon the success of a previously completed initiative which funded 19 programs between 1991 and 1996 which improved the capacity to do health services research in VHA and supported VHA's clinical mission in many ways. In addition to the design and development of research projects, the programs also have spawned Centers for Health Services Research on minority health care issues (including African-Americans, Hispanics, and Native Americans) and the development of educational workshops (e.g., to teach clinicians how to effectively prepare health services research proposals).

In recognition of changing priorities for VHA as it continues to reorganize its health care delivery system, a new solicitation for HSR&D Developmental Project Program proposals was released on October 31, 1996. This program provides VHA facilities with limited amounts of "venture capital" over a limited period of time (usually two years) to support innovative research collaborations. Proposals to establish these new programs are expected to have direct relevance for VHA's clinical research agenda, and collaborations among VHA medical facilities (and local community partners) are encouraged. Applicants may request up to \$100,000 per year for up to 2 years; a third year of funding is available by exception only.

The response of VHA field facilities to the latest request for proposals to establish new programs has greatly exceeded expectations, with nearly a three-fold increase over the number of proposals received for the 1994 solicitation. By FY 1998 we expect that as many as ten new programs will be underway.

Estimated Funds Required through FY01:	1997 - \$770 K
	1998 - \$1.1 M
	1999 - \$1.1 M
	2000 - \$1.1 M
	2001 - \$275 K

ESTABLISHMENT OF A NEW HEALTH SERVICES RESEARCH
FIELD PROGRAM (CENTER OF EXCELLENCE)

Established in 1982, the HSR&D Field Programs provide the supporting infrastructure for health services research on organizational and patient care issues. Currently, the HSR&D Service provides core support funding (approximately \$500,000/year/program) for nine Field Programs. These “Centers of Excellence” in selected health services research focus areas provide the primary means of enhancing VHA’s technical expertise in this critical area of patient outcomes research. The ultimate goal of the Field Program is to enhance the efficiency and cost effectiveness of VHA’s health care delivery system.

While operating within general guidelines established by the HSR&D Service, each Field Program develops a focused research agenda and maintains substantive relationships with supporting community institutions (e.g., graduate schools of public health, health administration programs, and research institutes). Core staff compete vigorously for peer-reviewed funding from the HSR&D Service (e.g., Investigator-Initiated Research program), from other federal granting agencies and private foundations. In collaboration with VHA’s Office of Academic Affiliations, Field Program staff also support four pre- and post-doctoral training programs for physicians and associated health professionals in health services research and medical informatics.

From fiscal year 1983 through April 1996, VHA’s HSR&D Field Program investigators have participated in 1,445 research projects with an estimated total funding of \$461.9 million. Federal grants (other than VA) account for over half of the funding awarded.

Given the historical success of the Field Program, a RFA will be issued to establish another Center of Excellence. Subject to annual (non-competitive) administrative review, the funding award is expected to last 5 years. As with all of the Field Programs, subsequent competitive renewal is possible (subject to the findings of an external peer-review panel).

Estimated Funds Required through FY01:	1997 - \$275 K
	1998 - \$495 K
	1999 - \$550 K
	2000 - \$550 K
	2001 - \$550 K

Health Services Research and Development

FACILITY INTEGRATION STUDY

Since January 1995, thirty-two VA Medical Centers have been approved to merge creating sixteen new integrated medical centers, and additional facility integrations are being considered. This two part study will provide a systematic evaluation of VHA facility integrations with a specific focus on management lessons that can be drawn. The first part of the study will document the planning and decision making processes; measure the extent of integration at each site; and describe the characteristics of the integrated facilities, including structures that are being put into place to manage the facilities and deliver care to veterans.

The second part of the study is an analysis of the effects of integration on aspects of cost/efficiency, access, patient satisfaction and quality enhancement. Management literature and VHA experience with earlier integrations indicate that hospital integrations usually take 18-24 months from the time of approval to planned integration, and even longer to reach levels of integration that can be expected to affect outcomes.

Estimated Funds Required through FY99:	1997 - \$130 K
	1998 - \$130 K
	1999 - \$ 30 K

EVALUATION OF VISN SERVICE LINE MANAGEMENT

This project is one of numerous collaborative efforts between researchers and managers. As a management consultation project it is funded jointly by medical care and research dollars, with research dollars funding fixed costs such as core research staff and the Veterans Integrated Service Networks, through the Under Secretary, funding the variable costs.

VHA is continuing to support improvements in the delivery of veterans health care by restructuring organization and management practices to increase efficiencies and responsiveness to veterans. VHA's move toward "Service Line Management" is one aspect of this restructuring. The term "Service Line Management" covers a variety of organizational arrangements for focusing management efforts on providing coordinated care that meets patient and customer needs. Examples of service lines include primary care, mental health, spinal cord injury, and women's health care.

Nineteen of the 22 VISNs intend to implement service line management. This study will look at the process of change and the actual effectiveness of service lines. Study objectives are to evaluate service line management using both qualitative and quantitative techniques to identify specific characteristics of the various forms of service line management and to measure its impact on a wide range of patient and organizational variables. The study design will be based on comparisons of (1) pre-and post-measurement of service line implementations within each VISN, and (2) across VISNs. The study will provide timely and supportive feedback to VHA management throughout the service line implementation process with substantial effort placed on measuring objective changes and describing alterations in how VISNs function under the service line structures.

In evaluating organizational changes, care will be taken to allow sufficient time for the intended changes to affect outcomes, as well as to avoid false negative results that may stem from the disruptive process of change rather than from the structure and management practices that are the desired focus of the evaluation

Estimated Funds Required through FY00:

	Total	HSR&D	Medical Care
1997	\$186 K	\$ 86 K	\$100 K
1998	\$386 K	\$160 K	\$226 K
1999	\$405 K	\$135 K	\$270 K
2000	\$111 K	\$ 30 K	\$ 81 K

Health Services Research and Development

Planned Initiatives

REHABILITATION OUTCOMES RESEARCH

During FY 1997, the Office of Research and Development plans another RFA to initiate a set of research projects focused on the outcomes of rehabilitation services provided by VHA. The scope of this announcement will be broad, encompassing rehabilitation for physical disabilities due to traumatic accidents and injuries as well as stroke, falls, and degenerative musculoskeletal or neurologic diseases. The rehabilitative services to be studied will include those designed to restore or compensate for lost ambulation, speech, vision, and other functions that affect independent living and quality of life. These studies will involve the perspectives and expertise of a wide range of health care providers, including physicians, nurses, physical and occupational therapists, speech therapists, and others. This initiative represents a collaboration between VHA's Rehabilitation Research and Development Service and Health Services Research and Development Service.

Estimated Funds Required through FY01:	1998 - \$330 K
	1999 - \$990 K
	2000 - \$1.1 M
	2001 - \$1.1 M

PATIENT-CENTERED CARE AND QUALITATIVE RESEARCH METHODS

As the VHA moves to a more cost-effective and efficient managed care model, managers are interested in ensuring that the VHA does not lose sight of the patient, and the importance of patient-centered care. 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, the social organization of medical practice and other factors that affect patient satisfaction with care. These more qualitative issues have not been adequately addressed with quantitative methods.

This initiative solicits studies that utilize the expanding number of rigorous qualitative methods, either exclusively or in ways that complement quantitative methods, to address questions of how and why health beliefs, patient preferences, satisfaction, and compliance vary across individuals, groups, and organizational settings.

Estimated Funds Required through FY01:	1998 - \$825 K
	1999 - \$1.1 M
	2000 - \$1.1 M
	2001 - \$1.1 M

Cooperative Studies Program

New Initiatives

In FY'96 there were many studies on the waiting list for funding from the Cooperative Studies Program (CSP). These studies had been recommended for approval by the Cooperative Studies Evaluation Committee (CSEC), but had not been initiated due to limitations in resources allocated to CSP. In late FY'96 CSP was reorganized and additional funds were made available. Consequently, 10 studies on the waiting list have now been approved for initiation in FY 1997

PTSD: TREATMENT OUTCOMES

We estimate that over 15% of male Vietnam theater veterans, or almost 480,000 men, currently suffer from PTSD, a disorder that commands a substantial amount of VHA resources yet shows relatively little improvement in response to standard therapy. This study is a randomized clinical trial to evaluate the efficacy of trauma focus group therapy compared to supportive group counseling in treating the symptoms and functional disabilities caused by PTSD in Vietnam veterans. Secondary outcomes include the effect of trauma focus group therapy on physical health and on utilization of medical and mental health services. 360 male outpatients with PTSD related to service in the Vietnam theater will be included in the study. The study duration will be 4 years.

Project Dates: 7/96 - 9/00

Projected Funding: \$3.65 Million

THE IRON AND ATHEROSCLEROSIS TRIAL

Vascular disease is the leading cause of death in our society. Technologically sophisticated cardiac practices and surgeries are major contributors to the rising cost of medical care today. Considerable evidence suggests that iron induces lipid oxidation, the products of which are found in fat deposits in arteries. Evidence also suggests that iron-induced oxidation can contribute to the development of coronary vascular disease.

The objective of the study is to test the hypothesis that low cost reduction of total body iron stores through controlled phlebotomy (like blood donation) will reduce the risk of specific adverse endpoints in a population of patients at risk of having a second heart attack. The current pilot study will recruit patients from two VA Medical Centers in order to determine feasibility of recruitment and acceptability of the intervention to patients; to develop more information about the variability of the outcome measure; and to determine the actual degree of iron reduction that can be achieved safely.

Project Dates: 10/96 - 10/97

Projected Funding: \$35,000

Cooperative Studies Program

NALTREXONE IN THE TREATMENT OF ALCOHOLISM

Alcohol dependence is a chronic, disabling disorder affecting veterans of all ages. If alcohol dependent patients can reduce their relapses and hospitalizations, they will be better able to function in the community, thereby improving their quality of life.

The objective of this study is to evaluate the efficacy of naltrexone augmentation of a standardized outpatient, individual, psychotherapy program modeled after 12-step approaches. Psychotherapy treatment will consist of individual psychotherapy involving a modified 12-step approach aimed at reinforcing abstinence, providing basic relapse prevention information, and reinforcing compliance with study medications. Therapy will include acceptance of the drug therapy (naltrexone) and will focus on the individual patient instead of a group.

The study is planned to include approximately 600 patients, with two years of patient intake and 18 months of patient follow-up.

Project Dates: 1/97 - 7/00

Projected Funding: \$4.3 million

TREATMENT OF SEIZURES IN THE ELDERLY POPULATION

Epidemiologic data indicate that seizures in the elderly population are more common than previously thought. Many elderly suffer from diseases, such as stroke or heart disease, which are complicated by epileptic seizures. These patients are often treated with multiple prescription drugs which increase the probability of drug-drug interactions and increased morbidity. Determining optimal therapy for elderly patients with epilepsy is a challenge which can improve the patients' quality of life.

The primary objective of this study is to determine the tolerance to and efficacy of two new antiepileptic drugs (gabapentin and lamotrigine) individually compared to a standard drug (carbamazepine) for the treatment of seizures in the elderly population (55 years or older) with new onset, unprovoked epileptic seizures. The study will also assess: mental functioning, mood and quality of life; the characteristics and cause of seizures in the elderly; differential responses of different seizure types to the three drugs; and serum levels of study drugs needed for seizure control.

If one of the drugs being studied is found to be more effective in the elderly with fewer side effects, this will allow elderly patients with seizures to live a better, more seizure-free life.

Project Dates: 3/97 - 12/02

Projected Funding: \$4.73 million

Cooperative Studies Program

THE EFFECTS OF ANTI-ARRHYTHMIC THERAPY IN MAINTAINING STABILITY OF SINUS RHYTHM IN ATRIAL FIBRILLATION

Atrial fibrillation (a serious disturbance in heart rate and rhythm) is now the most common cardiac rhythm disturbance encountered in clinical practice, giving rise to a significant increase in morbidity and death, especially in patients with existing heart disease. Atrial fibrillation is also a risk factor for congestive heart failure and stroke. The best approach to standardized therapy for atrial fibrillation remains to be developed. The maintenance of a normal heart rhythm in patients predisposed to atrial fibrillation is a major treatment goal and agents which are effective in this regard are of practical importance.

The objective of the study is to compare the effects of two anti-arrhythmic drugs (sotalol and amiodarone) in maintaining stability of normal rhythm in patients with atrial fibrillation. The primary hypothesis is that amiodarone is superior to sotalol and both are superior to placebo in maintaining a normal heart rhythm.

The primary outcome measure is the percentage of patients with normal heart rhythm at one year. Other outcome measures include time to recurrence of atrial fibrillation, exercise tolerance and frequency of adverse hearts events.

Project Dates: 4/97 - 6/01

Projected Funding: \$5 million

EVALUATION OF A COMPUTER ASSISTED NEUROPSYCHOLOGICAL SCREENING BATTERY

Many neurological conditions can have an effect on the functioning of the brain in different areas such as cognition, memory, vigilance, and motor skills. Measurement of these functions can be of critical importance in the diagnosis of different neurological disorders and in determinations of their severity. This study will evaluate a brief computerized battery of tests for patients referred for neuropsychological testing. This test battery can be an important adjunct in evaluating patients for the effects of exposure to neurotoxic environmental pollutants, such as in Persian Gulf veterans.

Project Dates: 4/97 - 4/00

Project Funding: \$2.6 million

Cooperative Studies Program

VARICELLA VACCINE FOR PREVENTION OF HERPES ZOSTER AND ITS COMPLICATIONS

Herpes zoster (HZ or shingles) is a localized disease characterized by a painful skin eruption that is generally limited to sensory nerve fibers in the skin. The incidence and severity of HZ increase with increasing age, and complications occur in almost one-half of older individuals. The most frequent complication of HZ is prolonged and disabling pain which occurs in 25-50 percent of patients over the age of 60 years.

The primary objective of the proposed study is to determine whether immunization with live attenuated varicella (chickenpox) vaccine (OKA/MERCK strain) can reduce the incidence and/or severity of herpes zoster and its complications in persons 60 years of age and older. Among the secondary objectives of the study are assessment of the effect of the vaccine on the quality of life of individuals who develop HZ, and on the incidence and severity of chronic pain. The study should also provide information on the natural history of HZ in terms of impact of the disease and its complications on older persons and provide additional data on vaccine safety.

Patients will be randomized to vaccine or placebo and followed monthly through a telephone-linked computer system. Duration of patient intake is planned for 18 months with minimum patient follow-up of 36 months. The study will recruit 27,000 subjects.

If the varicella vaccine reduces the incidence and severity of herpes zoster in the elderly, a vaccination program would be a cost-effective and safe means of reducing the potentially severe impact of herpes zoster and its complications on the quality of life of older veterans.

Project Dates: 9/97 - 3/02
Projected Cost of Study: \$13.8 M
Projected VA Funding: \$6.9 M

**SPECIALIZED MEDICATION VS. ANGIOPLASTY IN ASSESSING
REINFARCTION AND MORTALITY (SMART)**

During the last 15 years, percutaneous transluminal coronary angioplasty (PTCA, or balloon angioplasty) has become a widely-used, safe and effective procedure for the management of coronary heart disease patients with symptomatic myocardial ischemia (oxygen insufficiency). However, PTCA is being used increasingly for routine, prophylactic management of coronary artery abnormalities in heart disease patients — rather than for symptom relief of chest pain— where outcomes-derived research has not yet demonstrated a conclusive benefit of reduced death or recurrent heart attack in such patients.

The objective of this trial is to prospectively assess both “hard” outcomes (death; recurrent non-fatal heart attack ; persistent chest pain necessitating coronary artery bypass surgery) and other health care outcomes (quality of life, cost-effectiveness and cost-utility measures) during long-term (3-5 year) follow-up after randomization to PTCA + intensive medical therapy vs. intensive medical therapy alone in “non-high-risk” heart disease patients.

Angioplasty costs the national health care system billions of dollars annually. Therefore, prospectively assessing its current use by employing a randomized, controlled, clinical trial of existing PTCA indications vs. contemporary, intensive medical therapy seems long-overdue. Until the outcome of this study can be established conclusively, it would appear that the use of PTCA will remain largely unrestricted and costly to the health care system.

Project Dates: 7/98 - 7/04
Projected Cost of Study: \$23 M
Projected VA Funding: \$9 M

Cooperative Studies Program

FOLLOW-UP STUDY ON PATIENTS WHO RECEIVED MEDICAL AND SURGICAL THERAPIES FOR GASTROESOPHAGEAL REFLUX DISEASE

The most crucial and controversial issue concerning the proper role of anti-reflux surgery in the treatment of gastroesophageal reflux disease (heartburn) relates to the duration of the beneficial effects of surgery on chronic severe heartburn. The “Prospective Randomized Trial of Medical and Surgical Therapies for Gastroesophageal Reflux Disease” concluded that, after one year, anti-reflux surgery was more effective than medical therapy in improving the symptoms and endoscopic signs of chronic severe heartburn. However, relatively few reports deal with the long-term results of the operation. Since medical treatment of chronic severe heartburn requires daily dosing with costly anti-secretory medicines over a lifetime, anti-reflux surgery would be less expensive provided the results of surgery are long lasting.

The purpose of this study is to assess the current reflux, or heartburn, status of the 248 patients who participated in the previous trial. For all willing patients, the follow-up study would include heartburn symptoms, the severity of esophagitis, and 24-hour esophageal acid monitoring to document the duration of acid reflux. The study will be conducted at the same eight centers that originally participated in the trial.

Project Dates: 5/97 - 5/98

Projected Funding: \$450,000

THE CORONARY ARTERY REVASCLARIZATION
PROPHYLAXIS TRIAL (CARP TRIAL)

Cardiovascular disease accounts for 1 million deaths/year and is the leading cause of death among Americans. Studies have shown that in patients scheduled for elective vascular surgery, the frequency of coronary artery disease exceeds 50%. It is not surprising therefore, that the leading cause of complications is “post-operative cardiac morbidity” (defined as the occurrence of heart attacks, unstable angina, congestive heart failure, arrhythmia, and cardiac death). This study is designed to answer the question: Should prophylactic coronary artery revascularization (surgical restoration of blood flow to the heart) be performed prior to elective vascular surgery?

The primary objective is to determine whether prophylactic coronary artery surgery in high risk patients scheduled for elective vascular surgery reduces death and cardiovascular morbidity in the 3-month post-operative period and the 2 year follow-up period. Secondary objectives include comparison of quality of life and cost effectiveness.

The study will include patients requiring elective vascular surgery who are considered to be at risk for coronary artery disease. Those individuals with significant coronary artery disease which is amenable to revascularization will be considered for inclusion in the study. Patients will be randomized to either coronary artery surgery or intensive medical treatment prior to the elective vascular surgery.

A one-year pilot study to assess the feasibility of the study will begin in June 1997. Five participating centers will be selected, with the goal of recruiting a total of 60 patients during the pilot year.

Project Dates: 5/97 - 9/98

Projected Funding: \$460,000

Cooperative Studies Program

Initiatives Under Review

18-F-FLURODEOXYGLUCOSE (FDG) POSITRON EMISSION TOMOGRAPHY (PET) IMAGING IN THE MANAGEMENT OF PATIENTS WITH SOLITARY LUNG NODULES

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 will evaluate the utility of FDG-PET in differentiating benign from cancerous processes in patients with solitary lung nodules. The hypothesis is 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 noninvasive technique for accurate differentiation of benign and cancerous lung nodules.

RANDOMIZED CLINICAL TRIAL OF SURGICAL HERNIA REPAIR

The American College of Surgeons is interested in developing a long-term collaboration with the Department of Veterans Affairs and Northwestern University to conduct multi-center clinical trials to evaluate new, emerging surgical technologies. The first trial being proposed is in surgical hernia repair.

An estimated 500,000 groin hernia repairs are performed annually in the U.S. and as many as 800,000 Americans have groin hernias potentially in need of surgical repair. Preliminary studies indicate that laparoscopic hernia repair, compared to more invasive open surgical repair, reduces post-operative pain and permits the patient to return to work or everyday activities earlier, but the laparoscopic surgical approach is more expensive.

ANTI-THROMBOTIC AGENTS FOR PREVENTION OF HEMODIALYSIS ACCESS THROMBOSIS

Maintenance of vascular (blood vessel) access has been termed the “Achilles heel” of hemodialysis of kidney patients. The thrombosis (blood clotting) of hemodialysis grafts is a major cause of morbidity and hospitalization in hemodialysis patients. A recent review of the Medicare hemodialysis database indicated that access related stays represented 17% of all hospitalizations for hemodialysis patients. The total cost of placement and maintenance of vascular access for hemodialysis is estimated to be \$500 million annually. Patients dialyzing in the VHA comprise more than 3300 of the 120,000 patients on hemodialysis in the United States. The morbidity related to vascular access in the VA population also represents a significant burden for the patients and the VA system. Effective therapy to decrease the rate of blood clotting would have significant impact on VA patient morbidity, as well as reducing the current expense of more than \$12 million annually for maintenance of vascular access.

The primary objective of this study is to determine whether the combination of aspirin 325 mg daily and ticlopidine 250 mg bid is more effective than placebo in the prevention of clotting of hemodialysis access grafts. Secondary objectives are 1) performance of a cost analysis of access maintenance in the two groups, particularly the cost related to the repair of access clotting, and 2) a comparison of the clotting recurrence rates between the two groups. The period of subject enrollment will be six months and the follow-up period will be 24 months on therapy, for a total study duration of 30 months.

Initiatives in Planning

HORMONE REPLACEMENT THERAPY WITH DAILY PROGESTERONE: SAFETY, EFFICACY AND SIDE EFFECTS

Estrogen replacement therapy is effective treatment for hot flashes, insomnia and urogenital symptoms associated with menopause. Studies have also shown that estrogen replacement therapy reduces the risk of post-menopausal bone loss, osteoporotic fractures and coronary artery disease. Unfortunately, estrogen therapy alone causes side effects including irregular vaginal bleeding and increased risk of uterine cancer. Progestins added to estrogen prevent the development of cancer.

Micronized progesterone may be the preferred progestin for hormone replacement therapy because it is the natural ovarian hormone. It may have the “best” effects on cardiac risk factors and is likely to have the least side effects. The objective of the study is to compare the safety, efficacy and acceptability of medroxyprogesterone acetate, the current standard program used for combined continuous therapy, to micronized oral progesterone. The major endpoints are efficacy, safety and patient acceptability.

PROPHYLAXIS OF MEDICAL PATIENTS FOR THROMBOEMBOLISM

Pulmonary embolism (blood clot to the lungs) accounts for 15% of hospital deaths making it the most common preventable cause of hospital deaths. The data on heparin (an anti-blood clotting agent) prophylaxis for medical patients is inconclusive. Although frequently recommended, heparin prophylaxis is seldom used in practice

This study is proposed to determine if heparin will significantly reduce 90-day death rates in inpatient medical patients age 60 and above. Death among patients one year post-administration will be a secondary endpoint. The treatment group will receive daily administration of low molecular weight heparin throughout hospitalization.

We hypothesize that a 10% reduction in death rates would be attained, which is a very substantial benefit considering the low cost of heparin prophylaxis. Applied to eligible medical inpatients, this mortality reduction translates to 3,000 potential deaths averted each year in patients treated in VA medical centers. Findings generalized to the U.S. population could mean that 60,000 deaths could be averted annually. Conversely, if the study demonstrates that heparin is not an effective prophylaxis, the practice of not embarking on this type of treatment regimen could save \$9 to \$22 million per year.

Cooperative Studies Program

COST EFFECTIVENESS OF A TELEMEDICINE DIABETIC RETINOPATHY MANAGEMENT SYSTEM

Diabetes afflicts 4.9% of the American population, yet treatment of diabetes and its complications consumes a disproportionate 16% of the nation's health care resources.

This study seeks to improve access and quality of care, optimize treatment outcomes, and ultimately reduce costs for managing diabetic retinopathy (deterioration of vision), one of the most costly complications of diabetes in both human and economic terms. Clinical care guidelines for the prevention and management of diabetic retinopathy are well established, but access to appropriate care may be difficult. The study plans to examine the impacts of a telemedicine-driven disease management system for early detection, diagnosis, and treatment of diabetic retinopathy in VA patients.

This study will establish the "Telemedical Diabetic Retinopathy Management System" (TDRMS) at a number of VA Medical Centers. A prototype TDRMS was developed and previously tested on a small scale in a non-veteran population. With this system, patients will be screened for diabetic retinopathy during the same clinic visit for general diabetic care. Technicians at each site will take diagnostic images of the patients' eyes. These images, along with other clinical and demographic information, will be sent to a central "reading center" for interpretation.

The study will examine the effectiveness and costs of this system which systematically and routinely screens all diabetic patients for visual complications. Issues such as diagnostic accuracy, patient satisfaction and quality of life, and health outcomes will be addressed.

EFFECT OF TREATMENT OF CENTRAL SLEEP APNEA-HYPOPNEA SYNDROME
ON SURVIVAL OF PATIENTS WITH OPTIMALLY TREATED STABLE HEART FAILURE

Heart failure and sleep apnea (intermittent cessation of breathing during sleep) are two very frequent disorders in the VA patient population. Even though patients with heart failure can be treated successfully, their death rate is still unacceptably high. The cause of this mortality is not entirely clear, but sleep disordered breathing may play an important role. Sleep apnea is a frequent complication of heart failure, and episodes of sleep apnea are associated with many adverse effects which may increase death rate in patients with heart failure.

While this study is in the early stages of planning, it is intended to be a multi-center clinical trial investigating the treatment of sleep apnea with either oxygen or theophylline. The primary endpoints will be death and/or number of hospitalizations. Other objectives will include assessing the effect of treatment on patients' quality of life, and examining the risk factors associated with central sleep apnea syndrome.

Medical Research

New Initiatives

JOINT VA/JUVENILE DIABETES FOUNDATION (JDF) DIABETES RESEARCH CENTERS

In 1995 VA and JDF entered into an agreement to jointly fund up to six Diabetes Research Centers. The purpose of these centers is to focus VA research efforts in problems of both Type I and Type II diabetes especially where a bridge between the two forms exists, such as in the clinical complications of diabetes. These centers are intended to span the breadth of problems in diabetes from the basic understanding of pathogenesis to treatment of complications, and to include both fundamental and applied research components. Applications for these centers were reviewed in Fall, 1996 and three centers were awarded to Iowa City VAMC, San Diego VAMC, and Nashville VAMC.

The Iowa City Diabetes Research Center will focus on mechanisms by which vascular function is affected by diabetes mellitus. This research will provide important information that could lead to better treatment and prevention of vascular disease secondary to diabetes. The San Diego Diabetes Research Center will investigate the underlying mechanisms of insulin resistance in Type II diabetes. Insulin resistance is thought to be the primary metabolic disorder leading to destruction of pancreatic cells that produce insulin, leading to Type II diabetes. Better understanding of these mechanisms could improve prevention and treatment of Type II diabetes. The Nashville Diabetes Research Center will employ basic and applied research approaches to study the adverse side effects often associated with intensive treatment of diabetes. Such side effects include hypoglycemia (low blood sugar) and obesity. By better understanding the mechanisms of these side effects, long-term health outcomes and quality of life of persons with diabetes may be improved.

The ultimate goal of the VA/JDF program is to fund a total of six Centers. Consequently, a new solicitation for the remaining three centers is being prepared with an expected release in the second quarter of FY'97.

Estimated Funds Required:

	VA	+	JDF	=	Total
1997	\$1.0 M	+	\$500K	=	\$ 1.5 million
1998	\$1.5 M	+	\$1.5M	=	\$ 3 million
1999	\$1.5 M	+	\$1.5M	=	\$ 3 million
2000	\$1.5 M	+	\$1.5M	=	\$ 3 million
2001	\$1.5 M	+	\$1.5M	=	\$ 3 million

ENVIRONMENTAL HAZARDS RESEARCH CENTER FOR
REPRODUCTIVE AND DEVELOPMENTAL OUTCOMES

In past years veterans from different wars and conflicts have raised concerns for the health of their offspring, which may have been affected by military service of a parent. Such concerns have been expressed by World War II veterans with respect to ionizing radiation; Vietnam veterans with respect to herbicides; and Persian Gulf veterans with respect to a variety of potential environmental hazards. Consequently, in 1996 the VA Office of Research and Development solicited proposals for a new Environmental Hazards Research Center for Reproductive and Developmental Outcomes. The proposed Center is a consortium involving investigators from VA and other government and non-government agencies such as universities, state agencies, and other agencies of the federal government.

In October 1996 proposals were reviewed for scientific merit by an *ad hoc* committee of nationally and internationally recognized experts on the reproductive and developmental effects of exposure to environmental and occupational hazards. The Louisville VAMC in collaboration with the University of Louisville was selected for funding effective January 1, 1997. This center joins a complement of three other centers focusing more generally on environmental hazards. These centers are located at Boston VAMC, East Orange VAMC, and Portland VAMC.

Estimated Funds Required:	1997 \$350 K
	1998 \$300 K
	1999 \$300 K

MECHANISMS OF EMERGING PATHOGENS - VA/DoD COLLABORATIVE RESEARCH

Emerging pathogens are microorganisms (bacteria, viruses, protozoa, and fungi) that cause disease in humans, and for which the frequency of infection in humans has increased within the past two decades, or threatens to do so in the near future. Emerging infectious diseases are of vital importance to the military and to VA since many military personnel are exposed to infectious agents while serving in foreign countries. These individuals return to the United States while on active duty or as veterans. In addition, many veterans are susceptible to emerging pathogens because of age, hospitalization for acute illnesses, or predisposition due to chronic medical conditions.

This initiative is designed to address: (1) various ways newly discovered microorganisms become infectious to humans; (2) ways well-established infectious agents change to cause more serious disease, such as by development of antibiotic resistance; (3) effects of climate, ecological, and population changes on spread of infectious agents; and (4) ways in which infectious agents infect individuals with a suppressed immune system.

Estimated Funds Required:

1998	\$2.5 M
1998	\$2.1M
1999	\$2.5 M
2000	\$2.5 M

COMBAT CASUALTY AND WOUND REPAIR - VA/DoD COLLABORATIVE RESEARCH

Optimizing recovery from combat related injuries and surgical procedures is of vital interest to the military and to the VHA. This initiative will address research on tissue repair during short-term, intermediate, and long-term recovery from combat injury or surgery. Topics of interest included: (1) cell biology of tissue and organ responses to injury; (2) causes of shock following injury, 3) immediate and delayed effects of frostbite and non-freezing cold injury; (4) cell biology of normal tissue repair following a surgical incision; and (5) causes of abnormal healing of a wounds or surgical incisions.

Estimated Funds Required:

1998	\$2.4 M
1999	\$2.4 M
2000	\$2.4 M

Medical Research

MEDICAL RESEARCH REPLACEMENT EQUIPMENT

A Request for Proposals for Medical Research Replacement Equipment will be released in January 1997. Funding in the amount of \$1.5 million has been committed for fiscal year 1997. The purpose of the proposal is to modernize and upgrade research laboratory equipment. This will allow research laboratories to stay current with the latest technology and ensure that VA research is state-of-the-art.

Estimated Funds Required:	1997	\$1.5 M
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Planned Initiatives

PROSTATE DISEASE INCLUDING PROSTATE CANCER

The VA and DoD have agreed to sponsor research initiatives on Prostate Disease and Cancer. The initiative will address the cell biology, diagnostic developments, and treatment of benign prostate disease and prostate cancer. A joint VA and DoD oversight committee will be appointed to determine the content of the proposals.

Estimated Funds Required:

1998	\$1.5 M
1999	\$1.5 M
2000	\$1.5 M

Medical Research

STRESS RELATED DISEASES INCLUDING PTSD

The VA and DoD have agreed to sponsor research initiatives on Stress Related Diseases including Post Traumatic Stress Disorder (PTSD). This initiative will include studies on the biology of PTSD and other stress related diseases, and the biological effects of stress on Persian Gulf Veterans. A joint VA and DoD oversight committee will be appointed to determine the detailed content of the initiatives.

Estimated Funds Required:

1998	\$1.5 M
1999	\$1.5 M
2000	\$1.5 M

NEUROFIBROMATOSIS

Neurofibromatosis type 1 is an autosomal dominant genetic disorder with widespread effects on many systems of the body. The hallmark of the disorder is occurrence of benign tumors along peripheral nerves. The VA and DoD have agreed to sponsor research initiatives on Neurofibromatosis. The initiative will address the cell biology and molecular biology of Neurofibromatosis, including the genes which control development of tumors of the nervous system. A joint VA and DoD oversight committee will be appointed to determine the detailed content of the initiatives.

Estimated Funds Required:	1998	\$650 K
	1999	\$650 K
	2000	\$650 K

Medical Research

MEDICAL RESEARCH FUNDS EXPENDED IN DESIGNATED RESEARCH AREAS

For the Fall 1996 cycle of Merit Review, 143 of 627 proposals (22.8%) have been selected for funding at a cost of \$14,985,700 for the first year and \$55,972,200 for the term of the awards. Analysis of topic areas indicates that 119 out of 143 funded proposals (83.2%) are in Designated Research Areas (DRAs), recommended by the Research Realignment Advisory Committee. In terms of cost, funded DRA projects represent 81.4% of the total cost for the Fall 96 review cycle. The funding breakdown by DRA categories is listed below in Table 1.

Table 1

**FALL 1996 MEDICAL RESEARCH MERIT REVIEW
funding breakdown by
Designated Research Area (DRA)**

Designated Research Area	Number of Projects	Total Funding
Aging	7	\$ 2,284,200
Cancer	22	\$ 8,127,700
Cardiovascular	17	\$ 6,671,000
Chronic Infectious Diseases	12	\$ 4,359,700
CNS Injury	5	\$ 2,314,900
Degenerative Diseases of Bones and Joints	12	\$ 5,196,700
Dementia	9	\$ 3,245,400
Diabetes	9	\$ 3,726,000
Psychoses	9	\$ 3,640,700
Sensory	3	\$ 1,361,300
Substance Abuse	14	\$ 4,646,700
Other	24	\$ 10,397,900
Total	143	\$55,972,200

Rehabilitation Research and Development

Scientific initiatives in Rehabilitation Research and Development include investigator-initiated projects, centers of excellence, technology transfer, and information dissemination. New and planned initiatives focus on rehabilitation and disability management aspects of amputation, spinal cord injury, vision impairment, hearing loss, communication disorders, and other performance impairments.

New Initiatives

RESEARCH CAREER DEVELOPMENT

A request for applications (RFA) was developed in December of 1996 to establish a formal experience-based mentoring path for doctoral level rehabilitation professionals interested in establishing and enhancing research skills and methodology. Awards will be offered in support of two separate levels of investigator experience. Clinicians with a desire to develop independent research skills will be funded for up to three years. More advanced clinician researchers who are not yet fully independent investigators will be funded, also for up to three years, with the expectation that they will be fully independent research investigators at the end of the appointment. Applications will be considered from the following professions: Rehabilitation Engineering, Physical Therapy, Occupational Therapy, Rehabilitation Nursing, Prosthetics, Orthotics, Physiatry, Orthopaedics Surgery, Psychiatric Rehabilitation, Audiology, Speech Pathology, Optometry, Ophthalmology, Recreational Therapy, Social Work, Architectural and Environmental Designs, and Psychology. Deadline for applications is May 1, 1997. In congruence with other services within the Office of R&D, a biannual review and funding cycle will be established with application deadlines on May 1 and November 1 of each year.

Estimated Funds Required through FY01:	1998	\$450 K
	1999	\$900 K
	2000	\$1.0 M
	2001	\$1.5 M

Rehabilitation Research and Development

“INNER HARBOR” ROUNDTABLE CONFERENCES

A caucus of rehabilitation consumers, providers and administrators gathered in Baltimore on September, 1996 to chart new research directions in support of Rehabilitation Outcomes and Health Services Delivery. Discipline specific and interdisciplinary disability-focused scientific roundtables will be convened on a quarterly basis in Baltimore, site of Rehabilitation Research and Development offices, to promote sharing of scientific data, to foster discussion among researchers and clinicians, and to set directions in designated high priority research areas in RR&D. This will be a cost effective way to generate veteran relevant investigator initiated research proposals.

Estimated Funds Required through FY01:	1997	\$60 K
	1998	\$120 K
	1999	\$120 K
	2000	\$120 K
	2001	\$120 K

CLINICAL MONOGRAPHS

Annual monographs focused on areas of high interest to veterans will be published to provide better information dissemination of research findings and how they relate to consumers and their care providers,. In August of 1996, Physical Fitness: A Guide for Individuals with Spinal Cord Injury was issued in conjunction with the 1996 Paralympics. Demand for this publication resulted in two reprintings of 5,000 each in addition to the initial 25,000 printed. A monograph focused on clinical issues for veterans with hearing impairments is being compiled and will be distributed in 1997.

Estimated Funds Required through FY01:	1997 - \$25 K
	1998 - \$25 K
	1999 - \$25 K
	2000 - \$25 K
	2001 - \$25 K

Rehabilitation Research and Development

Planned Initiatives

CAREER DEVELOPMENT “REQUEST FOR PROPOSALS” FOR PRE-DOCTORAL CANDIDATES

Opportunities exist to take advantage of strong rehabilitation degree granting programs at VA affiliated universities by supporting pre-doctoral candidates for research career mentoring awards. This program will be patterned on the design of the existing health services research pre-doctoral programs. An emphasis will be placed on creating new opportunities at an early educational level for such rehabilitation professions as Clinical Rehabilitation Engineering.

Estimated Funds Required through FY01:	1998	\$150 K
	1999	\$300 K
	2000	\$500 K
	2001	\$500 K

REHABILITATION OUTCOMES AND
SERVICE DELIVERY R&D

During FY 1997, the Office of Research and Development plans another RFA to initiate a set of research projects focused on the outcomes of rehabilitation services provided by VHA. The scope of this announcement will be broad, encompassing rehabilitation for physical disabilities due to traumatic accidents and injuries as well as stroke, falls, and degenerative musculoskeletal or neurologic diseases. The rehabilitative services to be studied will include those designed to restore or compensate for lost ambulation, speech, vision, and other functions that affect independent living and quality of life. These studies will involve the perspectives and expertise of a wide range of health care providers, including physicians, nurses, physical and occupational therapists, speech therapists, and others. This initiative represents a collaboration between VHA's Rehabilitation Research and Development Service and Health Services Research and Development Service.

Estimated Funds Required through FY01:	1998 - \$330 K
	1999 - \$990 K
	2000 - \$1.1 M
	2001 - \$1.1 M

Rehabilitation Research and Development

REHABILITATION RESEARCH AND DEVELOPMENT CENTERS OF EXCELLENCE

A request for new and renewal applications for Rehabilitation Research & Development Centers of Excellence will be issued in the second quarter of FY 1997. The scope of this announcement will be broad, encompassing rehabilitation for physical disabilities due to traumatic accidents and injuries as well as stroke, falls, and degenerative musculoskeletal or neurologic diseases. The rehabilitative services to be studied will include those designed to restore or compensate for lost ambulation, speech, vision, and other functions that affect independent living and quality of life. These studies will involve the perspectives and expertise of a wide range of health care providers, including physicians, nurses, physical and occupational therapists, speech therapists, and others. New foci will include vision and other sensory impairment; prosthetics and amputation management; spinal cord injury; traumatic and other brain injury; rehabilitative health service delivery; and impact and consequences of aging with a disability. This initiative represents a collaboration between VA's Rehabilitation Research and Development Service and Health Services Research and Development Service.

Currently funded Centers were site visited in the fall of 1996 and will incorporate the review team's recommendations into their research plans for FY 1997. Through more aggressive leveraging of core funds, RR&D expects to be in a position to fund a total of six focused Centers of Excellence.

Estimated Funds Required through FY01:	1998	\$3.75 M
	1999	\$4.5 M
	2000	\$4.5 M
	2001	\$4.5 M

VISN ORIENTED DEMONSTRATION PROJECTS

A unique challenge for Veterans Integrated Service Network's (VISN) is providing comprehensive, quality service to the many special populations of veterans with disabilities. Rehabilitation Research & Development proposes to support rigorous evaluation of demonstration projects designed to pilot ideas for improving team approaches to disability management. For example, management of diabetes often requires preventive interventions coupled with therapeutic and rehabilitative measures best administered by a collaborating team of interdisciplinary professionals. In a demonstration pilot, efficiencies and benefits of team care can be evaluated for cost-effectiveness. So too, with multiple sensory impairments a combined application of therapeutic approaches might be proven effective, or not, when administered by an interdisciplinary team of speech, hearing, and vision therapists.

Estimated Funds Required through FY01:	1997	\$100 K
	1998	\$500 K
	1999	\$500 K
	2000	\$500 K
	2001	\$500 K

Rehabilitation Research and Development

Rehabilitation Research and Development Projects Approved for Funding in 1996

The Rehabilitation Research and Development Service supports and monitors a VA system wide program of peer reviewed research in area of relevance to veterans with disabilities. All of the investigator-initiated research projects (100%) supported by the Rehabilitation Research Service are in Designated Research Areas. In 1996, 41 projects were approved through a national scientific merit review process. The following breakdown is by review panel.

Review Panel	Number of Projects	1st Year Funding	Total Funding
Prosthetics/Amputation/ Orthotics	9	\$ 1,100,000	\$ 3,300,000
Spinal Cord Injury	18	1,700,000	6,600,000
Communication, Cognitive and Sensory Aids	6	800,000	2,000,000
Aging	4	500,000	1,600,000
TOTAL:	37	\$ 4,100,000	\$ 13,500,000

The Research Realignment Advisory Committee (RRAC) strongly recommended the Career Development Program be continued and viewed the recruitment, training and retention of outstanding clinician investigators as central to the VA mission. Furthermore, RRAC recommended that Career Development be integrated within the conceptual framework of designated research areas (DRA) and that emphasis on Career Development be placed in DRAs. In line with the RRAC's recommendations, a telegraphic message was sent on October 29, 1996, announcing that the Career Development program would again be accepting applications for the Associate Investigator and the Research Associate levels. These applications will be reviewed in the Spring round of 1997 for funding in July or August, 1997. Subsequent telegraphic messages were sent to the field on November 4 and December 9, 1996, providing further instructions for submission. The Medical Research Career Development office has received 147 letters of intent, of these 38 are for the Associate Investigator level and 109 at the Research Associate level. The Health Services Research & Development Service received 12 applications and the Rehabilitation Research & Development Service received 22 applications for the Spring round of 1997. The total number of Career Development applications for the Research Office was 181 for the Spring round of 1997. We anticipate that level 3 will also be available in the future.

The policy for a new Career Development is currently being developed that will bring Career Development in line with the recommendations of RRAC.

