

**Report of the
Health Economics Resource Center
to the VA Cooperative Studies Program**

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Cooperative Studies Program Coordinating Center
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Executive Summary

The Health Economics Resource Center (HERC) is a national resource center for VA health economics research, providing support for the Cooperative Studies Programs (CSP) and the Health Services Research and Development Service. HERC is the Economics Coordinating Center for CSP and is involved in planning, implementation, and analysis of clinical trials coordinated by all five CSP coordinating centers. HERC is also making improvements to the VA economics infrastructure needed by CSP and is providing economics consulting services to CSP, the VA research service, VA managers and clinicians, and the scientific community.

Significant economic findings of CSP studies. Results from the economic components of CSP studies the following notable findings.

CSP 006: Geriatric Evaluation and Management (GEM) units were not less expensive than usual care. However, GEM patients had significantly fewer nursing home admissions (manuscript in preparation).

CSP 368: Conservative strategy was significantly more cost-effective than invasive strategy for management of non-Q wave heart attacks. This result was published in Circulation.

CSP 27: Positron emission tomography (PET) with 18-fluorodeoxyglucose (FDG) was found to be a cost-effective in the diagnosis of solitary pulmonary nodules if it is used selectively, when pre-test probability of lung cancer and computed tomography (CT) findings disagree, or in patients with intermediate pre-test probability who are at high risk for surgical complications. This finding was published in the Annals of Internal Medicine. Meta-analyses of PET test characteristics were published in JAMA and the Annals of Internal Medicine. The results of a survey of study sites on the cost of PET was published in the American Journal of Roentgenology.

MR00-019 A survey of chairs and administrators of VA Institutional Review Boards determined that there are large economics of scale in reviewing research for human subjects protection: large review boards handled over 30 times the workload but had only four times the cost of small boards (paper is forthcoming in Medical Care).

Ongoing and planned studies. HERC economists are helping to conduct CSP studies of treatment strategies for HIV (CSP 512), heart disease (CSP 424), evaluation of Geriatric Management Units (CSP 006), analysis of care for Veterans with PTSD (CSP 420), screening for lung cancer (CSP 27), comparing radial artery and saphenous vein grafts in CABG (CSP 474), and the use of home monitoring of INRs (CSP 481). In the past year, patient enrollment has begun for one new study; comparing intensive and conventional renal support for acute renal failure (CSP 530). One study is scheduled for kick off in September 2004 on integrating smoking cessation into mental health care PTSD patients (CSP 519). HERC economists are also working on the planning of three CSP studies (529, 551, and 553).

Coordination of Economic Analysis for CSP. HERC coordinates the review of each CSP planning letter to evaluate the need for an economic analysis. In 2003, HERC conducted a systematic review of economic analyses in all current CSP studies. The results of this review are being used to draft guidelines on when CSP studies should include economic analyses. HERC is also developing guidelines on when a cost-effectiveness analysis is not appropriate and when other economic analyses should be considered for CSP studies.

Development of VA Economics Infrastructure. HERC economists revised and updated the VA guidelines for cost-effectiveness research, improved the methods for determining the cost of VA health care, and served as faculty in the CSP course for clinical investigators. They provided assistance to economists employed by CSP centers, and have created a comprehensive set of estimates of all VA health care encounters that have taken place since October 1, 1997, for use in CSP trials and other studies.

Service Work. HERC economists serve on VA advisory and steering committees and conduct biostatistical reviews of Merit Review proposals. They provide consultative advice to VA managers and conduct research on important managerial questions. They participate in scientific review for a number of journals, the VA Clinical, Laboratory, and Health Services Research Services, the National Institutes of Health, and the Centers for Disease Control.

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SECTION I. – UPDATE OF STUDIES

PROJECTS IN PLANNING STAGE

CSP STUDY 529 - A Randomized Trial Comparing Tumor Necrosis Factor-Inhibitor, Methotrexate, and Placebo for Ankylosing Spondylitis

Study Economist: Todd H. Wagner, Ph.D.
HERC

BACKGROUND / RATIONALE

Ankylosing spondylitis (AS) is a chronic inflammatory disease that typically strikes males during the third or fourth decades of life, potentially causing significant long-term morbidity and mortality. Until recently, medical therapy had been limited to nonsteroidal anti-inflammatory drugs, physical therapy, intra-articular corticosteroids, and antirheumatic drugs such as methotrexate (MTX). The recent introduction of novel biologic agents that inhibit tumors (TNF) is revolutionizing the treatment of this disorder, with very favorable preliminary indications. However, the TNF agents are expensive and remain largely unproven.

OBJECTIVE

The primary endpoint is a validated, widely used composite outcome measure based on the patient's self-report of axial symptoms. A secondary endpoint is health related quality of life. The proposed economic analysis will evaluate the incremental costs per quality adjusted life year.

RESEARCH PLAN

We propose a 6-month, randomized, double-blind, parallel trial comparing TNF-inhibitor, MTX, and placebo in patients with AS who are symptomatic despite conventional therapy, followed by an extension trial of TNF-inhibitor for nonresponders in the placebo group, or the combination of MTX and TNF-inhibitor for nonresponders in the methotrexate- or TNF-inhibitor groups, lasting up to 1.5 years. Six hundred patients at various stages of AS and levels of disease activity will be recruited to better define the subgroups most likely to benefit from this expensive therapy.

The economic analysis will be conducting using the societal perspective. Health care utilization and cost data from both VA and non-VA facilities will be collected. The VA data will be collected from the VA cost database and non-VA data will be collected through trial case report forms. Health care charges from non-VA facilities will be obtained, with permission of the patient. Quality of life will be measured by two instruments: Health Utilities Index Mark # (HUI3) and a Visual Analog Scale (VAS).

IMPACT STATEMENT

This study may impact methods for treating ankylosing spondylitis.

DURATION OF STUDY

In planning

FUNDING

In planning; possibly a binational with VA and Canada.

CSP STUDY 551 - Rheumatoid Arthritis: Comparison of Active Therapies in Patients With Active Disease Despite Methotrexate Therapy

Study Economist: Ciaran S. Phibbs, Ph.D.
HERC

BACKGROUND / RATIONALE

Methotrexate is the standard first-line therapy for rheumatoid arthritis. For patients who do not respond to methotrexate therapy, the standard of care is multiple drug therapy. TNF therapy is a promising, but more expensive, new biological therapy for treatment of rheumatoid arthritis (about \$10,000/year compared to about \$1,000/year for standard care). Both alternative therapies have been shown to be effective for patients who do not respond to methotrexate, but they have not been directly compared with each other. This study will compare the effectiveness and cost-effectiveness of alternative therapies for patients who do not respond to methotrexate therapy.

OBJECTIVES

This study will compare standard therapy (methotrexate plus sulfasalazine plus hydroxychloroquine) with TNF therapy for the treatment of patients with rheumatoid arthritis who have failed to respond the treatment with methotrexate alone. The primary endpoint will be clinical improvement, as measured by the Disease Activity Score (DAS-28), with cost-effectiveness as a secondary endpoint.

RESEARCH PLAN

This study is still in planning. The initial design is a randomized, double blind trial, with a one year follow-up period. The economics evaluation will assess costs and quality of life. Quality of life will be measured using the HUI and a single visual analog scale question. The cost-effectiveness analysis will be based on a model of the patient's lifetime to provide a complete economics evaluation. Data from the study will provide information for the one year study period. Data beyond one year will come from literature reviews. The study will be designed from the societal perspective. Health care utilization and cost data from both VA and non-VA facilities will be collected. The VA data will be collected from the VA cost databases and non-VA data will be collected through a trial report form. To facilitate the adoption of the study results by VA managers, a second economic analysis will be done from the perspective of VA managers. This will be a cost-consequences analysis, not a cost-effectiveness analysis, and the main focus will be a one year time horizon.

IMPACT STATEMENT

Rheumatoid arthritis is a condition that is becoming increasingly important at the VA population ages. There is a large cost difference between the two therapies

DURATION OF STUDY

In planning

FUNDING

In planning

CSP STUDY 553 - Adjuvant Therapy in Patients with Locally Advanced, Node-Negative Prostate Cancer, Treated with Prostatectomy

Study Economist: Wei Yu, Ph.D.
HERC

BACKGROUND / RATIONALE

Prostate cancer is the most common epithelial malignancy among men, affecting approximately 190,000 patients per year. The vast majority of men will be diagnosed with clinically localized disease (cT1-T2) and will be offered observation, androgen deprivation, brachytherapy, external beam radiotherapy or radical prostatectomy. A substantial proportion of patients opt for prostatectomy because of preferences for complete removal of tumor, and the ability to provide detailed pathologic staging. VA data indicate that over half of patients with cT1-T2 prostate cancer are treated with prostatectomy within the VA system. A majority of these patients have a risk of relapse of greater than 50% at 5 years with no adjuvant therapy. Identifying interventions that would decrease this risk is an important area for research. The proposed study will determine whether early chemotherapy will reduce the risk of relapse.

OBJECTIVES

The primary objective of the proposed study is to determine whether adjuvant chemohormonal therapy will improve progression-free survival, metastasis-free survival, and overall survival compared to initial observation in patients with clinically localized prostate cancer treated with prostatectomy with high risk features found at prostatectomy (pathologic stage T3-T4, N0M0, Gleason grade ≥ 7). A standard cost effectiveness analysis is proposed to find the incremental costs per quality adjusted life year.

RESEARCH PLAN

The economic evaluation will assess costs and quality of life in three stages: (1) at the end of the treatment period, (2) at the end of a follow-up period, and (3) during a patient's lifetime. The treatment period is one year starting from the intervention or the start of observation, usually right after the prostatectomy. The proposed follow-up time is 8 years. The rationale for dividing the study into three periods is that quality of life in the two treatment arms may be quite different during the treatment period but may converge one year after treatment. Quality of life may not be different across arms during the follow-up period unless there is relapse. A complete economic evaluation involves modeling the patient's lifetime costs and benefits.

The analytical strategy for the first and the second stages will involve comparing costs and quality of life between the intervention and the control groups. Both bivariate and multivariate methods will be used. The analytical strategy for the third stage will use decision analytic modeling.

The study will be designed from the societal perspective. Thus, costs that are not directly related to medical care will be included. Health care utilization and cost data from both VA and non-VA facilities will be collected. The VA data will be collected from the VA cost database and non-VA data will be collected through trial case report forms. Costs of health care utilization from non-VA facilities will be imputed. Quality of life will be measured by two instruments: QLQ-c30 developed by EORTC's quality of life unit and the utility assessment by the methods of standard gamble and time tradeoff (computer based). The QLQ-c30 (plus QLQ-pr25) is a multi-dimension instrument designed for patients with prostate cancer. Although it cannot generate a single score on quality of life, it is more sensitive to quality of life related to treatments for prostate cancer. The SG and TT are general utility assessments on quality of life that are based on patients' preference.

IMPACT STATEMENT

This study can potentially lead to a reduction in mortality for a cancer that has a high prevalence in VA patients.

DURATION OF STUDY

In planning

FUNDING

In planning

PROJECTS APPROVED – AWAITING START-UP

CSP STUDY 519 - Integrating Clinical Practice Guidelines for Smoking Cessation into Mental Health Care for Veterans with Posttraumatic Stress Disorder

Study Economist: Mark W. Smith, Ph.D.
HERC

BACKGROUND / RATIONALE

Tobacco use is the single most preventable cause of morbidity and death in the United States. Nicotine dependence is a costly and potentially lethal disorder that strikes especially hard at veterans with chronic mental illness, including posttraumatic stress disorder (PTSD). Existing methods for delivering smoking cessation interventions often do not offer adequate access to treatment or address the special needs of a large population of nicotine-dependent veterans with PTSD.

OBJECTIVE

The objective of CSP 519 is to determine the most effective method for delivering evidence-based treatment for nicotine dependence to veterans undergoing care for PTSD in VA Specialized Outpatient PTSD Programs (SOPPs). The study will compare two alternative treatment methods, integrated care (IC) and usual standard of care (USC). IC is a guideline-based treatment for smoking cessation administered by the primary mental health care provider. Usual care consists of referral to a specialized smoking cessation clinic. It is hypothesized that smoking cessation interventions involving integrated care will be more effective than the usual standard of care, as measured by reduction in prevalence of tobacco use and other smoking-related clinical outcomes. The economic analysis will determine the cost-effectiveness of integrated care relative to usual care.

RESEARCH PLAN

CSP 519 will be a multisite, randomized, and controlled clinical trial. The preliminary protocol calls for a total of eight VA SOPPs to enroll 175 patients each over a period of 36 months. Patients will be randomly assigned to the alternate treatments within sites, half into IC and half into USC. Data collection will consist of baseline demographic and clinical data. There will be follow-up data collected every three months through month 18, and every six months beyond that until the study end.

There will be several outcomes of interest. The primary outcome will be effectiveness, measured by prevalence of smoking abstinence in the 7 days prior to the post-randomization follow-ups. Salivary cotinine levels and CO readings will verify smoking status. Secondary outcomes will include rates of continuous abstinence from weeks 26-52 and other measures of smoking status, functional status and health-related quality of life, PTSD symptoms, depression symptoms, and cost-effectiveness.

The economic analysis will consist a cost-effectiveness analysis from the perspective of VA and from the perspective of society. Data will be gathered from VA administrative databases, patient surveys, public mortality databases, and quality-of-life surveys (SF-36 and the Smoking Cessation Quality of Life instrument). The cost-effectiveness analysis will have a lifetime horizon because smoking cessation incurs costs at the outset but yields its full benefits only after many years. We will therefore model lifetime costs and outcomes (mortality, quality of life) using appropriate statistical methods.

IMPACT STATEMENT

Application of IC system-wide has the potential to generate far more non-smokers among PTSD patients than does usual care (USC), if the study hypothesis is confirmed. Nationwide, about 70% of smokers

want to quit, including 60% of mentally ill patients. We may assume conservatively that at least 50% of smokers with PTSD are receptive to treatment. IC treatment of all PTSD patients within VHA who are receptive to smoking cessation intervention would yield 12,000 additional quitters beyond the expected quite rates from USC, assuming successful outcomes of 20% and 10% for the two methods, respectively.

Stopping smoking is known to prevent a range of serious medical illnesses, prolong quality-adjusted life years, and significantly curtail health care costs. Both VA and veterans stand to gain from CSP 519.

DURATION OF STUDY

09/04 – 09/09

FUNDING

\$11,000,000

ONGOING PROJECTS – PATIENT ACCRUAL STAGE

CSP STUDY 424 - Clinical Outcomes, Revascularization and Aggressive Drug Evaluation (COURAGE): VA Economic Study

Study Economist: Paul G. Barnett, PhD
HERC

BACKGROUND / RATIONALE

COURAGE is a randomized clinical trial that is examining the effect of cardiac catheterization on the cost and outcomes in heart disease patients who are receiving optimal medical therapy. The trial is enrolling patients with all but the most severe heart disease at 40 centers in the U.S. and Canada, randomizing half to cardiac catheterization, and following them for three years. A total of 3,120 patients will be randomized and followed for a mean of 4.5 years. A major focus of the trial is to determine the incremental cost-effectiveness of the more invasive strategy in dollars per quality adjusted life year (QALY). Additional detailed information will be obtained on participants' quality of life. The goal of the study is to learn whether cardiac catheterization is a cost-effective health care intervention in this type of heart disease patient when optimal medical management is being employed.

OBJECTIVE

It is not known whether percutaneous coronary intervention (PCI) is a cost-effective therapy for patients with moderate ischemic heart disease who also receive optimal medical therapy. Previous trials have compared balloon angioplasty to medical therapy, but they have been too small, have excluded sicker patients, lacked consistent medical care in follow-up, and did not include an economic comparison. The objective of the economic study is to determine if PCI is cost-effective. The VA Economic Study is determining the cost incurred by patients enrolled at VA sites. This cost data will be combined with cost data from other sites and patient preferences in order to find the incremental cost-effectiveness of angioplasty in dollars per quality-adjusted life year (QALY).

RESEARCH PLAN

The COURAGE VA Economic Study is using a variety of health services methods to determine the costs of health care used by COURAGE participants who enroll at VA Medical Centers. Although VA keeps careful account of the resources used by each of its medical centers, it does not routinely prepare patient bills, and thus lacks the detailed charge data that researchers in the rest of the U.S. health care sector use to estimate costs. We are evaluating whether DSS can be used to determine costs of the initial treatment, or whether we should estimate costs using parameters from a clinical cost function for Medicare charge data in non-VA hospitals. We are micro-costing these items to ensure that our method is sensitive to the variation in the amount of resources used in the different arms of the trial. We will use gross costing to determine the cost of other hospital stays and ambulatory care. We are identifying prescription medication and its cost from the pharmacy benefit management database.

IMPACT STATEMENT

CSP 424 is the largest trial of PCI conducted to date. Coronary heart disease is the single largest cause of morbidity and mortality among patients in the VA system. Many patients must travel great distances to centers that can provide these services. Results from the trial could result in substantial changes in the management of coronary heart disease, both within VA and in the U.S. and Canadian health care systems. Approximately \$6.0 billion is spent each year on the myocardial revascularization in patients with heart disease. ACE inhibitors, beta-blockers, and especially, the advent of more potent lipid lowering agents, have dramatically improved medical therapy. It has not been determined whether the best

coronary interventions, when coupled with the best available medical interventions, are superior to medical interventions alone. This study addresses this important research gap. If patients who do as well with medical therapy alone can be identified, hundreds of millions of dollars in health care costs could be saved.

FINDINGS

Enrollment in this study has now been completed. A draft of the economic methods paper has been completed, revised, and is ready for submission. We extracted information on health care utilization of study participants from VA databases through FY2002, as well as HERC and DSS data on the cost of this care. We are developing methods to identify the cost of cardiac procedures provided to outpatients. We identified the CPT codes used to characterize the procedures provided to study participants on an outpatient basis. We are now in the process of determining the average costs assigned by DSS to visits in which these procedures took place. This information will be useful to finding the cost of non-VA sites. For patients who were hospitalized at the time of randomization, we wished to exclude costs of the stay that were incurred before randomization. Daily costs vary over the course of hospital stays; earlier days in a stay are typically higher cost. We requested from the DSS Technical Support Office in Bedford, MA, a detailed report of the cost of index stays that took place between 2000 and 2003. This report will identify the cost and quantity of intermediate products used in each day of stay. This will allow us to develop a model to exclude costs incurred before randomization, and to validate that DSS cost estimates reflect participants' utilization of diagnostic and revascularization procedures. We obtained clinical data and DSS cost data on VA stays for heart attack, and compared it to Medicare-funded stays of veterans at non-VA hospitals for the same year. This comparison includes our survey data on DSS data quality practices. A manuscript describing this comparison is being prepared. We have obtained data on prescription medications used by participants from the VA Pharmacy Benefits Management System; we have requested an update of this prescription data. Finally, we are working with the statistical and economic coordinating centers to make sure that VA sites are collecting UB-92 hospital bills with the cost of care for stays by VA patients at non-VA hospitals.

DURATION OF STUDY

10/1999 – 10/2005

FUNDING

\$314,586 (budget for economic analysis only)

PUBLICATIONS

Barnett P, Lin P, Wagner T. (2003). Estimating the cost of cardiac care provided by the hospitals of the US Department of Veterans Affairs. Weintraub W (Ed.) Cardiovascular Health Care Economics. Humana Press.

CSP STUDY 474 - Radial Artery vs. Saphenous Vein Grafts in Coronary Artery Bypass Surgery

Study Economist: Todd H. Wagner, Ph.D.
HERC

BACKGROUND / RATIONALE

The saphenous vein graft is a standard conduit for coronary artery bypass grafting to all areas of the heart except the left anterior descending (LAD) artery. Although the radial artery was introduced as a potential conduit for coronary artery bypass grafting in the 1970s, enthusiasm for its use was limited by the technical difficulty of harvesting the vessel and problems with perioperative vascular spasm. In spite of this, some surgeons persisted based on their belief that arterial conduits would be better than vein grafts, in terms of long-term patency. With the development of new harvesting techniques and the introduction of calcium channel blockers to prevent vasospasm, the use of the radial artery graft has increased in recent years. This use of the radial artery as a conduit is not based on any long-term prospective data regarding its patency. However, because the VA has been a leader in defining the long-term efficacy/patency of saphenous vein and internal mammary grafts, it is appropriate for the VA to investigate radial artery grafts. In fact, the VA under its Cooperative Studies Program, is probably the only health care delivery system that has the ability to undertake this study.

OBJECTIVE

Primary Hypothesis: radial artery grafts will have a higher graft patency rate at one year after coronary artery bypass graft surgery (CABG) compared to saphenous vein grafts. Secondary Hypotheses: to determine if there are any differences in clinical outcomes, cost and quality of life in patients receiving radial artery versus saphenous vein grafts.

RESEARCH PLAN

The study is a prospective, randomized, unblinded clinical trial. The population consists of VA patients with coronary artery disease documented by coronary arteriography who have agreed to undergo coronary artery bypass surgery. Medical conditions that could affect blood flow through the patient's arm are the main exclusion criteria. These include Raynaud's symptoms, a positive Allen test, neurologic or musculoskeletal disease affecting the arm, and patients with one arm. Patients who are eligible and agree to participate in the study will be randomly assigned to receive one radial artery graft or one saphenous vein graft to the following vessels: left anterior descending if internal mammary not used, circumflex, diagonal, and right coronary artery. The surgeon will determine the subject vessel preoperatively by selecting the vessel that is suitable for grafting. The stratification factors will be the participating hospital and the vessel to be bypassed, left anterior descending versus all other vessels. History, physical examination, laboratory tests, and cardiac catheterization will be performed at baseline and at one year. Follow-up clinic visits will be at two weeks, three, six, and nine months post CABG. Coronary angiography will be performed one week and one year post surgery. Quality of life and hand/leg functional status will be assessed at baseline, three months, and one year.

The economic analysis will be conducting using the societal perspective. Health care utilization and cost data from both VA and non-VA facilities will be collected. The VA data will be collected from the VA cost database and non-VA data will be collected through trial case report forms. The cost of the index admission will be calculated using data from the case report forms. Health care charges from non-VA facilities will be obtained from the hospital, with permission of the patient. Quality of life will be measured

by the Health Utilities Index (HUI-3). The cost-effectiveness analysis will be based on the incremental cost per quality adjusted life year at one year post surgery.

For this trial, a sample size of 874 randomized patients will be required. This will provide 90% power to detect a difference in one year patency rates of 92% for the radial artery versus 83% for the saphenous vein and an expected one year catheter completion rate of 65%. This is a five-year study. There will be four years of patient accrual and one year of follow-up. Nine participating VA medical centers will be expected to randomize two patients per month.

IMPACT STATEMENT

This study may impact methods for conducting coronary artery bypass surgery.

DURATION OF STUDY

1/02-11/06

FUNDING

\$6,000,000

CSP STUDY 481 - The Home International Normalized Ratio (INR) Monitor Study (THINRS)

Study Economist: Ciaran S. Phibbs, PhD
HERC

BACKGROUND / RATIONALE

Patients on anticoagulation therapy need to be carefully monitored because the effectiveness of the medication is quite sensitive to dietary intake and the consequences of both under and over medication can be quite severe. Current standard practice is to have patients come into an anticoagulation clinic once a month for monitoring and medication adjustment, if necessary. New devices allow for the possibility of patient self-testing (PST) at home, which is more convenient for patients and also makes more frequent testing possible. This study will assess if the more frequent testing allowed by PST reduces the number of adverse clinical events.

OBJECTIVE

The purpose of this study is to compare patient self-testing (PST) of anticoagulation intensity to conventional monitoring in the clinic in terms of the number of events (strokes, bleeding or death). Secondary analysis will examine the effects of PST on quality of anticoagulation, health care utilization and cost, quality of life, and cost-effectiveness.

RESEARCH PLAN

This study will use 32 sites to enroll a sample size of 3,200 patients (1,600 per group) over three years (one for recruitment and two years of follow-up). The primary outcome is combined events (serious complications of anticoagulation and death). Cost-effectiveness is a secondary outcome for this study. VA costs will be determined from VA secondary data, with the HERC average costs data sets being the principal data source. Non-VA costs will be tracked using patient self-reports. The Health Utilities Index (HUI) will be used to measure quality of life for the incremental cost-effectiveness analysis. The time horizon for the study will be both the duration of the study and the patient's lifetime.

IMPACT STATEMENT

Prior studies indicate that home Prothrombin Time/International Normalized Ratio (PT-INR) monitors have the potential to improve the safety, quality, and convenience of chronic anticoagulation management. However, these trials were not conducted on veterans, so their results may not generalize to the VA population. Since home monitoring allows more frequent monitoring (as well as increased patient participation in his/her care), we hypothesize that this will lead to more precise anticoagulation control and thus, fewer clinical events.

Given the high costs associated with some of the adverse events, especially strokes, it is hypothesized that home PT-INR monitoring will be more cost-effective than current standards of care. If the intervention works as well as indicated in the small studies reported to date, it may even improve outcomes and reduce costs.

DURATION OF STUDY

8/03 – 8/06

FUNDING

\$11,787,448.

CSP STUDY 512 - OPTIMA – A Tri-National Randomized Controlled Trial to Determine the Optimal Management of Patients with HIV Infection For Whom First and Second-Line Active Anti-Retroviral Therapy has Failed

Study Economist: Wei Yu, PhD
HERC

BACKGROUND / RATIONALE

OPTIMA is a tri-national (Canada, UK, USA) randomized controlled trial to determine the optimal management of patients with HIV infection for whom first and second-line highly active anti-retroviral therapy has failed. The trial is using a 2X2 factorial design to evaluate the hypotheses that mega-anti-retroviral therapy (HAART) (compared to standard-ART) and an anti-retroviral drug-free period (compared to no anti-retroviral drug-free period) will delay the occurrence of new or recurrent AIDS events or death and will be more cost-effective in treating HIV-infected individuals previously exposed to HAART drugs from the current three main classes. This is the first large-scale, multi-center, randomized controlled trial to compare the relative efficacy of these different therapeutic strategies.

OBJECTIVE

The health economics analysis will evaluate the cost-effectiveness and short-term resource consumption of each alternative treatment strategy for treating HIV patients who have failed standard anti-retroviral therapy.

RESEARCH PLAN

The cost-effectiveness of the interventions will be estimated using the patients' life span as the time horizon for the analysis. Standard methods will be used. Sites in all three countries will gather a common set of utilization and outcomes data. To capture differences in patients' preferences to medical treatments across the three countries, three instruments are used to measure quality of life: EQ5D, Health Utility Index (HUI), and computer-based assessment. EQ5D is a commonly used instrument in European countries, HUI has been widely used in Canada, and the computer-based assessment has been used in studies in the United States. A Markov or statistical model will be developed to project trial participants' lifetime cost and outcomes for a cost-effectiveness analysis. These data will be used to create a separate economic analysis for each country. Each analysis will reflect the country's guidelines for accepted practices for performing for cost-effectiveness studies, sources of costs for pharmaceuticals and health services, factors affecting lifetime survival, and discount rate. In addition to country specific analysis, we will employ statistical methods to investigate the extent to which cost-effectiveness differs between countries.

IMPACT STATEMENT

The VA System cares for approximately 19,000 HIV patients who have access to HIV-knowledgeable health care providers, to the full spectrum of approved antiretroviral medications, and to laboratories that perform virologic and immunologic testing. It is estimated that 30-40% of HIV patients treated at VA facilities have detectable viral loads.

HAART therapy has been extremely beneficial but increasing numbers of patients are being failed by these therapies due to resistance and long-term toxicity. These patients are posing an increasing therapeutic dilemma. Clinicians currently utilize the different therapeutic approaches to be studied in this trial without any clinical trials-based evidence. This study has the potential provide information on

benefits and risks of the different therapeutic strategies.

DURATION OF STUDY

06/2001 -05/2006

FUNDING

\$1,038,312 (budget for economic analysis only)

PUBLICATIONS

Munakata J, Woolcott J, Anis A, Schulpher M, **Yu W**, **Sanders GD**, Bayoumi A, **Gulbinas V**, Philips Z, **Owens DK**. Design of a Prospective Economic Evaluation for a Tri-National Clinical Trial in HIV Patients (OPTIMA), Abstract, Controlled Clinical Trials, 2003

CSP STUDY 530 - Intensive vs. Conventional Renal Support in Acute Renal Failure

Study Economist: Mark W. Smith, Ph.D.
HERC

BACKGROUND / RATIONALE

Acute renal failure (ARF) is defined by the abrupt loss of renal function resulting in the failure of the kidney to excrete urea and other nitrogenous waste products. Despite more than a half-century of experience in the use of hemodialysis and other renal replacement therapies in the management of ARF, mortality remains high and many fundamental issues remain to be resolved. These include the indications for and timing of initiation of therapy, the optimal dose and modality of therapy, the selection of dialysis membranes, the composition of dialysate and replacement fluids, and indications for the discontinuation of therapy.

Intermittent hemodialysis is the most commonly prescribed form of renal support, usually provided on a 3-4 times per week schedule. Several recent clinical studies have suggested that more intensive renal support may result in improved survival. These studies have had significant limitations and have not been widely accepted in clinical practice.

OBJECTIVE

CSP 530 will compare a strategy of intensive renal support to conventional management of renal replacement therapy in critically ill patients with acute renal failure. The primary clinical outcome will be 60-day mortality from all causes. Secondary outcomes include all-cause in-hospital mortality, 12-month all-cause mortality, recovery of renal function, total costs after 60 days and after 12 months, and lifetime cost-effectiveness. The economic analysis will test whether intensive therapy is cost-effective relative to the control therapy. Two analyses will be performed, one from a societal perspective and one from the perspective of VA.

RESEARCH PLAN

CSP 530 will be a multi-site, randomized, and controlled clinical trial. The sites will include 20 VA medical centers and 12 non-VA facilities whose participation will be funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The study expects to enroll 1,400 patients over a 36-month period from intensive care units. Patients will be randomized to conventional therapy (three times per week) or intensive therapy (six times per week). Patients will remain on the assigned regimen for up to 30 days. Clinical data will be collected during the inpatient stay. Follow-up data will be collected at 60 days and at 12 months.

The economic analysis will consist of cost-effectiveness analyses from two perspectives, society and VA. Data will be gathered from the administrative data systems of the site facilities, from patient/proxy surveys, and from public mortality databases. The Health Utilities Index (HUI) will be used to evaluate quality of life. We will also analyze whether the VA Decision Support System (DSS) may be used to assign a cost to VA dialysis therapy.

Progress to Date

The study kicked off in September, 2003, and patient enrollment began two months later. As of June, 2004, over 100 patients have been enrolled. The first DSMB meeting has been held. Discharge summaries from non-VA inpatient providers have been received for two patients.

IMPACT STATEMENT

CSP 530 holds great promise to significantly benefit veterans with acute renal failure. Pilot studies indicate that intensive dialysis treatment for acute renal failure is likely to significantly improve 60-day mortality. Mortality rates under conventional therapy are typically 45-50% over 60 days, whereas preliminary studies have shown intensive therapy to reduce mortality to 30-40%. The intervention is likely to be cost-effective as well. The extra cost of intensive therapy should be approximately \$2000-3000 over a 30-day period. If the intensive therapy reduces hospital length of stay, something supported by preliminary studies, then the cost for additional dialysis treatment will be partly or even fully offset by the reduction in hospital days. Even if the intervention does not save costs, it may still be cost-effective by conventional standards.

DURATION OF STUDY

09/03 – 03/09

FUNDING

\$16,900,000

CSP STUDY 146 - Preference Measurement for Trial-Based Economic Evaluations

Study Economist: Paul G. Barnett, PhD
HERC

BACKGROUND / RATIONALE

Preferences, also known as patient utilities, are a measure of the effect of health status on quality of life that are used to value the effect of health interventions in cost-effectiveness analysis. There are no standards for how patient utilities should be measured in VA Cooperative Trials; several different methods have been used. The choice of methods to measure patient utilities can potentially affect the results of cost-effectiveness analysis. This study is part of HERC's effort to coordinate a more systematic application of economic analyses to VA Cooperative Trials.

OBJECTIVES AND METHODS

The project will (1) conduct a literature review on preference measures and the alternatives, (2) survey CSP operational experience in preference measurement, (3) combine literature review and CSP experience into the development of practical guidelines for measuring quality of life outcomes, (4) develop a condensed review for non-economists, and (5) disseminate results via training provided to staff at CSP coordinating centers and students at the CSP investigators course.

STATUS

Research psychologist Forest J. Baker was hired to be the principal analyst on this project. We have obtained more than 500 journal articles on assessment of health related quality of life and patient utilities. We developed a template to review this literature; the research assistant characterized literature using this template, identifying high priority articles for further review. We developed criteria for determining which methods are the best. We identified six methods of assessing utilities, and have focused our efforts on these. We completed a review of the literature on quality of life assessments in HIV/AIDS. We identified 36 relevant papers. We evaluated instrument responsiveness to symptoms and disease status. We assessed instrument validity by assessing the correlations among the different instruments and their correlation to the different subscales of the SF-36 and the HIV-MOS. Two seminars were presented to obtain feedback on these preliminary findings. A manuscript with our findings is now being prepared. Dr. Baker participated in planning of CSP 551, a trial on arthritis treatments, and made recommendations about the most appropriate way to measure HRQL utilities for this trial. A survey to assess sites' experience with HRQL measures has been drafted.

IMPACT STATEMENT

This special project will improve methods used by the Cooperative Studies Program to assess economic outcomes

DURATION OF STUDY

7/03-6/05

FUNDING

\$112,288

PRIMARY ANALYSIS AND MANUSCRIPT WRITING

CSP STUDY 027 - Economic Study of 18-F Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) Imaging in Patients with Solitary Pulmonary Nodules

Study Co-Principal Proponents: Paul G. Barnett, PhD
HERC

Michael K. Gould, MD, MSc
Douglas K. Owens, MD, MSc
Gillian Sanders, PhD

BACKGROUND / RATIONALE

When chest x-rays reveal a solitary pulmonary nodule (SPN), malignancy must be excluded or promptly identified if surgical treatment is to be timely. Computed tomography (CT) is insufficiently specific to avoid biopsy of patients with negative results. Positron Emission Tomography (PET) using 18-F-Fluorodeoxyglucose (FDG) may be sufficiently specific to avoid invasive biopsy in when results are negative. The cost-effectiveness of FDG-PET diagnostic strategies has not been fully evaluated.

OBJECTIVE

This study is evaluating the cost-effectiveness of alternate management strategies, including the use of FDG-PET scans, for patients with solitary pulmonary nodules. It will identify patient populations and clinical circumstances in which FDG-PET is most cost-effective. The study is also addressing the cost-effectiveness of FDG-PET for staging the mediastinum of patients with non-small cell lung cancer (NSCLC).

RESEARCH PLAN

We are constructing decision models to find the impact of all reasonable sequences of diagnostic strategies with and without PET. One decision model evaluates strategies for diagnosis of SPN, the other evaluates mediastinal staging in patients with NSCLC. The SPN model includes 40 possible sequences of five diagnostic interventions: CT, PET, transthoracic needle biopsy (TTNB), surgery, and observation with serial chest radiographs. We are surveying VA clinical centers to determine the cost of PET scans. The models are being constructed with data from meta-analysis, literature review, and data on the natural history of untreated lung cancer. We are analyzing Medicare claims data merged with clinical information from the National Cancer Institute's Surveillance, Epidemiology and End-Results (SEER) registry to estimate life expectancy and health care costs associated with different stages of lung cancer.

IMPACT STATEMENT

It is difficult to diagnose a solitary pulmonary nodule found in a chest x-ray. Between 15% and 75% of nodules prove to be malignant. Surgery is diagnostic and the definitive treatment of resectable nodules, but is unnecessary when the lesion is benign. Needle biopsy is invasive, potentially risky, and frequently non-diagnostic. Watchful waiting avoids unnecessary surgery, but may cause delay when speedy treatment is essential. Positron emission tomography (PET) with 18-fluorodeoxyglucose (FDG) is a potentially useful but expensive test. This economic model will determine if the high cost of PET is justified. Improved diagnosis will save costs by avoiding unnecessary resection of benign nodules; it could also speed diagnosis, prolonging the lives of patients with malignancy. The project will also determine if PET is worth using in the management of patients with non-small cell lung cancer.

FINDINGS

We published papers on the cost of PET scans and a decision model that compared 40 clinically plausible management strategies for patients with solitary pulmonary nodules. We also published a meta-analysis of 39 studies that examined the accuracy of FDG-PET for identifying mediastinal lymph node metastasis in patients with non-small cell lung cancer.

We updated the model of PET for pulmonary nodule diagnosis by using preliminary estimates of conditional test performance for PET and computed tomography (CT). Completion of this work awaits release of final results of PET test performance from CSP 27. We developed a model to identify the most cost-effective practices for mediastinal staging in two commonly encountered clinical scenarios: patients without lymph node enlargement on CT and patients with enlarged nodes in mediastinal stations accessible to bronchoscopy. Meta-analyses of bronchoscopy and mediastinoscopy are being finished to provide accurate parameters needed to complete this model.

DURATION OF STUDY

6/1998 – 12/2004

FUNDING

\$377,500 (budget for economic analysis only)

PUBLICATIONS

Berger M, Gould MK, Barnett PG. (2003). The cost of positron emission tomography in six United States Veterans Affairs hospitals and two academic medical centers. American Journal of Roentgenology: 181(2):359-65.

Gould MK, Kushner WG, Rydzak CE, et al. (2003). Test performance of positron emission tomography and computed tomography for mediastinal staging in patients with non-small-cell lung cancer: a meta-analysis. Annals of Internal Medicine: 139(11), 879-892.

Gould MK, MacLean C, Kushner W, Rydzak C, **Owens D.** (2002). Accuracy of positron emission tomography for diagnosis of pulmonary nodules and mass lesions: A meta-analysis. Journal of the American Medical Association: 7, 914-924.

Gould MK, Sanders GD, Barnett P, Rydzak CE, Maclean CC, McClellan MB, **Owens DK.** (2003). Cost-effectiveness of alternative management strategies for patients with solitary pulmonary nodules. Annals of Internal Medicine: 138(9), 724-735.

CONTINUING ACTIVITY

CSP STUDY 006 - Effectiveness of Geriatric Evaluation and Management Units (GEMU) and Geriatric Evaluation and Management Clinic (GEMC)

Study Economists: Ciaran S. Phibbs, PhD
HERC

BACKGROUND / RATIONALE

Geriatric Evaluation and Management Units (GEMU) are dedicated hospital units where a multidisciplinary team provides comprehensive geriatric assessment, detailed treatment plans, and attention to the rehabilitative needs of older patients. Geriatric Evaluation and Management Clinics (GEMC) provide similar services on an outpatient basis. Early, single site, clinical trials reported that GEMUs dramatically reduced mortality. More recent studies have reported mixed results.

OBJECTIVE

This large, multi-site, clinical trial was designed to definitively determine the effect of GEM care on mortality. The study evaluated both inpatient and outpatient GEMs using a 2x2 randomized design. Secondary objectives included cost-effectiveness analysis and a description of health care utilization and the costs of these services.

RESEARCH PLAN

Patients were recruited from inpatient units when they were medically stable. They were randomized to receive GEMU or usual inpatient care (UCIP). At discharge to home, a second randomization assigned patients to usual outpatient care (UCOP) or the GEMC. Patients were assessed at 3 month intervals for one year. Follow-up data included SF-36 scores, activities of daily living (ADLs), and use of non-VA nursing home care. Utilization of VA care was tracked using VA databases.

HERC Clinical Panel members Drs. Mary Goldstein and Alan Garber directed an approved sub-study of the GEM trial that obtained direct utility measures for the possible health states of the GEM trial from a sample of Kaiser patients. This project used the sub-study results to obtain utilities for each patient in the GEM study. These were linked with the cost and utilization data from the GEM study to conduct an incremental cost-effectiveness analysis.

For the utility measures sub-study, ADLs were administered to subjects, in addition to direct utility measurement. Various combinations of ADLs from the GEM study were used to determine the health states for which utilities were measured. Since it was not possible to directly measure the utility for all possible combinations of ADLs, a model was developed to map various combinations of ADLs to utilities. This model was applied to the data from the GEM study to obtain a utility measure for each patient.

IMPACT STATEMENT

With a large and growing elderly population, the provision of geriatric care is a major concern to the VA. The VA aggressively adopted the GEM model of care based on the results of the early clinical trials. This large clinical trial found neutral results, no added benefit or costs. Since GEM care does seem to improve patient satisfaction, continuation of GEM care is warranted. Information on how the costs were distributed across study subjects and between types of health care may be useful to VA managers.

FINDINGS

The study enrolled 1388 patients out of a target enrollment of 1400 patients at 11 sites. The main paper of the GEM study was published in the New England Journal of Medicine (Cohen, et al., 2002) and reported a small, but statistically insignificant reduction in the costs of care for patients treated in GEM units. There was no difference in mortality by arm of the study and the point estimates were virtually identical. Most of the differences in outcomes, as measured by the SF-36, Activities of Daily Living Scale (ADLs), or Instrumental Activities of Daily Living Scale (IALDs), were not statistically significant, but GEM patients did do better on two of the components of the SF-36.

As might be expected, given the limited differences in other outcomes measures, there was no significant difference in utilities. Nursing home placement was not incorporated into the utility assessment, which may have influenced this result. A complete cost-effectiveness analysis, including bootstrap estimates of the confidence area, also showed no effect. An examination of the details of resource utilization, found that GEMU care was associated with a reduction in the use of nursing home care (odds ratio 0.65, $p=0.001$). If reduced use of nursing home care is considered a benefit, the GEMU care can be considered cost-effective; it improved outcomes with no increase in costs. A manuscript that emphasizes this nursing home result is under review.

DURATION OF STUDY

01/1995 - 01/2002

FUNDING

\$4,118,901 (Total trial budget)

PUBLICATIONS

Cohen H, Feussner J, Weinberger M, Carnes M, Hamdy R, Hsieh F, **Phibbs C**, Lavori P. (2002). A controlled trial of inpatient and outpatient geriatric evaluation and management. New England Journal of Medicine: 346, 905-912.

CSP STUDY 420 - Analysis of Health Care and Work among Veterans with PTSD

Study Economist: Mark W. Smith, PhD
HERC

BACKGROUND / RATIONALE

This project will study the impact of posttraumatic stress disorder (PTSD) symptoms and their severity on use of health services and on economic outcomes. It relates employment outcomes to health care use within VA and from other providers. Although many studies have linked economic outcomes to mental health, here we have the unusual ability to link economic outcomes to several specific clinical measures. It will also shed new light on the extent to which veterans with PTSD receive services from both VA and non-VA providers, and how the mix of VA and non-VA services relates to the type and severity of PTSD symptoms.

OBJECTIVE

The purpose of CSP 420 was to test a novel approach to group therapy for veterans with posttraumatic stress disorder (PTSD). In the CSP 420 protocol, data were collected on subjects' employment history and on their use of health care services from the VA and from other providers.

The first part of this study consisted of an investigation of employment outcomes, focusing on how variation in PTSD symptoms correlated with variations in employment status and earnings. The next step will be to extract VA health care utilization data for study participants. These data will include all inpatient and outpatient encounter records for the 24 months prior to and 24 months following the date of randomization into CSP420. We will then merge VA pharmacy data onto the analytic file. We will ask the Pharmacy Benefits Management Strategic Healthcare Group (PBM/SHG) to create an extract of outpatient pharmacy data from its PBM V3.0 database. The final source of VA administrative data will be the Fee Basis Files, which records care provided by non-VA providers but paid by VA.

RESEARCH PLAN

Costs must be attributed to VA and non-VA health care events. We will assign national-average costs derived by the VA Health Economics Resource Center.

Four analyses are planned: (1) the relative importance of PTSD symptoms scores and patient functional scores in predicting health care use and expenditures; (2) what factors predict non-VA health care use and expenditures; (3) the relation of economic outcomes (employment status and income) to PTSD symptom scores and treatment modality, and (4) two issues about facility-level variation: how much variation in patient outcomes is explained by the variation in treatment site, and whether treatment in one site versus another explains more variation in patient outcomes than the patients' own characteristics.

Standard regression models will be employed for the utilization models, including probit or logit for binary outcomes (e.g., presence of an inpatient stay) and negative binomial models for integer-valued outcomes (e.g., number of outpatient visits). Depending on preliminary analyses, the expenditure models will be estimated with one of several linear and nonlinear regression models.

IMPACT STATEMENT

Of the total veteran population, 1.2-2.4 million males and 140,000-250,000 females can conservatively be estimated to have had PTSD during their lifetimes. The VHA systems of specialized outpatient care for

PTSD report an annual workload of approximately 200,000 veterans. By obtaining a better understanding of the link between PTSD symptoms and the use of VA and non-VA health care use, we may improve the ability of VHA managers to forecast facility needs and expenses due to changes over time in the population of persons with PTSD. An investigation of the link between PTSD symptoms and economic outcomes may lead to improvements in services for persons with PTSD, whether within VA or from other sources.

FINDINGS

In the employment study we found that veterans with more severe symptoms were more likely to work part-time or not at all. Among workers, more severe PTSD symptoms were weakly associated with having a sales or clerical position. Conditional on employment and occupation category, there was no significant relation between PTSD symptom level and earnings. Alternative PTSD symptom measures produced similar results. Our findings suggest that even modest reductions in PTSD symptoms may lead to employment gains, even if the overall symptom level remains severe.

DURATION OF STUDY

01/2002 - 06/2005

FUNDING

No additional funding for economic analysis.

PUBLICATIONS

Smith M, Schnurr P, Rosenheck R. (In Press). Employment outcomes and PTSD symptom severity. Mental Health Services Research.

COMPLETED PROJECTS

CSP STUDY 020 - Cost and Outcome of Telephone Care - Pilot

Study Economist: Ciaran S. Phibbs, PhD
HERC

BACKGROUND / RATIONALE

Enhanced clinician-patient communication can help improve health outcomes and lower health care costs. Traditionally such communication has taken place during a face-to-face visit. A single site VA study that randomized half of the patients to receive more frequent, physician-initiated "telephone appointments" in place of some clinic visits reported lower utilization and costs with no effect on patient health. The two site pilot study for CSP 020 was to test the feasibility of a multi-site VA trial of this mode of treatment.

OBJECTIVE

The objective of the pilot study was to test the feasibility of conducting this study and to obtain preliminary results to guide the sample size determinations for the main study.

RESEARCH PLAN

Patients were randomized to receive usual primary care or telephone care. Patients in the telephone care arm were to have the time between face-to-face visits double, with three scheduled, physician-initiated, telephone contacts in between visits. Data were collected on patient's satisfaction and health status and on their utilization of VA and non-VA health care services.

IMPACT STATEMENT

If the main study had confirmed the findings of the earlier studies, this would represent an opportunity for VA to both improve outcomes and decrease costs. Given the resource constraints in VA, this would allow VA to provide additional services to veterans. The results of this study would also be applicable to health care outside of the VA.

FINDINGS

Although the interval to the next face-to-face visit was doubled for the telephone care patients after the initial clinic visit, the interval between visits was the same for both telephone care and usual care patients for all subsequent visits. Thus, telephone care became an additional service, instead of substituting for face-to-face visits. There was no difference between groups in self-reported health status, hospital admission, mortality, total number of clinic visits, number of outpatient laboratory tests, or number of outpatient radiologic tests. Telephone care patients did have fewer unscheduled visits than usual care patients. While the study didn't find any differences, the intervention was not implemented as designed. Because the effect on utilization and costs was thought to have come from reduced face-to-face contact, these results were not a valid test of the hypothesis.

DURATION OF STUDY

9/1995 – 2/1999

FUNDING

\$724,343

PUBLICATIONS

Welch HG, Johnson DJ, Edson R Writing for the Telephone Care Study Group. (2000). Telephone care as an adjunct to routine medical follow-up, a negative randomized trial. Effective Clinical Practice: 3:123-130.

CSP STUDY 368A - VA Non Q-Wave Infarction in Hospital (VANQWISH): Economic Study

Study Economist: Paul G. Barnett, PhD
HERC

BACKGROUND / RATIONALE

The VA Non-Q-wave Infarction Strategies in Hospital (VANQWISH) trial demonstrated that a conservative, ischemia-guided strategy was safe and effective for management of non-Q-wave myocardial infarction. It was not known whether this strategy was cost-effective.

OBJECTIVE

This project applied health services methods to find total cost incurred by study subjects and to analyze trial data from an economic perspective.

RESEARCH PLAN

We studied 876 of the 920 VANQWISH participants who enrolled at VA sites and tracked their use of VA hospitals and outpatient clinics in utilization databases. We estimated cost of initial VA hospital stays with a function estimated with data from the Myocardial Infarction Triage and Intervention (MITI) registry. We used average cost methods to estimate the cost of subsequent care, using a Medicare based rate for acute hospital stays and VA derived estimates for outpatient care and non-acute inpatient stays. Data also included cost-adjusted charges of non-VA hospital stays. We employed a bootstrap method to estimate the variance of the cost-effectiveness result.

IMPACT STATEMENT

Non-Q wave infarcts account for approximately 40% of new heart attacks. We found conservative strategy saved \$2,186 per heart attack treated. This cost difference applied to 40% of 10 thousand VA stays for myocardial infarction represents \$9 million in annual health care cost. If results can be generalized throughout the U.S. health care system, where 750 thousand new heart attacks are treated annually, the difference represents an annual savings of \$650 million.

FINDINGS

Subjects randomized to the invasive strategy incurred an average of \$41,893 in cost, significantly more than the \$39,707 cost incurred by the conservative strategy group ($p=.037$). The initial hospital stay cost an average of \$19,256 for the invasive group, significantly more than the \$14,733 mean cost of the initial stay for the conservative group ($p=.0001$). The mean cost of follow-up care was not significantly different (\$22,626 for invasive group vs. \$24,974 for conservative strategy). Conservative strategy had lower all-cause mortality (relative risk ratio of .72) but this difference was not significant ($p=.058$). The conservative strategy was significantly more cost-effective than the invasive one ($p=.044$). This result held over a wide range of critical cost-effectiveness threshold values, for a different discount rate, and for the alternate cost method. We found a conservative, ischemia-guided strategy more cost-effective than the routine use of invasive procedures in the management of non-Q wave infarcts.

DURATION OF STUDY

7/1998 - 2/2002

FUNDING

\$78,000 (Economic study only)

PUBLICATIONS

Barnett P, Chen S, Boden W, Chow B, Every N, Lavori P, Hlatky M. (2002). Cost-effectiveness of conservative management of non Q-wave myocardial infarction. Circulation: 105, 680-684.

we found that substance abuse treatment may be regarded as a highly cost-effective means of preventing death. This work was published in the American Journal of Public Health; a more technical paper was published by Management Science. This paper set the groundwork for the pharmacoeconomic evaluation of buprenorphine.

Original data from five clinical trials comparing buprenorphine to methadone were analyzed and combined in a meta-analysis that was published in Addiction. We incorporated this information in the epidemic model to find the cost and effectiveness of maintenance therapy of buprenorphine. It was determined that if buprenorphine is sold for less than \$15 per dose, it will be regarded as cost-effective if medium to high values are set on the quality of life of injection drug users and those in buprenorphine maintenance. At price of less than \$5 a dose, it will be considered cost-effective regardless of the quality of life values employed. This paper was also published by Addiction. Other research on this project include a literature review of methadone cost-effectiveness published in Mt. Sinai J Med.

DURATION OF STUDY

12/1995-4/2001

FUNDING

\$272,975 (Economic analysis only)

PUBLICATIONS

Barnett, P. (1999). The cost-effectiveness of substance abuse treatment. Current Psychiatry Reports: 1(2), 166-171.

Barnett, P. (1999). The cost-effectiveness of methadone maintenance as a health care intervention. Addiction: 94(4), 479-488.

Barnett P, Hui S. (2000). The cost-effectiveness of methadone maintenance. Mount Sinai Journal of Medicine: 67(5-6), 365-374.

Barnett P, Rodgers J, Bloch D. (2001). A meta-analysis comparing buprenorphine to methadone for treatment of opiate dependence. Addiction: 96, 683-690.

Barnett P, Zaric G, Brandeau M. (2001). The cost-effectiveness of buprenorphine maintenance for opiate addiction in the U.S. Addiction: 96, 1267-1278.

Zaric G, **Barnett P, Brandeau M.** (2000). HIV transmission and the cost effectiveness of methadone maintenance. American Journal of Public Health: 90(7), 1100-1111.

Zaric G, Brandeau M, **Barnett P.** (2000). Methadone maintenance and HIV prevention: A cost-effectiveness analysis. Management Science: 46(8), 1013-1031.

CSP Studies Planned By HERC in Previous Years, But Not Funded

Study	Year	Status
CSP #020 Cost and Outcome of Telephone Care, Main Study	1997-1998	Not submitted to CSEC, PI left VA
CSP #445 Effect of Treatment of Sleep Apnea with Oxygen on Hospitalization and Survival of Patients with Stable Heart Failure	1999	Approved, not funded
CSP #455 A Double-Blind, Randomized, Placebo-Controlled Trial to Evaluate the Cost-Effectiveness of Alternative Management Strategies in Patients with Dyspepsia	1999	Approved, not funded
CSP #473 Cost and Outcome of Varying Primary Care Revisit Intervals	1999	Not approved
CSP #490 Efficacy and Safety of Testosterone in Elderly Men (ESTEEM)	1999-2001	Approved, not funded
CSP #503 Improving Outcomes Among Patients with Co-Occurring Depression and Diabetes	2003	Stopped in planning
CSP #509 Clopidogrel and Aspirin Versus Aspirin Stroke Study: A Tri-National Collaboration	2001	Stopped in planning

Section II. – Status of HERC

The Health Economics Resource Center (HERC) is the economic coordinating center for the Cooperative Studies Program (CSP). HERC conducts economic analyses of clinical trials. It coordinates the economic analyses for CSP studies, advises other CSP economists in their work, and improves the infrastructure of VA health economics research. HERC receives additional core funding from and the Health Services Research & Development (HSR&D) Service and project-specific funding from VA and NIH.

HERC was founded by CSP economists in response to a 1998 HSR&D Service request for a health economics center. HSR&D funding of HERC began in September 1999. Because HERC staff members also worked on Cooperative Studies trials, HERC receives additional financial support from CSP. In 2002, HSR&D renewed its funding of HERC for five years. HERC also became an independent Cooperative Studies economic coordinating center that year.

This section of the report summarizes all recent HERC activities, with an emphasis on those important to the Cooperative Studies Program.

A. Activities of the CSP Economics Coordinating Center

1. Coordination of Economic Analyses for CSP studies

Resource limitations make it impossible to include an economic analysis in all CSP studies. HERC coordinates the decision about which studies should include an economic analysis. The goal is to systematically allocate CSP economics resources to those studies for which economic analysis is most important. Historically, CSP did not have standard procedures or criteria for determining which new studies should include a cost-effectiveness analysis. The process differed across coordinating centers, and economist input was not always included in determining which studies should include economic analysis. Since it became the Economics Coordinating Center for CSP, HERC now receives a copy of all planning letters submitted to CSP. HERC has two economists independently review each planning letter to evaluate the need for an economic analysis. Based on these reviews, a recommendation is made to the Director of the CSPCC planning the study on whether an economic analysis should be considered. In the last year five planning letters have been reviewed, three were recommended for full economic analysis, a modified economic analysis was recommended for one study, and economic analysis was not recommended for the other study.

Results of HERC Reviews of CSP Planning Letters

CSP Planning Letter	Recommendation of Economic Review
CSP 529: A randomized trial of Adalimumab and/or Methotrexate for seronegative spondyloarthritis	Include economic analysis
CSP 551: Outcomes and an economic analysis of store and forward tele dermatology	Modified economic analysis
CSP 551: Rheumatoid arthritis: comparison of active therapies in patients with active disease despite methotrexate therapy	Include economic analysis
CSP 552: A Phase 3 Randomized, Double-Blind, Multicenter, Non-Inferiority Study in Vaccinia-Experienced Volunteers of Take Rate, Safety, Tolerability, and Immunogenicity Comparing Cell-Cultured Smallpox Vaccine at 3 Concentrations	No economic analysis
CSP 553: Adjuvant Therapy in Patients with Locally Advanced, Node-negative Prostate Cancer, Treated with Prostatectomy	Include economic analysis

HERC has developed standard criteria for determining when economic analysis should be included in VA cooperative studies. In 2003 HERC lead a comprehensive review of the economic analyses of past and current CSP trials, including those where economic analyses were specifically rejected. The reasons for including or excluding an economic analysis were considered and each study was assigned a score on a three-point scale for importance of including an economic analysis. The results of this review are being used to draft guidelines on when economic analysis should be included in CSP studies. These guidelines will be used to assist the reviews of all future CSP planning letters.

As a result of HERC's coordination of the economic reviews of all planning letters it has become apparent that some studies that do not merit a full cost-effectiveness analysis are good candidates for other types of economic analysis. In talking with VA policy managers it has also become clear that it is important to conduct analysis of the short term economic impacts from the perspective of VA managers, in addition to full cost-effectiveness analyses. This is important from a policy perspective as VA managers, constrained by fixed budgets, may be as concerned with the impacts on their budgets as with overall cost-effectiveness. HERC has started to develop guidelines for the inclusion of analysis from the perspective of VA managers, and for when alternative types of economic analysis should be considered.

2. Review of CSP Use of Preference Measurement for Trial-Based Economic Evaluations

HERC is conducting an evaluation of how preferences are measured in CSP trials that include economic analysis. Preference measurement is needed to convert the patient outcomes into quality adjusted life years (QALYs) for cost-effectiveness analysis. Several different methods have been used to measure preferences in CSP trials. Since the method used to measure preferences can affect the study results, this is a very important issue for CSP economic analyses. This study will conduct an extensive survey the literature and evaluate the CSP experience with different preference measures. The results will be used to formulate methodological guidelines for CSP. The initial results from study are being used to assist the current planning of new trials.

3. Performance Measures for HERC and CSP Studies Involving Economics

HERC has developed a draft set of performance criteria to measure the contributions of economic analysis to CSP. The first draft was shared with the economists working on CSP trials at the Hines and Perry Point CSPCCs and HERC set up a conference call for all CSP economists to discuss these criteria. The revised criteria were presented to the CSP directors in November 2002.

4. Consulting Service for Other Cooperative Studies Program Economists

In addition to conducting economic analyses on CSP trials, HERC also assists other economists who work with CSP. Below is a list of CSP projects for which HERC provided assistance.

- CSP 385, Urgent Revascularization in Unstable Angina (AWESOME). The Hines CSPCC conducted a retrospective analysis of this trial comparing angioplasty to bypass surgery in unstable angina patients HERC helped Hines CSPCC economist Kevin Stroupe develop cost determination methods and reviewed the proposal. HERC is providing Dr. Stroupe with information on the average cost of the types of VA care received by patients, and with the results of its cost model for inpatient cardiology care.
- CSP 498, The Veterans Affairs Open Versus Endovascular Repair (OVER) Trial for Abdominal Aortic Aneurysms. HERC helped Yvonne Yonk determine how to measure costs care for this study. HERC has also provided periodic consulting to Dr. Yonk on methodology issues.

- CSP 535, Anabolic Steroid Therapy on Pressure Ulcer Healing in Persons with Spinal Cord Injury. This trial is looking at the effect of Anabolic Steroids (Oxandrolone) on difficult-to-heal pressure ulcers in SCI patients. HERC reviewed the economic parts of the protocol and provided feedback to Perry Point economist Doug Bradham. This resulted in major revisions to the economic analysis section of the proposal.

B. Development of the VA Health Economics Infrastructure

1. Development of Comprehensive VA Cost Datasets

One of the major obstacles to conducting cost-effectiveness in VA Cooperative Studies has been the difficulty in estimating the costs of care provided by VA. The VA databases at Austin provide information on the utilization of VA care, but until recently, there were no cost estimates available for these data. Thus, the economist for each Cooperative Studies Program (CSP) study had to create cost estimates for each encounter. HERC has estimated costs for every VA inpatient and outpatient encounter recorded in the VA Austin databases for FY 1998-2003. Work on the 2004 HERC average cost data will begin as soon as the VA cost and utilization databases are closed in the fall of 2004. These cost estimates are based on relative cost estimates derived from Medicare data, which are then scaled to actual VA costs from the Cost Distribution Report. Starting in FY04, we will use the Monthly Product Cost Report (MPCR) dataset, which replaces the CDR. HERC has produced guidebooks that described how the inpatient and outpatient cost estimates were derived and how to use them.^{1,2,3} Seven papers by HERC staff were recently published in a special issue of Medical Care Research and Review on estimating the costs of VA care. These cost databases are already being used on CSP trials and have greatly increased the efficiency and quality of economic analyses. These standardized estimates can be used for all encounters where the trial doesn't directly affect the care provided. In most trials, the HERC average cost estimates can be used for all follow-up care.

2. Improvement of Other Methods for Determining VA Health Care Costs

In addition to the average cost estimates described above, HERC has developed other methods of measuring the costs of VA health care and guidelines on when it is appropriate to use each method.⁴ We produced guidebooks on using the VA Decision Support System (DSS) and micro-cost methods to measure VA costs.^{5,6} The special issue in Medical Care Research and Review also included papers on VA pharmacy costs, microcosting, and a comparison of costing methods. HERC also completed a technical report on determining the cost of VA care for fiscal years 1993-1997. We plan to expand this work to include documentation on additional VA data sets relevant to economic research, and are conducting additional validation and comparisons of the DSS and HERC average cost data.

The methods used to measure costs in more detail are collectively referred to as micro-cost methods. These methods are often needed to estimate the cost of the intervention that is being evaluated in a Cooperative Study. Average cost methods, which rely on administrative datasets and some strong assumptions, are often inadequate for this task. Therefore, HERC has produced a guidebook to support VA applications of micro-costing methods. Procedures to apply Medicare reimbursement methods to data on VA outpatient visits have been developed. The Resource Based Relative Value System is used to find physician fees. Medicare Ambulatory Payment Categories are applied to determine facility fees. HERC staff have prepared a new bibliography of VA cost studies that consists of more than 100 items published over the last 25 years, and it is updated quarterly and available for download from the HERC web site. HERC also assists researchers to directly measure the cost of care that is not on Medicare reimbursement schedules, such as treatment innovations or services that are unique to VA. HERC also plans to work with the Measurement Excellence Training Resource and Information Center (METRIC), an HSR&D-resource center, to develop guidance for VA researchers on instruments for capturing patient reported health care costs such as use of non-VA care and travel costs

VA adopted the Decision Support System (DSS) to estimate the cost of health care products and patient encounters. HERC has devoted much of its effort towards DSS in the belief that it will eventually become the primary source of VA cost data. DSS is already a valuable source of information for economic analyses of CSP trials. It includes data on some types of care not captured in the NPCD and PTF files, most notably outpatient pharmacy costs. The HERC DSS Guidebook provides information for VA researchers on how to use DSS cost data.⁵

In 1999 we published a preliminary study evaluating the potential to use the Decision Support System (DSS) for cost-effectiveness research.⁷ Since then we have used DSS data as an alternate method of estimating VA costs in an economic evaluation of data from the VANQWISH trial.⁸ We are now evaluating the use of DSS to estimate the costs incurred by participants in other trials coordinated by the Cooperative Studies Program. HERC has also compared DSS cost estimates with those from the HERC average cost data. Although the overall correlation between the HERC and DSS cost estimates is high, there are differences. HERC has focused its analysis on the outliers, and is working to develop information for researchers about when the DSS estimates appear to be problematic. VA is in the process of transitioning from cost reports based on the Cost Distribution Report (CDR) to the DSS based Monthly Product Cost Report (MPCR). This transition will eliminate some of the differences between the HERC and DSS cost estimates.

HERC economists Wei Yu and Paul Barnett have evaluated DSS national extracts for fiscal years 2000-2002.^{9,10,11} They found discrepancies between the DSS outpatient national data extracts and the NPCD outpatient databases. Our findings were shared with the DSS Bedford Technical Support Office (BTSO) and will be disseminated through the *HERC Bulletin*. HERC provided workshops on DSS at the 2002 and 2003 HSR&D national meetings. HERC also represents the Research and Development Service to the DSS steering committee. The HERC DSS team plans to continue its evaluation of the DSS National Data Extracts (NDEs), and to document the DSS department-level extract. Starting in FY 2003, DSS created NDEs for laboratory results for selected tests and pharmacy prescriptions. HERC is planning to evaluate these files and explore their usefulness for CSP trials. HERC collaborates with the VA Information Resource Center (VIREC), the BTSO, and the VISN Service Support Center (VSSC) to provide information and training to research users of DSS.

3. HERC Training Activities

HERC helps VA researchers learn about VA cost data and cost-effectiveness analysis. In addition to providing training that will assist other VA investigators in conducting cost-effectiveness analyses, HERC activities raise the general awareness of these issues among VA investigators and data custodians, which may facilitate economic analyses in future CSP trials.

HERC has put a priority on helping economists new to the VA get established as VA investigators, especially for those at VA facilities without another economist. As a group, these individuals have been the heaviest users of the HERC help desk. HERC has also extended to new VA economists assistance that it normally does not provide, such as extensive help in the design of a grant proposal.

HERC provides an instructor for the annual CSP randomized clinical trials course.

HERC provides an introductory course on cost-effectiveness analysis, with emphasis on methods of VA cost determination. This course includes presentations on VA cost databases, determination of VA health care cost by micro-costing and average costing methods, DSS, Medicare databases, cost-effectiveness research, measurement of economic outcomes with preference assessment, and medical decision-making models. The first time the course was taught, it was held monthly via hour-long videoconferences that were attended by 75 VA researchers. In response to an e-mail poll of potential students, the format of this class was changed to a two and one half day in person course. Twenty-one VA researchers, clinicians, and managers attended this course in August 2003. The course evaluation forms indicated very high levels of student satisfaction with the content and format. The course will be offered next in

2005 and every other year thereafter.

HERC started a monthly teleconference in May 2004, the HERC Health Economics Cyber Seminar series. The audience for these conferences is more experienced health services researchers and health economists. The teleconferences focus on a variety of topics: (1) workshops on VA databases, including new DSS national extracts, (2) examples of cost determination and cost-effectiveness research, and (3) presentation of other health economics studies. This seminar will start using the new HSR&D cyber seminar technology when it becomes available later this year.

HERC will continue to offer workshops at VA research meetings. These workshops will focus on cost determination issues: (1) use of DSS national data extracts, (2) the new method to extract DSS intermediate product detail, (3) use of HERC average cost datasets, (4) new VA financial databases, and (5) micro-cost methods.

4. Other Activities in Support of VA Cost-Effectiveness and Health Economics Research

HERC conducts a number of other activities that support cost-effectiveness and health economics research within VA. HERC economists helped draft the HSR&D *Information for Applicants and Reviewers on Cost Analyses* in 1997 and updated these guidelines in 2001 and 2004.

To provide a forum for continuing input of VA staff interested in cost and health economics issues, HERC has organized an annual meeting for VA health economists and other VA researchers interested in health economics issues that is held in conjunction with the HSR&D Annual Meeting. HERC has hosted five of these meetings (1999-2003). It was not possible to schedule this meeting in 2004, but HERC will try to resume the meetings in 2005.

HERC health economists help CSP investigators, biostatisticians, and economists from other coordinating centers, as well as researchers and managers from throughout VA. The consultations have been given via e-mail, telephone, and in person. A weekly call schedule has been implemented so that a Ph.D. economist is always on duty to answer requests. HERC handled 176 help requests in the 12 months ending March 31, 2004 and a total of 665 requests since the help desk was opened in November 1999. HERC measures customer satisfaction with a follow-up survey and provides follow-up customer service support.

To make its research on costing methods more accessible, HERC published a supplement to the September 2003 issue of Medical Care Research and Review. Entitled "Estimating VA Treatment Costs: Methods and Applications," it featured six articles describing HERC efforts to measure VA costs and one that applied these methods to estimate the costs of chronic conditions among VA users. The issue also featured two commentaries from non-VA experts.

HERC offers a variety of resources on its web site: www.herc.research.med.va.gov. The site features essays with details of the three cost methods: average costing, micro-costing, and the Decision Support System. Also available in PDF format are copies of articles in the September 2003 supplement to Medical Care Research and Review as well as articles in a 1999 VA supplement to Medical Care. Additional web resources include a searchable database of health economics experts, an e-mail link to submit help requests, answers to 49 Frequently Asked Questions, links to HERC's technical papers and other publications, and training materials for the Health Economics Seminar Series course.

C. Service Provided to the VA Research Service

1. Determining the Cost of Institutional Review Boards

Many claim that Institutional Review Boards (IRBs) are under-funded and/or under-staffed, compromising

IRB quality and the protection of human subjects from research risks. Little is known, however, about the actual costs of operating an IRB. In response to a request from the VA Chief Research and Development Officer, the cost of operating a human subjects protection program was estimated.¹² Todd Wagner led the project with assistance from Paul Barnett. Results were published in a HERC technical report. Dr. Wagner and colleagues from University of Rochester and University of North Carolina expanded this research, publishing it in Academic Medicine in 2003.¹³

A second, more detailed study on the costs of IRBs was conducted to follow-up on the initial findings. This study, also led by Todd Wagner, estimated the actual costs of operating IRBs in the VA by surveying the IRB administrators and chairs in VA medical centers throughout the United States. On average, small, medium, and large IRBs cost approximately \$78,000, \$153,000, and \$319,000 per year, respectively. Large economies of scale were found in reviewing research for human subjects protection; large review boards handled 50 times the workload of small boards at only four times the cost. (Workload was defined as the number of actions, including initial full reviews, amendments, continuing reviews, and adverse event reports.) The multivariate results confirmed that there were strong and statistically significant economies of scale. In a multivariate regression, the average cost per action at small, medium, and large IRBs was \$2,556, \$448, and \$124, respectively. A paper describing these results is in press in Medical Care.¹⁴

The final report was submitted in October 2002. Dr. Wagner has provided additional documentation to VACO staff about the study and answered their follow-up questions. Although the study sheds light on the costs of a system of local IRB review boards, the benefits of local review need more discussion. Without a better understanding of costs relative to benefits, it will be difficult for VA to design a more cost-effective human subjects protection program.

2. Developing a New Financing System for VA Research Administration

The VA Office of Research and Development (ORD) asked HERC to develop a new method for allocating research administration funds, also known as 101 funds. We conducted in-depth interviews with staff from eight VA health care systems representing different facility sizes and geographic areas. We then surveyed all Administrative Officers (AOs) in the research offices, asking about staff, expenditures, and revenues. We used the results to investigate the underlying needs of research administration at VA health care systems. Through an iterative process, we developed three alternative allocation models to meet these needs. We then compared the models through a simulation exercise. A final report was submitted October 2002.

The three proposed allocation models provide research offices with funds for core personnel, although they use slightly different formulae in the calculation. All three use the number of VA-funded projects in the health care system to calculate the number of core personnel. Funds for additional personnel are based on the volume of protocols undergoing review by oversight committees, such as Research Safety, Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC). Additional funds are provided for supplies and education. Finally, to meet each health care system's unique needs, flexible funds equal to 3% of VA-funded research conducted at the health care system would be distributed concurrently with the research allocation.

Of the three models, we recommended the Continuous Model, in which every VA health care system that conducts research would receive 2 FTE and an additional 0.12 FTE per VA-funded project. Approximately 7% of ORD's budget is spent on research administration support. The new models would increase that amount to approximately 9.5%, a 35% increase. All sites would receive increased funding, with the largest increase going to small sites.

3. Biostatistical Reviews for VA Medical Research Service

HERC health economists assist CSP with biostatistical review on merit review applications for funding from the VA Clinical and Laboratory Research Services. The economists typically review 1-3 proposals each year on an as-needed basis.

4. Service on VA Advisory and Steering Committees

HERC health economists serve on the following VA national advisory committees and steering committees:

- DSS Steering Committee. VA has adopted a comprehensive information system for determining the costs and evaluating processes of VA health care, the Decision Support System (DSS). Paul Barnett serves on the committee that oversees the implementation of this system.
- VA Information Resource Center (VIREC) Advisory Committees. VIREC is an HSR&D center that supports the data information needs of VA researchers. Paul Barnett served on the center's steering committee, reviewing the VIREC strategic plan. In December 2002, he switched to serve on the VIREC Technical Advisory Committee.
- QUERI Substance Use Disorders Steering Committee. Paul Barnett serves on the steering committee that advises the VA Quality Enhancement Research Initiative (QUERI) that works to improve treatment of substance use disorders.
- QUERI Research and Methods Committee. Mark Smith has been attending recent meetings of this committee to assist them in the reviews of the QUERI steering committees and of phase 2 QUERI projects.
- Linkage of VA and Medicare data. To learn about Medicare utilization of veteran patients, researchers have linked VA and Medicare databases. Ciaran Phibbs has undertaken projects that involve this linkage. He has been advising VIREC on a project that identifies all Medicare data of veterans and links these data to VA databases. He also serves on the data request review board that VIREC has established to review research requests for access to these linked data.
- Evaluation of Community-Based Outpatient Clinics (CBOCs). Since 1995, VA has rapidly increased the number of CBOCs in an effort to improve access and primary care. The purpose of this study is to evaluate CBOC cost-based performance measures and to explore CBOC costs and quality of care for veterans with ambulatory-care sensitive conditions. Todd Wagner and Wei Yu serve on the project's advisory board.
- VA Task Force for Dementia Data Registry. This task force was created by Central Office to provide advice on the methods and structure for a national VA registry of patients with dementia. Wei Yu is a member of this task force.
- VA Health Services Research and Development Ethics Committee. This national VA committee was established to provide advice on how to improve the research review process. Todd Wagner serves on this committee.
- Measurement Excellence Training Resource and Information Center (METRIC). METRIC is an HSR&D national resource center that provides guidance and training on psychometrics and the choice of appropriate survey instruments. Mark Smith serves on the METRIC Steering Committee.

5. Service on the Scientific Review Panels

Wei Yu has served for several years on the Scientific Review and Evaluation Board (SREB) of the VA HSR&D Service, where he reviews funding proposals.

Mark Smith served as an *ad hoc* SREB reviewer in January, 2004.

Todd Wagner and Mark Smith were members of the abstract review committee for the 2003 VA HSR&D national meeting.

6. Service to QUERI

As noted earlier, Paul Barnett serves on the Steering Committee of the Substance Use Disorders QUERI center.

In May, 2004, Mark Smith served as a non-voting member of the QUERI Research and Methodology committee. A month later, he acted as an *ad hoc* reviewer for a large QUERI project proposal.

HERC economists and research associates regularly attend national meetings in an effort to support economic research in QUERI and other implementation projects. These meetings have included the December annual QUERI meetings, a May 2004 conference on care following traumatic amputation, and an upcoming August 2004 HSR&D SOTA (state of the art) conference on implementation research.

D. Projects in Service to VA Management

1. Assistance to VA Central Office

Chief Research and Development Officer Nelda Wray asked HERC for assistance in preparation for a meeting on VA participation in the Medicare plus choice initiative. Paul Barnett briefed CRDO on comparisons of VA to Medicare costs and evaluations veteran's dual use of Medicare and VA.

VA Central Office asked HSR&D to review a study on the additional cost of adopting optimal, evidence-based care for serious mental illness, substance use disorders, and PTSD. Paul Barnett served on the HSR&D panel that reviewed this study.

The VA HS&RD management consultation service requested an estimate of the possible cost savings from adoption of lower cost anti-hypertensives. Paul Barnett responded to this request.

2. Assistance to the Sierra-Pacific VISN

VA's method of allocating its health care resources, the Veterans Equitable Resource Allocation (VERA) system, uses capitation payments to set regional budgets. It shifts control over facility budgets to the 22 regional networks. HERC provides technical assistance to the staff of the Sierra Pacific Network to develop a method to allocate funds to VA facilities in Northern California, Nevada, and Hawaii. Paul Barnett has participated in the extensive deliberations by the network's fiscal management group and executive leadership committee and helped design an allocation method to reflect the new incentives under VERA. As a result of these meetings, facility budgets are determined by the number of VA health care users living in the geographic area served by each facility, adjusted to reflect patient referrals. HERC staff continue to do analysis in support of this budget process.

3. Nursing wages

Ciaran Phibbs evaluated the 1990 VA Nurse Pay Act, which changed the way VA set RN salaries from a national wage scale to setting salaries in each local market to match prevailing wages. His research found that this policy increased recruitment and retention of VA nurses.^{15,16} It also found that in small markets, where VA was a major buyer of RN services, non-VA hospitals responded to VA wage increases. The results of this research were reported by VA to Congress to help consider the future of this policy. The manuscript with the results from this study is under review.

4. Demand for VA health care

Ciaran Phibbs studied veterans' choice of provider and the demand for VA services. He studied veteran demand for inpatient services nationwide and found that distance was the most important predictor of demand, with an effect that varied by age, eligibility class, and population density.¹⁷ The effect of travel distance on demand is very important to VA managers, as many veterans do not live close to VA facilities. The methods developed by this project to estimate the number and characteristics of veterans in each zip code have been adopted by VA Central Office staff.

Ciaran Phibbs extended this work to VA outpatient services. Overall, the results are similar to the inpatient work, except that demand for outpatient services is more sensitive to distance. These findings strongly support recent VA efforts to expand the number of outpatient facilities to improve veterans' access to care. VA Central Office staff have presented the results of this research to Congress.

E. Service Provided to the Medical Research Community

HERC health economists have served as reviewers for the following journals since 1999: JAMA, Medical Care, Health Services Research, Addiction, Addictive Behaviors, American Journal of Health Promotion, American Journal of Managed Care, American Journal of Preventive Medicine, American Journal of Public Health, Drug and Alcohol Dependence, Effective Clinical Practice, Health Affairs, Inquiry, Intensive Care Medicine, International Journal of the Economics of Business, Journal of the American Geriatrics Society, Journal of Clinical Epidemiology, Journal of Health Economics, Journal of Human Resources, Journal of Information Technology in Healthcare, Journal of Rural Health, Journal of Studies on Alcohol, Journal of Women's Health, Pharmacoeconomics, Preventive Medicine, Social Science and Medicine, and Southern Economic Journal.

Ciaran Phibbs serves as one of the three leaders of the expert panel for the Leapfrog Group's Evidence Based Hospital Referral program. Dr. Phibbs serves on the steering committee of the Health Services and Policy Research scholarly concentration at the Stanford University School of Medicine. He was an invited speaker at the NICHD Conference, "Research on Prevention of Bilirubin-Induced Brain Injury and Kernicterus: Bench-to-Bedside." Dr. Phibbs also served on the Clinical Advisory Panel of a project by the Blue Shield Foundation of California to define the essential benefits for a universal health insurance plan. Dr. Phibbs served on the Agency for Healthcare Quality and Research's Health Care Research Training study section from 1999-2001.

Todd Wagner reviewed grants for the NIH National Human Genome Research Institute, National Institute on Aging, and for a CDC Special Emphasis Panel in 2003. He is the Co-Chair of the Committee on Economics of the International Consultation on Incontinence

Mark Smith was on the abstract review committee of the 2003 AcademyHealth Annual Research meeting.

Wei Yu is the Chair of the Finance Committee of the Chinese Economist Society. He is also program coordinator for the Stanford University China-US post doctoral training and research program on aging studies (10/2001 - present) that is funded by the NIH Fogarty International Center

F. Faculty Appointments

Paul G. Barnett

Consulting Associate Professor
Department of Health Research and Policy
Stanford University School of Medicine

Associate
Center for Primary Care and Outcomes Research
Stanford University School of Medicine

Ciaran S. Phibbs, Ph.D.

Consulting Associate Professor
Department of Health Research and Policy
and Department of Pediatrics
Stanford University School of Medicine

Associate
Center for Primary Care and Outcomes Research
Stanford University School of Medicine

Mark W. Smith, Ph.D

Associate
Center for Primary Care and Outcomes Research
Stanford University School of Medicine

Todd H. Wagner, Ph.D.

Consulting Assistant Professor
Department of Health Research and Policy
Stanford University School of Medicine

Fellow
Center for Primary Care and Outcomes Research
Stanford University School of Medicine

Wei Yu, Ph.D.

Fellow
Center for Primary Care and Outcomes Research
Stanford University School of Medicine

G. HERC Staff by CSP Project

Study Number	Economist	Research Health Science Specialist(s)	Coordinating Center
Studies Being Planned			
529	Todd Wagner		Boston
551	Ciaran Phibbs		Boston
553	Wei Yu		Palo Alto
Approved Studies – Awaiting Start-up			
519	Mark Smith		Palo Alto
Ongoing Studies – Patient Accrual			
424	Paul Barnett	Shuo Chen Jeannie Butler	West Haven
474	Todd Wagner	Leonor Ayyangar	Palo Alto
481	Ciaran Phibbs	Pon Su	Palo Alto
512	Wei Yu	Vandana Sundaram Vilija Gulbinas	West Haven
530	Mark Smith	Ariel Hill Vilija Gulbinas	West Haven
146	Paul Barnett Wei Yu Forest Baker	Vilija Gulbinas	Palo Alto
Primary Analysis and Manuscript Writing			
27	Paul Barnett	Lakshmi Anath, Jo Kay Chan	Palo Alto
Continuing Activity			
6	Ciaran Phibbs		Palo Alto
420	Mark Smith		Palo Alto
Completed Projects			
20	Ciaran Phibbs		Palo Alto
368A	Paul Barnett		Palo Alto
1008	Paul Barnett		Palo Alto

H. HERC Publications and Presentations 2001-2004, by CSP Study

CSP No.	Title	Peer Reviewed Journal Publications	Abstracts/ Presentations	Other	Total
006	Effectiveness of Geriatric Evaluation and Management Units (GEM)	1		1	2
027	FDG Positron Emission Tomography (PET) Imaging in the Management of Patients with Solitary Pulmonary Nodules (SNAP)	4		1	5
368A	VA Non Q-wave Infarction Strategies in Hospital (VANQWISH)	1			1
420	Analysis of Health Care and Work among Veterans with PTSD	1	1		2
424	Clinical Outcomes, Revascularization, and Aggressive Drug Evaluation (COURAGE)			1	1
1008	Pharmacoeconomics of Buprenorphine Maintenance for Opioid Dependence	2	1		3
-	Health Economics Resource Center (ECN 99-017)	51	68	29	148
	Total	60	70	32	162

I. Center Publications and Conference Presentations 2001-2004

Peer-Reviewed Journal Publications

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- Baker LC, **Phibbs CS**, Guarino C, Supina D, Reynolds JL. (2004). Within-year variation in hospital utilization and its implications for hospital costs. Journal of Health Economics: 23(1), 191-211.
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- Barnett PG**. (2003). Determination of VA health care costs. Medical Care Research and Review: 60(3/Supplement), 124S-141S.
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- Barnett P**, Rodgers J, Bloch D. (2001). A meta-analysis comparing buprenorphine to methadone for treatment of opiate dependence. Addiction: 96, 683-690.
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- Cowper D, **Yu W**, Berger M, Kuebler M, Kubal J, Manheim L. (In Press). Using GIS in Government: The VA Health Care Atlas, FY-2000. Journal of Medical Systems.

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- Crown W, Olufade A, **Smith M**, Nathan R. (2003). Seasonal versus perennial allergic rhinitis: drug and medical resource use patterns. Value in Health: 6(4), 448-456.
- Crystal-Peters J, Neslusan C, **Smith M**, Togias A. (2002). Healthcare costs of allergic-rhinitis-associated conditions vary with allergy season. Annals of Allergy, Asthma and Immunology: 89(5), 457-462.
- Cuellar AE, **Wagner TH**, Hu T-w, Piefer K, Kitzman H, Tobin S, Shih V. (2003). New opportunities for integrated child health systems: results from the multi-faceted Pre-to-Three program. American Journal of Public Health: 93(11), 1889-1890.
- Emanuel EJ, Ash A, **Yu W**, Gazelle G, Levinsky NG, Saynina O, McClellan M, Moskowitz M. (2002). Managed Care, hospice, site-of death, and medical expenditures in the last year of life. Archives of Internal Medicine: 162, 1722-1728.
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- Hu T-w, **Wagner TH**, Bentkover JD, LeBlanc K, Piantentini AL, Stewart WF, Corey R, Zhou Z. (2003). Economic costs of overactive bladder in the U.S. Urology: 61(6), 1123-1128.
- Humphreys K, Trafton J, **Wagner TH**. (2003). The cost of institutional review board procedures in multicenter observational research. Annals of Internal Medicine: 139(1), 77.
- Levinsky N, **Yu W**, Ash A, Moskowitz M, Gazelle G, McClellan M, Saynina O, Emanuel E. (2001). Influence of age on Medicare expenditures and medical care in the last year of life. Journal of the American Medical Association: 286 (No. 11), 1349-1355.
- Masson CL, **Barnett PG**, Sees KL, Delucchi KL, Rosen A, Wong W, Hall SM. (in press). Cost and cost-effectiveness of standard methadone maintenance treatment compared to enriched 180-day methadone detoxification. Addiction.
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Yu W, Barnett P. Handbook of the Decision Support System National Data Extracts. Health Economics Resource Center. Menlo Park, CA. September, 2001.

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Papers Under Review

Berger M, **Wagner TH**, Baker LC. Internet use and stigmatized illness

Bhandari A, **Wagner TH**. Accuracy of self reported health care utilization.

Bhutani VK, Johnson LH, Maisels MJ, Newman TB, **Phibbs CS**, Yeargin-Allsopp M. Kernicterus: Epidemiological Strategies for its Prevention Through Systems-Based Approaches

Bowen J, **Wagner TH**, Singer SJ, Bundorf MK, Baker LC. Complementary and alternative medicine and the role of the Internet

McLean A, Koffler H, **Phibbs CS**, Gould J, Cope N, Kirkpatrick K. Effectiveness of Systematic Care Management on NICU Length of Stay.

Palevsky PM, O'Connor T, Zhang JH, **Smith MW**, for the VA/NIH ATN Study. Design of the VA/NIH Acute Renal Failure Trial Network (ATN) Study: Intensive versus Conventional Renal Support in Acute Renal Failure.

Piette JD, Heisler M, **Wagner TH**. Pain or death? Choices by chronically-ill patients regarding cost-related medication under-use.

Phibbs CS, Holty JKC, Goldstein MK, Garber AM, Wang Y, Feussner JR, Cohen HJ. Inpatient and Outpatient Geriatric Evaluation and Management: Less Nursing Home Time without Adverse Cost or Health Effects.

Retajczyk C, Phibbs R, Ciu L, **Phibbs CS**. The Effect of Adding Congenital Anomalies to the Score for Neonatal Acute Physiology (SNAP) on Predicting Neonatal Mortality.

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VanVonno C, Ozminkowski R, **Smith MW**, Thomas E, Kelley D, Goetzel R, Berg G, Jain S, Walker D. A return-on-investment evaluation of a pilot congestive heart failure disease management program offered to federal employees.

Wagner TH, Bundorf M K, Singer S, Baker LC. Free Internet Access, the Digital Divide, and Health Information

Yu W, **Ravelo A**, **Wagner TH**, **Barnett PG**. The Relationships The Relationships Among Veterans' Ages, Chronic Conditions, and Healthcare Costs

Yu W, **Wagner TH**, **Barnett PG**. Disease, not Age, is the Critical Variable Influencing Cost of Final VA Nursing-Home Stays.

J. HERC Administration

Staff. HERC has five full-time health economists at Menlo Park. The HERC expert panel is made up of three additional economists who are affiliated with Cooperative Studies and HSR&D. Members of this panel serve as faculty for HERC training courses, and meet monthly by telephone conference call to review HERC activities.

The Menlo Park staff also consists of a Project Manager, a Research Psychologist, seven Research Associates providing programming and analytical support, three Research Assistants, a Technical Writer/Administrator, and an Administrator. HERC also receives assistance from clinical consultants who provide invaluable assistance on a number of projects, and a decision modeling expert, Gillian Sanders, PhD.

Health Economics Resource Center Staff

FY2004

Staff	Position
Paul Barnett, PhD	Director & Health Economist
Mark Smith, PhD	Assoc. Dir. & Health Economist
Todd Wagner, PhD	Health Economist
Wei Yu, PhD	Health Economist
Ciaran Phibbs, PhD	Health Economist
Forest Baker, PhD	Research Psychologist
Shuo Chen, PhD	Research Associate
Pon Su, MS	Research Associate
Leonor Ayyangar, MS	Research Associate
Magdalena Berger, MPH *	Research Associate
Shirley Kim, MHSA *	Research Associate
Ariel Hill, AB	Research Associate
Lakshmi Ananth, MS +	Research Associate
Jesse Velez, BS *	Research Associate
Reiling Lee, MS +	Research Associate
Yesenia Luna, MPH +	Research Associate
Jeannie Butler, BA	Technical Writer/Administrator
Sharon Abas, AA +	Administrator
Vandana Sundaram, MPH	Project Manager
Vilija Gulbinas, BA	Research Assistant
Sam Richardson, AB	Research Assistant
Jo Kay Chan, BS	Research Assistant
Ann Hendricks, PhD	Health Economist Expert Panel
Anne Sales, PhD	Health Economist Expert Panel
Douglas H. Bradham, PhD	Health Economist Expert Panel
Gillian Sanders, PhD	Medical Decision Analyst
Michael Gould, MD	Clinical Expert
Doug Owens, MD	Clinical Expert
Mary Goldstein, MD	Clinical Expert
Alan Garber, MD	Clinical Expert

+ hired during FY 2004

* departed during FY2004

Budget. HERC is funded by both the VA Cooperative Studies Program and the VA Health Services Research and Development Service. This support consists of Cooperative Studies core funding, HSR&D support for HERC, and Palo Alto HSR&D Center of Excellence funding. The Cooperative Studies Program provides additional support for the CSP 146 and the ATN, THINRS, SNAP, OPTIMA, and COURAGE studies. HERC also receives funding from an HSR&D investigator-initiated project, a NIH study, and a RR&D Service investigator-initiated project. The annual budget for HERC and its investigators for FY2004 was \$1,703,372.

**Health Economics Resource Center
FY2004 Budget**

Cooperative Studies Program Coordinating Center	419,186
Cooperative Studies Project Funds	370,602
HSR&D Health Economics Resource Center	400,000
HSR&D Investigator Initiated Research	211,082
Other VA	180,400
National Institutes of Health	122,102
Total	\$1,703,372

Steering Committee. HERC is governed by a 7-member steering committee made up of researchers, clinicians, managers, and health economists from VA and outside VA. The steering committee meets by telephone conference call every 3 months, and in an annual face-to-face meeting.

Members of the HERC Steering Committee

Rodney Hayward, MD (Steering Committee Chair)	Director, VA HSR&D, Center for Practice Management and Outcomes Research
David Bach	CFO, VA Southwest Network (VISN 18)
John Bonsall	Deputy Director for DSS Resource Management, VHA
Jim A. Jackson, BRN, BBA	Manager, Decision Support & Clinical Facilitator, Portland VA Medical Center
Robert J. McNamara	Director, VA Allocation Resource Center
Ann Sales, PhD, RN	Health Economist, VA HSR&D Northwest Center for Outcomes Research in Older Adults

Endnotes

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- ¹⁰Yu W, Barnett P. Reconciliation of DSS Encounter-Level National Data Extracts with the VA National Patient Care Database FY2001. HERC Technical Report #4. Health Economics Resource Center. Menlo Park, CA. September, 2002.
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- ¹³Staiger D, Spetz J, Phibbs CS. (1999). Is there monopsony in the labor market? Evidence from a natural experiment. NBER Working Paper No. W 7258: Cambridge, MA.
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