



# *Annual Report 2000*

*The Permanente Medical Group, Inc. and  
Kaiser Foundation Research Institute*



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## DIVISION OF RESEARCH VISION STATEMENT

*The **Division of Research** aims to conduct, publish, and disseminate high-quality epidemiologic and health services research to improve the health and medical care of Kaiser Permanente members and the society at large. It seeks to understand the determinants of illness and well-being and to improve the quality and cost-effectiveness of health care. To accomplish these goals, the Division of Research is committed to providing a supportive research environment that fosters independent thinking, creativity, continued learning and adherence to the highest scientific standards.*

## DIVISION OF RESEARCH DIRECTORS



**Gary Friedman, MD**  
1991 – 1998

**Morris Collen, MD**  
1961 – 1979

**Ted Van Brunt, MD**  
1979 – 1991

**Joe Selby, MD, MPH**  
1998 – present

## DIRECTOR'S REPORT

This 2000 Annual Report chronicles the 40<sup>th</sup> year in the life of Kaiser Permanente Northern California's Division of Research. DOR's longevity and success are attributable first and foremost to the training, diligence and teamwork of its 40 scientists and 300 staff members. DOR has also benefited from the constant support of Kaiser Permanente leaders, who have understood the advantages of having an internal public-domain research center; and from the unique research opportunities that arise within an integrated health care system, its population of more than 3,000,000 members, 4000 clinicians in all specialties, and ever-improving clinical data bases.

Several noteworthy events touched DOR in 2000. Two new investigators joined the DOR community. Dr. Andrew Avins, formerly an assistant professor in the Departments of Medicine and Epidemiology at the School of Medicine, University of California San Francisco, became the Division's Associate Director for Healthcare Effectiveness Research. Dr. Avins' research interests include preventive medicine, complementary and alternative medicine, and cardiovascular diseases. Among his responsibilities will be facilitation of the interface between DOR and TPMG clinician and organizational leaders and coordination of DOR's Healthcare Effectiveness Section. Dr. Lisa Croen, an epidemiologist who was formerly with the California Birth Defects Monitoring Program, joined our Perinatal Research Unit. Dr. Croen's research interests focus on pre- and perinatal risk factors for congenital disorders of childhood. 2000 also witnessed establishment of DOR's first formal research traineeship program. In collaboration with the University of California at San Francisco, DOR was funded by the National Institutes of Health to support one to two post-doctoral researchers annually to pursue research in the area of women's health.

The year 2000 will also be remembered at DOR as the year of strategic planning. Fifty three staff members, organized into a coordinating committee and 8 subcommittees, set new directions for the department that are transforming DOR internally, establishing an infrastructure for more formal planning of research directions, and clarifying our relationships with the larger Kaiser Permanente organization and the academic community.

DOR's research portfolio continues to grow, now amounting to nearly \$25 million per year in directly funded research activities. Research topics cover a broad range of acute and chronic illnesses and a variety of research disciplines. Science is increasingly a collaborative effort among investigators with specialized expertise. A growing proportion of DOR studies involves collaborations with colleagues from government, academic institutions, other HMO research centers, and industry.

This report is organized by research topic and also by investigator. I invite you to use it to gain an understanding of the breadth and depth of the DOR research enterprise, or perhaps to find the researcher most appropriate for a collaboration you would like to pursue.

Joseph V. Selby, MD, MPH  
May 2001

**DIVISION OF RESEARCH FUNDING  
1994 - 2000**

	1994	1995	1996	1997	1998	1999	2000
<b>INTERNAL FUNDING</b>							
<b>KFH/KFHP</b>							
Community Services/Direct Community Benefit Investment Program							
Clinical Research	\$601,007	\$522,910	\$635,690	\$494,770	\$533,070	\$587,118	\$713,907
Health Services	589,000	530,100	504,000	501,158	501,158	475,950	475,949
Other	192,550	355,680	267,500	234,845	266,748	371,384	400,000
<b>TPMG Research</b>							
Innovations	278,994	776,677	1,084,818	1,425,386	753,243	370,976	178,911
Non-physician Personnel	1,069,042	1,638,246	1,607,044	1,714,440	1,001,426	1,635,093	1,401,221
Physician Personnel <sup>1</sup>	1,155,531	1,555,531	915,967	1,151,030	1,834,536	636,416	780,154
Non-personnel	138,352	154,718	137,346	190,822	145,370	149,290	266,551
<b>EXTERNAL FUNDING</b>							
Federal	5,521,996	7,213,852	6,650,807	7,707,446	10,229,350	10,632,450	12,226,190
Pharmaceutical	3,575,533	2,457,792	3,026,857	3,351,721	3,964,573	3,203,072	3,613,583
Other <sup>2</sup>	2,178,725	1,637,567	2,320,279	2,494,133	2,281,495	2,889,410	4,685,608
<b>TOTAL</b>	<b>\$15,300,730</b>	<b>\$16,443,073</b>	<b>\$17,060,308</b>	<b>\$19,445,751</b>	<b>\$21,510,996</b>	<b>\$20,931,159</b>	<b>\$24,742,074</b>

<b>EMPLOYEES</b>							
	1994	1995	1996	1997	1998	1999	2000
Total Number	230	228	268	310	330	310	333
Full Time Equivalents <sup>3</sup>	166	164	193	245	247	242	266

<sup>1</sup> Total MD allocation for year, of which a significant portion is recharged to other funding sources and credited to TPMG

<sup>2</sup> Includes foundations, subcontract from universities

<sup>3</sup> Estimates

## SUMMARY OF RESEARCH PROJECTS IN 2000

### AIDS/HIV

#### **Fat Redistribution and Metabolic Change in HIV Infection (FRAM)**

Source of Funding: Northern California Institute for Research Education  
Total Project Period: October 1999 – August 2001  
Principal Investigator: Stephen Sidney, MD, MPH  
Goals/Objectives: A cross-sectional study of the prevalence of “peripheral lipodystrophy” syndrome in HIV infected patients, including fat redistribution, insulin resistance, and pre-atherogenic hyperlipidemia.

#### **HIV-1 Antiretroviral Treatment: Cost-Effectiveness of Triple Combination therapy Vs Dual Therapy under a Markov Model**

Source of Funding: Pharmacia  
Total Project Period: February 1999 – June 2001  
Principal Investigator: Gerald N. DeLorenze, PhD  
Goals/Objectives: To test a Markov chain model of the cost-benefit and quality of life adjusted cost-benefit of triple combination therapy relative to dual combination therapy.

#### **HIV-1 Virologic Response and Survival Patterns Associated with Highly Active Antiretroviral Therapy (HAART)**

Source of Funding: Universitywide AIDS Research  
Total Project Period: July 1999 – June 2001  
Principal Investigator: Gerald N. DeLorenze, PhD  
Goals/Objectives: To estimate rates of maximum virologic response and virologic treatment failure in HIV patients under HAART. To determine the distribution of time to AIDS diagnosis and the time to death after initiation of HAART. To measure health care usage trends both pre- and post HAART.

### AIR POLLUTION

#### **Air Pollution and Morbidity and Mortality Among California Kaiser Permanente Members**

Source of Funding: Environmental Protection Agency  
Total Project Period: October 1995 - September 2001  
Principal Investigator: Stephen K. Van Den Eeden, PhD  
Goals/Objectives: To evaluate the relationship between ambient air pollution and respiratory and cardiovascular disease morbidity and mortality among members of Northern and Southern California Kaiser Permanente.

#### **Air Pollution, Race, SES and Asthma Hospitalization Risk**

Source of Funding: National Institute of Environmental Health Sciences  
Total Project Period: August 2000 – July 2002  
Principal Investigator: Stephen K. Van Den Eeden, PhD  
Goals/Objectives: This is a case-crossover study to assess the risk of asthma hospitalization that is associated with exposure to ambient air pollution and how SES, race/ethnicity, and disease severity modify the association.



**Case-Crossover Analysis of Ambient Air Pollution and Cardiopulmonary Hospitalizations of Kaiser Members in Sacramento and Fresno Metropolitan Areas**

Source of Funding: American Lung Association  
Total Project Period: December 2000 – November 2001  
Principal Investigator: Stephen K. Van Den Eeden, PhD  
Goals/Objectives: This study will examine how exposure to air pollution in the Sacramento and Fresno areas is associated with asthma hospitalizations. Modification of this association by prior illness will be examined.

**Particulate Air Pollution and Morbidity in the California Central Valley: A High Particulate Pollution Region**

Source of Funding: California Air Resources Board  
Total Project Period: November 1997 - February 2001  
Principal Investigator: Stephen K. Van Den Eeden, PhD  
Goals/Objectives: To examine the association of particulate matter air pollution morbidity among Kaiser Permanente members in the California Central Valley.

**Risk of IHD Hospitalization Associated with exposure to Air Pollution**

Source of Funding: Kaiser Foundation Research Institute  
Total Project Period: January 2000 – December 2000  
Principal Investigator: Stephen K. Van Den Eeden, PhD  
Goals/Objectives: This study will estimate the risk of an IHD hospitalization associated with exposure to ambient air pollution.

ALCOHOL AND OTHER DRUGS (also see HEALTH SERVICES)

**Alcoholic Beverage Choice and Mortality**

Source of Funding: Wine Institute  
Total Project Period: July 2000 – December 2001  
Principal Investigator: Arthur L. Klatsky, MD  
Goals/Objectives: A prospective study of alcohol use and alcoholic beverage choice (wine, liquor and beer) in relation to 20 year mortality in a cohort of almost 129,000 persons who supplied baseline data in 1978-85.

**Alcohol Drinking and Risk of Cerebrovascular Disease**

Source of Funding: National Institute of Alcoholism and Alcohol Abuse  
Total Project Period: August 1996 - July 2000  
Principal Investigator: Arthur L. Klatsky, MD  
Goals/Objectives: To examine prospectively the relationship of all levels of alcohol drinking and beverage choice to hospitalizations and deaths attributed to CVD after the baseline examination.

**Follow-up Study of Medicaid Chemical Dependency Patients in a Private HMO: Do High Medical Costs Come Down Over Time?**

Source of Funding: Robert Wood Johnson Foundation  
Total Project Period: November 1998 – October 2001  
Principal Investigator: Lawrence J. Walter, MA  
Goals/Objectives: To describe utilization trends and associated costs of a group of low-income Kaiser Permanente members in Solano County entering KP's chemical dependency treatment program.

**Impact of Services on Trajectories**

Source of Funding: National Institute on Alcohol Abuse and Alcoholism  
Total Project Period: August 1994 – June 2004  
Principal Investigator: Constance M. Weisner, DrPH, MSW  
Goals/Objectives: The aims of the project are: 1) To compare the three primary systems of service delivery, the public, private indemnity, and health maintenance organization (HMO), investigating patient characteristics and patterns of service utilization among populations entering each type of treatment setting. 2) By expanding on a theoretical framework drawn from the medical literature on help seeking, the study models the process of "treatment entry," testing hypotheses examining why some problem drinkers enter treatment while others do not. Sub-analyses focus on divergences from general patterns of help-seeking among important demographic groups, including women and ethnic minorities.

**Long-term Impact of Day Treatment on Outcome and Cost**

Source of Funding: National Institute on Drug Abuse  
Total Project Period: September 1993 – August 2004  
Principal Investigator: Constance M. Weisner, DrPH, MSW  
Goals/Objectives: This study examines determinants of 7-year substance abuse treatment readmission, substance use and medical services cost and utilization. The original study randomized 1204 individuals entering an HMO's substance abuse treatment program to two treatment intensities, day hospital and traditional outpatient. We study the effects of treatment and other hypothesized influences such as personal characteristics, on long-term outcomes of these patients.

**Outcome and Cost of Day Hospital vs. Outpatient Care**

Source of Funding: National Institute of Alcoholism and Alcohol Abuse  
Total Project Period: December 1994 – May 2004  
Principal Investigator: Constance M. Weisner, DrPH, MSW  
Goals/Objectives: This study compares the effects of day hospital treatment and traditional outpatient treatment for post-treatment outcome and improvement rates in the areas of alcohol consumption, levels of psychosocial functioning, and medical care utilization of the two regimens at five and seven years after treatment entry. It attempts to specify patient characteristics associated with successful treatment outcomes in each setting. Finally, it compares the costs of day hospital and traditional outpatient treatment, and assesses cost-effectiveness and cost offsets of the two programs.

**Pathways to Substance Abuse Treatment in Adolescents in an HMO: Implications for Policy**

Source of Funding: Robert Wood Johnson Foundation (subcontract from the University of California, San Francisco)  
Total Project Period: November 1999 – October 2002  
Principal Investigator: Constance M. Weisner, DrPH, MSW  
Goals/Objectives: This study will examine the access to and utilization of substance abuse services in a health maintenance organization (HMO) by adolescents. The principal objective is to inform health care policy for adolescents in a managed care setting by describing those identified as substance abusers, identifying successful system pathways and potential barriers to treatment access of those identified, describing pretreatment patterns of health service utilization which may facilitate identification, and characterizing who enters and remains in treatment, thus identifying those at risk for early dropout and the factors related to dropping out.

## Alcohol and Other Drugs (cont.)

### **Post-Partum Alcohol, Tobacco, and Other Drug Use: Impact of the Early Start Program**

Source of Funding: Kaiser Foundation Research Institute  
Total Project Period: January 2000 – December 2001  
Principal Investigator: Mary Anne Armstrong, MA  
Goals/Objectives: To investigate the post-partum impact of a substance abuse treatment program for pregnant women (the Early Start Program), in terms of inpatient and outpatient utilization of health services and substance use one year post delivery.

### **Primary Care Behavioral Health Risk Screening and Referral**

Source of funding: National Institute on Drug Abuse (subcontract from University of California, San Francisco)  
Robert Wood Johnson Foundation  
Total Project Period: August 1998 – February 2001  
Principal Investigator: Constance M. Weisner, DrPh, MSW  
Goals/Objectives: This study will assess the policy implications of screening for substance abuse and related behavioral health problems in an HMO primary care clinic mobile health van serving the medically indigent. The approach involves brief, user-friendly, low-cost computerized screening instrument (PCscreen) to detect substance abuse and other behavioral health problems. Those with problems are then linked to appropriate interventions. Policy implications stem from: 1) assessing the effectiveness, 2) assessing the effectiveness of the referral/linkage mechanism, including patient preferences, and 3) examining policy issues serving as barriers or incentives in integrating screening in a managed care primary care setting.

CANCER (by type) (also see HEALTH SERVICES and WOMEN'S HEALTH)

## General

### **Cancer Epidemiology in a Large Health Care Plan (Outstanding Investigator Grant)**

Source of Funding: National Cancer Institute  
Total Project Period: June 1989 - March 2001  
Principal Investigator: Gary D. Friedman, MD, MS  
Goals/Objectives: A multifaceted research program whose main components are: studies of the possible carcinogenic effects of pharmaceutical drugs, studies of the health effects of cigarette smoking, studies of precursors of cancer using the Kaiser-Orentreich frozen serum bank, evaluation of cancer screening methods and other studies of risk factors for cancer.

### **Evaluation of Risk Factors for Barrett's Esophagus**

Source of Funding: National Institutes of Health  
Total Project Period: September 2000 – August 2001  
Principal Investigator: Theodore R. Levin, MD  
Goals/Objectives: This study will evaluate risk factors for esophageal adenocarcinoma/Barrett's metaplasia using a large population-based database, explore some reasons for their increasing incidence and provide a cohort for subsequent detailed longitudinal studies.

### **H. Pylori Phenotype and Stomach Cancer**

Source of Funding: National Cancer Institute (subcontract from Stanford University)  
Total Project Period: June 1997 – December 2000  
Principal Investigator: Laurel A. Habel, PhD  
Goals/Objectives: Using archived tissue from Kaiser Permanente patients with stomach cancer to examine differences in molecular and cellular changes in stomach cancer by H. pylori phenotype.

**Surveillance for Esophageal Carcinoma**

Source of Funding: University of California San Francisco  
Total Project Period: July 1999 – January 2000  
Principal Investigator: Theodore R. Levin, MD  
Goals/Objectives: The purpose of this study is to evaluate the effectiveness of upper endoscopy surveillance of esophageal adenocarcinoma in patients with Barrett’s Esophagus.

**Breast Cancer**

**Cancer Research Network (CRN) 7 Across Health Care Systems – Infrastructure, Screening, Breast Cancer, Tobacco**

Source of Funding: National Cancer Institute  
Total Project Period: January 1999 – December 2002  
Principal Investigators: Lisa J. Herrinton, PhD  
M. Michele Manos, PhD  
Nancy P. Gordon, ScD  
Carol Somkin, PhD  
Goals/Objectives: The overall goal of the CRN is to increase the effectiveness of preventive, curative and supportive interventions for major cancers, through a program of collaborative research to determine the effectiveness of cancer control interventions that span the natural history of major cancers among diverse populations and health systems. The 10 health plans, with approximately 9 million enrollees, are distinguished by their longstanding commitment to prevention and research, and collaboration among themselves and with affiliated academic institutions. The CRN includes an Infrastructure, three Research Projects, and an Evaluation. The three Research Projects examine the effectiveness and cost-effectiveness of cancer control interventions across several HMOs. They include:  
Project 1 - "Tobacco Control in Managed Care: Implementation Effectiveness and Impact on Cost of Care"  
Project 2 - "Toward Reducing Late Stage Breast and Cervical Cancer"  
Project 3 - "Effectiveness of Early Screening and Prophylactic Mastectomy in Women at Increased Risk for Breast Cancer"  
An additional important aim is to develop and test methods to increase the participation of HMO patients in cancer clinical trials.

**DCIS: Mammographic Features and Prognosis**

Source of Funding: National Cancer Institute  
Total Project Period: May 1999 – February 2004  
Principal Investigator: Laurel A. Habel, PhD  
Goals/Objectives: Among Kaiser Permanente members diagnosed with DCIS from 1990 to 1997 and treated with breast-conserving surgery, to determine whether mammographic features of the breast at diagnosis predict risk of subsequent ipsilateral breast cancer.

**Induced Abortion and Breast Cancer Risk**

Source of Funding: National Cancer Institute  
Total Project Period: August 1998 – May 2002  
Principal Investigator: De-Kun Li, MD, PhD  
Goals/Objectives: A population-based case-control study that will examine the association of induced abortion with breast cancer risk. To increase the accuracy of information on induced abortion, the study will be conducted in Shanghai, China, where induced abortion is not stigmatized and where family planning records document reproductive history. The study will also examine the effect of maternal age, parity, and gestational age at the procedure on the risk of breast cancer.

**Life After Cancer Epidemiology (LACE)**

Source of Funding: National Cancer Institute  
Total Project Period: May 1999 – February 2004  
Principal Investigators: Bette J. Caan, DrPH  
Erica P. Gunderson, PhD  
Goals/Objectives: This proposal is intended to examine how behavioral correlates, especially diet, exercise and weight gain, measured subsequent to breast cancer diagnosis and treatment, affect recurrence of secondary tumors and new primaries. Secondly, we will examine the effects of diet and exercise on weight gain and weight gain and exercise on quality of life.

**Mammographic Density and Breast Cancer After DCIS**

Source of Funding: National Cancer Institute  
Total Project Period: July 1999 – June 2001  
Principal Investigator: Laurel A. Habel, PhD  
Goals/Objectives: To determine whether mammographic density at diagnosis of DCIS is associated with the risk of second breast cancer among patients in the National Surgical Adjuvant Breast and Bowel Program (NSABP) B-17 clinical trial.

**Management Options for Women at Potential Risk for Inherited Breast Cancer in a Multiethnic Health Plan Population: A Randomized Control Trial**

Source of Funding: United States Army Medical Research and Development Command  
Total Project Period: September 1996 – September 2000  
Principal Investigator: Catherine Schaefer, PhD  
Goals/Objectives: A randomized controlled trial of three tailored interventions that can be used to educate women from diverse populations about the decision to undergo genetic testing for inherited susceptibility to breast cancer.

**Preventive Oncology Academic Award**

Source of Funding: National Cancer Institute  
Total Project Period: May 1996 – April 2001  
Principal Investigator: Lisa A. Herrinton, PhD  
Goals/Objectives: To obtain training and experience needed to become an independent investigator with emphasis in expanding knowledge of B-cell neoplasia to include non-Hodgkin's lymphoma.

**Recurrence and Survival Among Women Diagnosed with Breast Cancer While Pregnant**

Source of Funding: Kaiser Foundation Research Institute  
Total Project Period: January 2000 – December 2000  
Principal Investigator: Catherine Schaefer, PhD  
Goals/Objectives: This study complements the study titled " Safety of Pregnancy After Breast Cancer" through comparison of a sample of women diagnosed with breast cancer while pregnant with a matched sample of controls who did not become pregnant after diagnosis of breast cancer. This study uses the control pool developed for the larger study. The aim is to determine the effect of pregnancy ( and its attendant changes in hormonal status) on reoccurrence and survival of breast cancer.

**Safety of Pregnancy After Breast Cancer**

Source of Funding: United States Army Medical Research and Development Command (subcontract from Columbia University)  
Total Project Period: September 1996 – September 2000  
Principal Investigator: Catherine Schaefer, PhD  
Goals/Objectives: This study compares recurrence rates and disease-free survival of women who became pregnant following treatment for breast cancer and a matched group of women with a history of breast cancer who did not become pregnant after treatment of their cancer.

**Study of Tamoxifen and Raloxifene (STAR)**

Source of Funding: National Surgical Adjuvant Breast and Bowel Project (NSABP)  
National Cancer Institute  
Total Project Period: October 1998 - planned to be 10-15 year study  
Co-Principal Investigator: Carol P. Somkin, PhD  
Goals/Objectives: A multi-site randomized controlled trial to compare the effectiveness of tamoxifen and raloxifene in reducing incidence of invasive breast cancer and their associated side effects among women at high risk for breast cancer.

**Tubal Sterilization and Breast Cancer Risk**

Source of Funding: Kaiser Foundation Research Institute  
Total Project Period: January 2000 – December 2000  
Principal Investigator: Laurel A. Habel, PhD  
Goals/Objectives: Tubal sterilization is considered a safe and effective method of permanent birth control; however, the long-term sequel of this procedure are not fully known. It has been hypothesized that local damage and scarring of the perineum can occur, leading to decreased blood flow to the ovaries and lower levels of ovarian hormone production. Recently, others have reported an inverse association of tubal sterilization with breast cancer mortality, offering support of a possible protective effect of sterilization on breast cancer risk. In the current investigation, we propose to use an existing database of 39,502 sterilized women and 40,505 matched controls from the Kaiser Permanente health plan to study the relative incidence of breast cancer after sterilization. In addition to the overall relative risk, we will examine the relative risk of breast cancer associated with different methods of tubal sterilization.

**Women’s Intervention Nutrition Study (WINS): Low-Fat Diet in Localized Breast Cancer- Outcome Trial**

Source of Funding: National Cancer Institute (subcontract from the American Health Foundation)  
Total Project Period: September 1993 – December 2001  
Principal Investigator: Bette J. Caan, DrPH  
Goals/Objectives: To assess the efficacy of a low-fat diet on survival after treatment of localized breast cancer.

**Women’s Healthy Eating and Living (WHEL) Trial: A Randomized Controlled Trial of the Effect of a Plant-Based Diet on Breast Cancer Recurrence**

Source of Funding: National Cancer Institute (subcontract from University of California, San Diego)  
Total Project Period: December 1997 – November 2001  
Principal Investigator: Bette J. Caan, DrPH  
Goals/Objectives: To evaluate the effect of a low fat, high fruit and vegetable diet on breast cancer survival and recurrence in women with early stage breast cancer.

**Young Breast Cancer Survivors: A Population Based Cohort**

Source of Funding: National Cancer Institute  
Total Project Period: September 1998 – September 2002  
Principal Investigator: Carol P. Somkin, PhD  
Goals/Objectives: To develop a survey questionnaire, recruit and conduct focus groups to determine the needs of women originally diagnosed with breast cancer before the age of 50 who have not had a recurrence for five years.

**Cervical Cancer**

**Towards Avoiding Cervical and Late-Stage Breast Cancers: A Program Project Award Increasing Effectiveness of Cancer Control Interventions: The HMO Research Network**

Source of Funding: National Cancer Institute  
Total Project Period: January 1999 – December 2002  
Principal Investigator: M. Michele Manos, PhD  
Goals/Objectives: To understand the failure (in screening, detection, and follow-up) that account for the occurrence of cervical cancer and late-stage breast cancer in women who are HMO members.

**Colorectal Cancer**

**Adding New Fecal Occult Blood Tests to Sigmoidoscopy**

Source of Funding: National Cancer Institute  
Total Project Period: May 1997 – April 2001  
Principal Investigator: Theodore R. Levin, MD  
Goals/Objectives: To evaluate the added yield and added cost of adding a new fecal occult blood test (FOBT), the combination FOBT, to an existing colorectal cancer screening program relying on sigmoidoscopy alone.

**Diet, Activity and Reproduction as Risks for Rectal Cancer**

Source of Funding: National Cancer Institute (subcontract from University of Utah)  
Total Project Period: August 1997 - July 2002  
Principal Investigator: Donna Schaffer, RD, MPH  
Goals/Objectives: To examine the environmental and genetic risk factors for rectal cancer and the interactive effects of these risks.

**Prostate Cancer**

**California Men's Study (CMS): A prospective Cohort Study for Prostate Cancer**

Source of Funding: California Department of Health Services  
Total Project Period: June 2000 – May 2002  
Principal Investigator: Bette J. Caan, DrPH  
Goals/Objectives: This prospective study of 100,000 Northern and Southern California Kaiser Permanente members between the ages of 45 and 69 will examine behavioral and demographic characteristics related to incident prostate cancer among men of different ethnicities.

**Case-Control Study of Prostate Cancer Screening and Mortality Feasibility Study for Prostate Cancer Screening**

Source of Funding: Centers for Disease Control and Prevention  
Total Project Period: September 1998 – December 2001  
Principal Investigator: Stephen K. Van Den Eeden, PhD  
Goals/Objectives: This is a case-control study to assess the efficacy of PSA screening to reduce prostate cancer mortality.

**Saw Palmetto Extract in Benign Prostatic Hyperplasia**

Source of Funding: National Institute of Diabetes and Digestive and Kidney Diseases  
Total Project Period: August 1999 – July 2002  
Principal Investigator: Andrew L. Avins, MD  
Goals/Objectives: This study is a double-blind, placebo-controlled randomized clinical trial of the effect saw palmetto extract on symptoms, objective parameters of disease severity, and quality of life in men with moderate-to-severe benign prostatic hyperplasia.

## Cardiovascular Disease

### CARDIOVASCULAR DISEASE (also see Women's Health)

#### **A New Assay for Cholesterol as a Predictor of Coronary Disease**

Source of Funding: Otsuka Pharmaceutical Company  
Total Project Period: June 1996 – December 2001  
Principal Investigator: Joseph F. Terdiman, MD, PhD  
Goals/Objectives: A retrospective case-control study for a new lipoprotein-cholesterol assay using frozen plasma taken from patients with and without angiographically documented coronary artery disease. The test may provide a clinically practical method to predict progression of coronary artery disease and subsequent coronary events.

#### **A Study of the “Early Repolarization Normal Variant” ECG Pattern: A Common and Vexing Problem**

Source of Funding: Kaiser Foundation Research Institute  
Total Project Period: January 1999 – December 2000  
Principal Investigator: Arthur L. Klatsky, MD  
Goals/Objectives: The purpose of this study is to examine the traits and medical outcomes of persons with a common (about 1-6% of all ECGs) variant pattern of the electrocardiogram (ECG), known as “early repolarization ST normal variant.”

#### **Angiography in Angina (ANGINA) Study: Cardiac Procedure Use and Outcomes in New Onset Angina**

Source of Funding: The Permanente Medical Group  
Total Project Period: July 1998 - Ongoing  
Principal Investigator: Alan S. Go, MD  
Goals/Objectives: A longitudinal cohort study of 10,627 patients with presumed new onset angina that will evaluate the variation across Northern California Kaiser Permanente facilities of invasive cardiac procedure use (coronary angiography, percutaneous transluminal coronary angioplasty, coronary artery bypass surgery) and the effect of this variation on the outcomes of incident myocardial infarction and cardiac death over three years of follow-up. This study will also assess the quality of medical care (e.g., hyperlipidemia screening and management, use of maximal anti-anginal medical therapy) and cost-effectiveness of different therapeutic strategies in patients with suspected ischemic heart disease.

#### **CARDIA Psychosocial Questionnaire**

Source of Funding: MacArthur Foundation  
Total Project Period: April 2000 – June 2001  
Principal Investigator: Stephen Sidney, MD, MPH  
Goals/Objectives: A supplementary battery of psychosocial questionnaires for participants in the CARDIA study.

#### **Cardiac Arrhythmia Patient Outcomes Research Team**

Source of Funding: Agency for Health Care Policy and Research  
Total Project Period: August 1994 – January 2000  
Principal Investigator: Joseph V. Selby, MD, MPH  
Goals/Objectives: To 1) follow a cohort of patients with life-threatening ventricular arrhythmias, 2) assess functional status and quality of life, depression and anxiety, arrhythmia-related symptoms, 3) measure and study determinants of outcomes including underlying disease and its severity, comorbid conditions, therapies, diagnostic practices, and patient preferences/values, and 4) understand selection of treatment and maintenance of treatment as a function of patient role in decision-making.



**Cardiovascular Disease Research Interest Group**

Source of Funding: Merck/TAP  
Total Project Period: November 2000 – December 2002  
Principal Investigator: Alan S. Go, MD  
Goals/Objectives: To support the development and growth of cardiovascular research at the Division of Research.

**Clinical and Genetic Predictors of Myocardial Infarction in Coronary Disease**

Source of Funding: Reynolds Foundation  
Total Project Period: October 2000 – September 2001  
Principal Investigator: Alan S. Go, MD  
Goals/Objectives: To determine the clinical and genetic determinants of the type of initial presentation of symptomatic ischemic heart disease and specifically fatal and non-fatal myocardial infarction within a large health maintenance organization.

**Effects of Exposure to Secondhand Smoke**

Source of Funding: Tobacco-Related Disease Research Program (TRDRP)  
Total Project Period: July 1999 – June 2001  
Principal Investigator: Carlos Iribarren, MD, MPH, PhD  
Goals/Objectives: To study the relationship between exposure to environmental tobacco smoke (ETS) and several long-term health outcomes including cardiovascular disease, smoking-related cancers and respiratory diseases.

**Epidemiology of Anticoagulation in Atrial Fibrillation**

Source of Funding: National Institutes of Health (subcontract from Massachusetts General Hospital)  
Total Project Period: September 1997 – August 2000  
Principal Investigator: Alan S. Go, MD  
Goals/Objectives: A longitudinal cohort study involving 17,124 patients to evaluate the epidemiology of non-valvular atrial fibrillation in ambulatory patients. Studies will include assessment of warfarin use for stroke prevention; determination of precise rates of stroke and major bleeding events, especially in the elderly; and ascertainment of clinical and genetic risk factors for ischemic stroke in the setting of atrial fibrillation.

**Epidemiology, Practice, Outcomes and Cost of Heart Failure in Managed Care**

Source of Funding: G.D. Searle & Company, Inc.  
Total Project Period: May 2000 – April 2002  
Principal Investigator: Alan S. Go, MD  
Goals/Objectives: This cohort study of Kaiser Permanente members hospitalized with heart failure will assess the changing epidemiology, medical and surgical therapies, variation in treatment and clinical outcomes, and identification of modifiable barriers to optimal heart failure care.

**Epidemiology: Oxidative Stress and Early Atherosclerosis**

Source of Funding: National Heart Lung and Blood Institute  
Total Project Period: April 2000 – June 2001  
Principal Investigator: Stephen Sidney, MD, MPH  
Goals/Objectives: To describe the distribution and correlation of oxidative damage and test the association between oxidative damage and clinical CHD in a cohort of 3500 black and white young men and women.

**Evaluating Pre-Hospital Delay Among Acute Myocardial Infarction Patients**

Source of Funding: Genentech, Inc  
Total Project Period: April 2000 – September 2000  
Principal Investigator: Mark Alexander, PhD  
Goals/Objectives: This study will address patient-related knowledge, perceptions, and attitudes about hypertension and blood pressure control on a random sample of hypertensive patients enrolled in Kaiser Permanente Northern California.

**Glycemic Control and Congestive Heart Failure Among Diabetics Over 20 Years Old**

Source of Funding: Kaiser Foundation Research Institute  
Total Project Period: January 1999 – September 2000  
Principal Investigator: Carlos Iribarren, MD, MPH, PhD  
Goals/Objectives: This retrospective cohort study will examine the association between metabolic control of diabetes and incidence of hospitalization for congestive heart failure (CHF) among diabetic patients in the Kaiser Permanente Northern California region, aged 20 or older.

**Lipid Profiles of Kidney Transplant Recipient Patients in a Managed Care Setting**

Source of Funding: Novartis Pharmaceuticals  
Total Project Period: June 2000 – June 2001  
Principal Investigator: Mark Alexander, PhD  
Goals/Objectives: This study will provide epidemiological data on lipid screening practices and the prevalence of dyslipidemia in patients who received a kidney transplant within Kaiser Permanente Northern California, between 1989 and 1999.

**Longitudinal Study of Coronary Heart Disease Risk Factors in Young Adults (CARDIA)**

Source of Funding: National Heart, Lung, and Blood Institute  
Total Project Period: December 1983 – November 2003  
Principal Investigator: Stephen Sidney, MD, MPH  
Goals/Objectives: To describe the distribution of coronary heart disease risk factors in a biracial cohort of men and women, aged 18-30 years at entry; to identify habits, behaviors, and life-styles that are associated with initial levels of risk factors and with the evolution of risk factors.

**Measuring Allostatic Load: A CARDIA Ancillary Study**

Source of Funding: MacArthur Research Network on Socioeconomic Status  
Total Project Period: April 2000 – June 2001  
Principal Investigator: Stephen Sidney, MD, MPH  
Goals/Objectives: A comprehensive set of physiological assessments with which to develop a summary measure of allostatic load, i.e. a multisystems conceptualization of the cumulative biological wear and tear that can result from greater stress exposure, will be obtained on 1,000 CARDIA study participants.

**Oral Contraceptives and Thromboembolic Disease**

Source of Funding: National Heart, Lung, and Blood Institute  
Total Project Period: September 1997 – August 2001  
Principal Investigator: Stephen Sidney, MD, MPH  
Goals/Objectives: To determine 1) the relative and attributable risk of venous thromboembolic disease (deep venous thrombosis and pulmonary embolism) in current users of low-dose (<50 micrograms estrogen) oral contraceptive preparations and 2) the prevalence of the factor V Leiden mutation in cases and controls and the relative and attributable risk of venous thromboembolic disease associated with its presence.

## Cardiovascular Disease (cont.)

### **Patient-Clinician Factors Influencing Racial/Ethnic Variation in the Treatment of Coronary Disease**

Source of Funding: Agency for Healthcare Research and Quality  
Center for Disease Control  
Total Project Period: August 2000 – August 2004  
Principal Investigator: Alan S. Go, MD  
Goals/Objectives: To examine the variation in the presentation to care and treatment received across race/ethnic groups with heart disease. To determine how patient attitudes, risk perception, and physician-patient communication affects treatment and cardiovascular outcomes.

### **Visceral Fat, Metabolic Rate and CHD Risk in Young Adults**

Source of Funding: National Heart, Lung, and Blood Institute  
Total Project Period: September 1995 – March 2003  
Principal Investigator: Stephen Sidney, MD, MPH  
Goals/Objectives: To determine whether there are race and gender differences in visceral adipose tissue and resting energy expenditure, and to determine the relationships of visceral adipose tissue and resting energy expenditure to risk factors for coronary heart disease.

## DIABETES (also see Women's Health)

### **A Cohort Study of the Incidence of Acute Hepatic Failure and Lesser Degrees of Liver Injury in Patients with Diabetes Mellitus**

Source of Funding: Parke-Davis Pharmaceuticals  
Total Project Period: August 1999 – February 2001  
Principal Investigator: Joseph V. Selby, MD, MPH  
Goals/Objectives: A retrospective cohort study of diabetic patients to estimate the incidence of hospitalization for acute hepatic injury by type of diabetes treatment, with particular attention to newer agents such as the thiazolidinediones.

### **Gestational Diabetes: Diagnostic Criteria and Outcomes**

Source of Funding: National Institute of Diabetes and Digestive and Kidney Diseases  
Total Project Period: September 2000 – August 2001  
Principal Investigator: Assiamira Ferrara, MD, PhD  
Goals/Objectives: The study will provide important knowledge about the risk of severe perinatal complications associated with degrees of maternal hyperglycemia below the current glucose cut-points for gestational diabetes.

### **Hormone Replacement Therapy and Cardiovascular Disease Risk in Type II Diabetics**

Source of Funding: American Heart Association  
Total Project Period: July 1998 – June 2000  
Principal Investigator: Assiamira Ferrara, MD, PhD  
Goals/Objectives: To examine whether postmenopausal hormone replacement therapy is prospectively associated with reduced risk of fatal and non-fatal ischemic heart disease and stroke among women with Type II diabetes.

### **Increasing the Evidence Base for Retinopathy Screening Guidelines**

Source of Funding: American Diabetes Association  
Total Project Period: July 2000 – June 2002  
Principal Investigator: Joseph V. Selby, MD, MPH  
Goals/Objectives: This study uses the Kaiser Permanente Diabetes Registry to explore clinical outcomes following negative retinal screening examinations and exams showing only minimal retinopathy, with the goal of identifying optimal screening intervals following these examinations.

**Insulin Resistance, Hyperglycemia, and Atherosclerosis Study (IRAS)**

Source of Funding: National Heart, Lung, and Blood Institute  
Total Project Period: September 1991 - August 2001  
Principal Investigator: Joseph V. Selby, MD, MPH  
Goals/Objectives: Multi-site cross-sectional epidemiologic study of insulin resistance, hyperinsulinemia and hyperglycemia and their associations with atherosclerotic disease and other cardiovascular disease risk factors. The Division of Research's grant calls for examination of 400 individuals, age 40 to 69 years, beginning in October 1992.

**Myocardial Infarction and Antecedent Antibiotic Use Among Patients With Diabetes Mellitus**

Source of Funding: American Diabetes Association  
Total Project Period: January 2000 – December 2000  
Principal Investigator: Andrew J. Karter, PhD  
Goals/Objectives: This is a case-control study investigation of the hypothesis that certain classes of antibiotic treatment reduce the risk of myocardial infarction in patients with diabetes mellitus.

**Natural History of Glycemic Control Among Patients With Diabetes: The Northern California Kaiser Permanente Diabetes Registry**

Source of Funding: Pfizer Inc.  
Total Project Period: June 1999 – July 2000  
Principal Investigator: Andrew J. Karter, PhD  
Goals/Objectives: This cohort study will assess how glycemic control varies with aging (“glycemic drift”), by diabetes treatment regimen, and demographic factors. Additionally, we will generate models that predict future glycemic control and that characterize those with diabetes who lack adequate glycemic control.

**Pilot Study of Trends and Risks in Gestational Diabetes**

Source of Funding: Centers for Disease Control  
Total Project Period: September 1999 – September 2001  
Principal Investigator: Assiamira Ferrara, MD, PhD  
Goals/Objectives: The purpose of this study is to estimate and describe the prevalence of pre-existing diabetes and gestational diabetes in pregnancies between 1992 and 1999 among women who were members of the Kaiser Permanente Medical Care Program of Northern California.

**Population-Level Improvements in Glycemic Control Among Patients with Diabetes: A Real Individual-Level Effect or an Ecologic Fallacy**

Source of Funding: Kaiser Foundation Research Institute  
Total Project Period: January 2000 – December 2000  
Principal Investigator: Andrew J. Karter, PhD  
Goals/Objectives: This cohort study will assess how glycemic control varies with aging (“glycemic drift”), by diabetes treatment regimen, and demographic factors. Additionally, we will generate models that predict future glycemic control and that characterize those with diabetes who lack adequate glycemic control.

**Translational Research Center for Diabetes Control Within Managed Care**

Source of Funding: Centers for Disease Control and Prevention  
Total Project Period: November 1998 – November 2003  
Principal Investigator: Joseph V. Selby, MD, MPH  
Goals/Objectives: To describe current levels of diabetes care, to analyze system-level determinants of level of care, to study health care professional and patient-level factors that influence the effectiveness of care, to develop new quality indicators, and to identify and evaluate the aim to improve levels of screening and risk management for patients with diabetes.

**Type 2 Diabetes among Children and Adolescents: Case Definitions, Characteristics and Quality of Care**

Source of Funding: Centers for Disease Control  
Total Project Period: September 1999 – March 2001  
Principal Investigator: Assiamira Ferrara, MD, PhD  
Goals/Objectives: The purpose of this study is to develop case definition(s) for diagnosis and classification of Type 1 and 2 diabetes in youths that are suitable for surveillance and/or clinical purposes and to describe the quality of care received by youths with Type 2 diabetes. This study will be conducted among children and adolescents with diabetes who were aged 10 to 19 and who were members of the Kaiser Permanente Medical Care Program of Northern California between 1992 and 1999.

HEALTH AND HEALTH CARE IN THE ELDERLY

**Can Trained Volunteers Provide Social Support and Increase Access and Health-Related Services for Functionally Disabled Adults?**

Source of Funding: Interregional Committee on Aging  
Kaiser Foundation Hospitals, Direct Community Benefit Investment Program  
Total Project Period: October 1998 – September 2000  
Principal Investigator: Enid M. Hunkeler, MA  
Goals/Objectives: To develop and evaluate a multi-divisional, six site project to train volunteers to provide emotional comfort, social and instrumental support and increased access to health and community services for a diverse population of elderly and functionally disabled adults.

**Corticosteroid-Induced Osteoporosis (CIO): Identification of Patients at Risk**

Source of Funding: Proctor and Gamble  
Total Project Period: February 2000 – July 2000  
Principal Investigator: Bruce Ettinger, MD  
Goals/Objectives: A study of Kaiser Permanente patients who are on high dosage corticosteroids. The study will develop methods for identification from PIMS and will examine what percentage of high risk patients are receiving osteoporosis prevention therapy.

**Epidemiology of Aging and Physical Function**

Source of Funding: National Institute of Aging  
Total Project Period: June 1998 – March 2002  
Principal Investigator: Barbara Sternfeld, PhD  
Goals/Objectives: To test the importance of physical activity for maintaining health and independence in the elderly population.

**Epidemiology of Fractures in Persons Age 45 and Older**

Source of Funding: National Institute of Arthritis and Musculoskeletal and Skin Diseases  
Total Project Period: May 1996 – April 2001  
Principal Investigator: Stephen Sidney, MD, MPH  
Goals/Objectives: To perform a case-control study of fractures of the distal forearm, foot, proximal humerus, pelvis, and shaft of the tibia and fibula among females and males of age 45 years and older in an ethnically diverse population

**Treatment of Depression Among the Elderly**

Source of Funding: California Healthcare Foundation  
Total Project Period: January 1999 – December 2002  
Principal Investigator: Enid M. Hunkeler, MA  
Goals/Objectives: To compare disease management of depression in primary care to usual care in the treatment of older adults, particularly minority and severely chronically ill elderly.

HEALTH SERVICES (also see Alcohol and Other Drugs, Cancer, Women's Health)

**Health Services Research and Evaluation**

Source of Funding: Kaiser Foundation Research Institute  
Total Project Period: January 2000 – December 2000  
Principal Investigator: Enid Hunkeler, MA  
Goals/Objectives: Ongoing institutional support for studies of the effectiveness of various physician and patient education programs, including Kaiser Permanente's alcohol and drug abuse treatment programs.

**Disease Management**

**Asthma Care Quality in Varying Managed Medicare Plans**

Source of Funding: American Association of Health Plans Foundation  
Agency for Health Care Policy and Research  
Total Project Period: July 1998 - March 2001  
Principal Investigator: Tracy A. Lieu, MD, MPH  
Goals/Objectives: To evaluate health plan, provider group, clinician, and patient-level features associated with quality of care for children with asthma insured by Medicaid.

**Evaluation of Care Manager Programs for Four Chronic Conditions**

Source of Funding: Operation Support Services  
Total Project Period: March 2000 – December 2001  
Principal Investigator: Bruce Fireman, MA  
Goals/Objectives: To evaluate five specialized care manager programs in Kaiser Permanente - Northern California (Cholesterol Management, Multifit Cardiac Rehabilitation, Heart Failure, Asthma, and Diabetes). For each program, the questions addressed are: What has been the impact of the program on the quality of care? What has been the impact of the program on the cost of care? Does the program increase quality and efficiency enough to justify its cost?

**Health-Related Quality of Life Adults With Asthma and Allergy in a Health Maintenance Organization**

Source of Funding: Integrated Therapeutics Group  
Total Project Period: October 1998 – July 2000  
Principal Investigator: Lynn M. Ackerson, PhD  
Goals/Objectives: To describe health-related quality of life among adults with asthma and in adults with only allergy using a generic and two disease specific measures, and to evaluate the ability of the measures to predict future asthma- and allergy-related health care utilization.

**Stomach Study - Study of Management and Costs of Helicobacter Pylori Infection**

Source of Funding: Astra Merck (May 1996 – June 2000)  
Beckman Coulter, Incorporated (October 1994 – December 1998)  
Total Project Period: October 1994 – June 2000  
Principal Investigator: James E. Allison, MD, FACP  
Goals/Objectives: An unblinded randomized controlled trial assessing clinical and cost-effectiveness of different workup and therapeutic strategies for patients on chronic acid reduction therapy for peptic ulcer disease or ulcer like dyspepsia. Objectives are 1) determine if patients requiring frequent use of stomach acid reducing drugs for ulcer or ulcer-like symptoms are infected with H. pylori, and 2) determine if eliminating the bacteria in those who have it will prevent recurrence of symptoms once stomach acid reducing drugs are stopped.

**Cost/Cost-effectiveness Studies**

**A Study to Develop and Evaluate an Instrument to Predict Utilization and Costs for Patients With GERD**

Source of Funding: TAP Holdings, Incorporated  
Lewin-TAG, Incorporated  
Total Project Period: July 1998 - June 2000  
Principal Investigator: Theodore R. Levin, MD  
Goals/Objectives: To describe the health care utilization costs incurred by a cohort of patients with GERD, and to describe the predictors of high cost utilization using self-report, clinical and administrative data.

**Cost of Obesity Follow-Up**

Source of Funding: Amgen Pharmaceuticals  
Total Project Period: January 1999 – December 2000  
Principal Investigator: Charles P. Quesenberry Jr., PhD  
Goals/Objectives: This study relates changes in weight to changes in co-morbidity status and costs of care through electronic administrative databases and questionnaires.

**Cost of Screening Sigmoidoscopy**

Source of Funding: National Cancer Institute  
Total Project Period: September 1999 – August 2000  
Principal Investigator: Chris J. Colby, PhD  
Goals/Objectives: The purpose of this study is to precisely estimate the cost of delivering screening sigmoidoscopy in a large HMO population.

**Integrated Drug and Medical Care: Cost and Effectiveness**

Source of Funding: National Institute on Drug Abuse  
Total Project Period: September 1996 - August 2000  
Principal Investigator: Constance M. Weisner, DrPH, MSW  
Goals/Objectives: This project compares the effects of two models of service delivery, post-treatment outcome, patient characteristics associated with successful treatment outcomes, the costs of integrated and independent conditions, and assesses the cost effectiveness of the two sets of service arrangements. The two conditions are: 1) “integrated” services, where patients receive all their primary health care from medical personnel within the substance abuse unit itself, and 2) an “independent” treatment as usual group, where patients receive their primary health care through the regular HMO clinics.

**Improving Quality of Care by Restructuring Provider Payments**

Source of Funding: Robert Wood Johnson Foundation  
Total Project Period: February 1997 – January 2000  
Principal Investigator: Joseph V. Selby, MD, MPH  
Goals/Objectives: To examine the costs and the outcomes of care for some of the leading and most costly chronic conditions in a managed care setting with the purpose of identifying new methods for capitating populations that take into account both underlying risks and the performance of the health care plan.

**Obesity Registry Pilot study**

Source of Funding: Roche Laboratories  
Total Project Period: March 2000 – September 2000  
Principal Investigator: Charles P. Quesenberry Jr., PhD  
Goals/Objectives: The objective of this study is to develop a sampling frame for a cohort study to examine the effects of weight and weight change on the prevalence and incidence of obesity related comorbidities, costs of care, quality of life, and for the study of the effectiveness of obesity treatments.

## Health Services – Cost /Cost-effectiveness Studies (cont.)

### **Utilization, Quality of Life, and Direct Medical Costs Associated in Treated and Untreated Urinary Incontinence**

Source of Funding: Pharmacia  
Total Project Period: June 2000 – May 2001  
Principal Investigator: Stephen K. Van Den Eeden, PhD  
Goals/Objectives: This study will estimate the differences in costs and quality of life between treated and untreated urinary incontinence among women.

### **Primary Care**

#### **Improving the Physician - Patient Match in HMO's**

Source of Funding: Robert Wood Johnson Foundation  
Total Project Period: October 1998 – September 2000  
Principal Investigator: Joseph V. Selby, MD, MPH  
Goals/Objectives: A randomized trial conducted at the Santa Clara medical center to evaluate three approaches to assisting adult members in choosing a new primary care physician. The study found that encouraging and helping members select a physician led to greater satisfaction, trust, and retention of the primary care physician at one year compared to assigning the member to a physician.

#### **Evaluation of Centralized Call Centers in Kaiser Permanente Northern California and Colorado Regions**

Source of Funding: Garfield Memorial Fund  
Total Project Period: October 1999 – September 2000  
Principal Investigator: Bruce Fireman, MA  
Goals/Objectives: To compare patient access to care, patient and provider satisfaction, and health care utilization and associated costs before and after establishment of a Centralized Call Center Advice Function.

#### **Impact of the Adult Primary Care Redesign in Northern California on Quality, Cost, Patient Satisfaction and Physician Satisfaction**

Source of Funding: Garfield Memorial Fund  
Total Project Period: October 1999 – October 2001  
Principal Investigator: Bruce Fireman, MA  
Goals/Objectives: Evaluate the Adult Primary Care redesign, assessing its consequences for patient satisfaction, quality of care, use of services, cost and efficiency of care, and provider satisfaction.

### **Screening**

#### **Cancer Screening, Managed Care and the Underserved**

Source of Funding: National Cancer Institute (subcontract from Northern California Cancer Center)  
Total Project Period: February 1998 – November 2003  
Principal Investigator: Carol P. Somkin, PhD  
Goals/Objectives: A multi-site program project to increase breast and cervical cancer screening and improve follow-up among low income multi-ethnic women. To develop items to measure core survey domains including satisfaction with screening and with providers, satisfaction with cultural competence, as well as access to services and health care skills, and to conduct methodological studies on accuracy of self report and attrition.



**BAT-26 Mutations and Flexible Sigmoidoscopy Colorectal Cancer Screening**

Source of Funding: EXACT Labs  
Total Project Period: October 2000 – August 2001  
Principal Investigator: Theodore R. Levin, MD  
Goals/Objectives: An evaluation of the potential value of BAT-26 mutations and microsatellite instability in the detection of colorectal cancers not detected by sigmoidoscopy alone.

**Study of Sigmoidoscopy Complications**

Source of Funding: Alliance of Community Health Plans (subcontract from the Centers for Disease Control)  
Total Project Period: March 1999 – September 2000  
Principal Investigator: Theodore R. Levin, MD  
Goals/Objectives: The purpose of this study is to determine the prevalence of bowel perforation and lower gastrointestinal bleeding in the weeks immediately following flexible sigmoidoscopy and to determine whether the rate of acute coronary events is increased in the weeks following flexible sigmoidoscopy.

**Veterans Affairs Prostate Specific Antigen Prostate Cancer Study**

Source of Funding: Veterans Affairs Puget Sound  
Total Project Period: January 2000 – July 2000  
Principal Investigator: Stephen K. Van Den Eeden, PhD  
Goals/Objectives: This study is part of a larger case-control study to evaluate the effectiveness of PSA screening in reducing prostate cancer mortality.

INFECTIOUS DISEASES AND VACCINES, EXCLUDING AIDS/HIV

**A Phase III Open Label Multicenter Study of the Safety and Immunogenicity of a Booster Dose of SmithKline Beecham Biological DTPA Vaccine (Infanrix) and Pasteur Merieux's HIB Conjugate Vaccine (OmniHIB) When Administered Intramuscularly as Separate Injections Between 12 and 18 Months of Age Following Primary Immunization at the Age of 2 Months, 4 Months, and 6 Months in the Study DTPA-HBV-027(CPMS NO 217744/027)**

Source of Funding: SmithKline Beecham Pharmaceuticals  
Total Project Period: November 1999 – May 2000  
Principal Investigators: Steven Black, MD  
Goals/Objectives: Title defines study.

**Comprehensive Linked Data Collection of Medical Events and Immunization (Vaccine Safety and Development Datalink)**

Source of Funding: Centers for Disease Control and Prevention  
Total Project Period: September 1995 – September 2001  
Principal Investigators: Steven Black, MD  
Henry R. Shinefield, MD  
Goals/Objectives: To expand and maintain a large linked database which constitutes a comprehensive medical events file for an annual birth cohort of 28,000 children within Kaiser Permanente Northern California Region and to assess the rates of occurrence of medical events after immunization in children and adolescents.

**Infectious Etiology of Multiple Sclerosis: A pilot study**

Source of Funding: National Multiple Sclerosis Foundation  
Total Project Period: July 2000 – June 2001  
Principal Investigator: Gerald N. Delorenze  
Goals/Objectives: Pilot study of diagnostic confirmation of Multiple Sclerosis among patients with frozen serum specimens from Multiphasic exams. The results will contribute to a larger study of the infectious etiology associated with MS.

## Infectious Diseases and Vaccines, Excluding AIDS/HIV (cont.)

### **Postmarketing Evaluation of Prevnar Pneumococcal 7-Valent Conjugate Vaccine: Local and Systematic Reactogenicity of Prevnar Administered in Catch-Up Populations of Children Aged 7 to 11 months, 12 months to 2 years, 2 to 5 years, and 5 to 9 years**

Source of Funding: Wyeth-Ayerst Pharmaceutical Corporation  
Total Project Period: May 2000 – October 2000  
Principal Investigators: Steven Black, MD  
Goals/Objectives: Title defines study.

## MENTAL HEALTH

### **Improving Care of Depression**

Source of Funding: National Institute of Mental Health (subcontract from RAND Corporation)  
Total Project Period: September 1995 - August 2000  
Principal Investigator: Nancy P. Gordon, ScD  
Goals/Objectives: This study, being conducted collaboratively with researchers from the RAND Corporation, was designed to determine whether team-based quality improvement approaches are more effective than guideline distribution alone for increasing adherence to clinical practice guidelines for management of major depression in the primary care (adult medicine) setting. Additionally, it evaluated the use of interventions developed by the teams to enhance assessment and follow-up of patients whom primary care providers suspected were clinically depressed.

### **Prenatal Determinants of Schizophrenia**

Source of Funding: National Institute of Mental Health (subcontract from Research Foundation for Mental Hygiene)  
Total Project Period: January 1997 – December 2000  
Principal Investigator: Catherine Schaefer, PhD  
Goals/Objectives: To investigate the relation of prenatal exposures to the development of schizophrenia in adults, using a cohort of 19,000 individuals born in 1959-66 and continuously followed as Kaiser Health Plan members into adulthood.

### **Screening and Follow-up for Postpartum Depression at Pediatric Well-Baby Visits**

Source of Funding: Kaiser Foundation Hospitals, Innovation Program  
Total Project Period: November 1998 - October 2000  
Principal Investigator: Catherine Schaefer, PhD  
Goals/Objectives: The aim of this study is to : 1) determine the prevalence of untreated postpartum depression in the Kaiser Permanente population, 2) test the effectiveness of screening for postpartum depression and referral for treatment scheduled well-baby visits in decreasing prevalence of untreated depression and improving outcomes of depression at 6 months postpartum well-baby visits.

### **The Depression Initiative**

Source of Funding: Garfield Memorial Fund  
Eli Lilly and Company  
SmithKline Beecham  
Pfizer, Incorporated  
Kaiser Foundation Hospitals, Direct Community Benefit Investment Program  
Total Project Period: September 1997 - Ongoing  
Principal Investigator: Enid M. Hunkeler, MA  
Goals/Objectives: A national initiative to fund, solicit, conduct and disseminate innovative, practical research to improve care for depression.

## Mental Health (cont.)

### **The Efficacy of Nurse Telephone Follow-Up and Peer Support in Treating Depression in Primary Care**

Source of Funding: SmithKline Beecham  
The Permanente Medical Group, Innovations Program  
Kaiser Foundation Hospitals, Direct Community Benefit Investment Program  
The Depression Initiative

Total Project Period: September 1997 - January 2001

Principal Investigator: Enid M. Hunkeler, MA

Goals/Objectives: To evaluate the efficacy of nurse telehealth care with or without peer support to improve patient outcomes and patient satisfaction for depressed patients treated in the primary care setting.

### **The Impact of Mental Health Problems on the Use of Non-Psychiatric Health Services in a Managed Care Setting**

Source of Funding: DuPont Merck Pharmaceuticals  
Agency for Health Care Policy and Research (AHCPR)

Total Project Period: May 1998 - May 2005

Principal Investigators: Enid M. Hunkeler, MA; William D. Spector, PhD (AHCPR)

Goals/Objectives: A collaborative effort with AHCPR to determine the health care utilization and cost of patients with sub-clinical and clinical depression and their families. It also explores the importance of psychiatric co-morbidities, role dysfunction and utilization and cost.

## NEUROLOGICAL DISEASE

### **Epidemiology of Primary and Secondary Dystonia in a Multi-Ethnic Population: "A Pilot Planning Grant"**

Source of Funding: Parkinson's Institute

Total Project Period: April 2000 – March 2002

Principal Investigator: Stephen K. Van Den Eeden, PhD

Goals/Objectives: This is a pilot study to develop diagnostic criteria for dystonia that can be used in large scale epidemiologic studies. In addition, this study will develop the epidemiologic case identification and confirmation process that can be used in a large managed care organization.

### **Establishing a Traumatic Brain Injury Registry and Tracking System**

Source of Funding: Kaiser Permanente Innovation Program

Total Project Period: January 2000 – December 2001

Principal Investigator: Joseph F. Terdiman, MD, PhD

Goals/Objectives: To develop a Web-based computer system to promote early identification and monitoring of the traumatic brain injury population, to assure provision of cost-effective care and optimal clinical management.

### **Explaining the Inverse Smoking Relation to Parkinson's Disease (PD)**

Source of Funding: Tobacco-Related Disease Research Program (TRDRP)

Total Project Period: July 1999 – June 2002

Principal Investigator: Stephen K. Van Den Eeden, PhD

Goals/Objectives: The study objectives are focused on investigating selected mechanisms that may explain the inverse association that has been observed between smoking and PD.

**Parkinson's Disease and Quality of Life, Utilization and Natural History**

Source of Funding: Pharmacia & Upjohn  
Total Project Period: September 1999 – March 2001  
Principal Investigator: Stephen K. Van Den Eeden, PhD  
Goals/Objectives: This study will assess predictors of quality of life, utilization and change in disease progression over time among an inception cohort of 496 men and women with Parkinson's disease.

**Predictors of Spontaneous Cerebral AVM Hemorrhage**

Source of Funding: University of California at San Francisco  
National Institute of Neurological Disorders and Stroke  
Total Project Period: February 2000 – August 2002  
Principal Investigator: Stephen Sidney, MD, MPH  
Goals/Objectives: A study of the natural history of cerebral arteriovenous malformations (AVMs) including the incidence, prevalence, treatment, and hemorrhage rates.

PREGNANCY AND CHILD HEALTH

**5 Year Outcome of Severe Neonatal Jaundice & Dehydration**

Source of Funding: National Institute of Neurological Disorders and Stroke (subcontract from University of California San Francisco)  
Total Project Period: July 1999 – June 2000  
Principal Investigators: Gabriel J. Escobar, MD  
Tom Newman, MD  
Goals/Objectives: This project will assess neurodevelopmental outcome at 5 years of age of children who had (a) severe neonatal jaundice (serum bilirubin  $\geq$  25.0 mg/dl) and/or (b) severe neonatal dehydration (weight loss  $\geq$  12% of birth weight and/or serum sodium  $\geq$  150 mEq/L).

**A Perinatal Health Services Research Laboratory Pilot**

Source of Funding: Agency for Healthcare Research and Quality  
Total Project Period: September 2000 – September 2001  
Principal Investigator: Gabriel J. Escobar, MD  
Goals/Objectives: To perform exploratory analyses in perinatal health services research using Kaiser Permanente datasets to design more complex projects which will enhance our future collaborations with Harvard University.

**Does Pregnancy Glycemia Predict Perinatal Complications Among Women Without Gestational Diabetes Mellitus?**

Source of Funding: American Diabetes Association  
Total Project Period: January 2000 – December 2000  
Principal Investigator: Assiamira Ferrara, MD, PhD  
Goals/Objectives: The purpose of this study is to predict subsequent selected infant perinatal complications by estimating the sensitivity and specificity over a range of maternal glucose levels that were obtained during screening and diagnostic tests for gestational diabetes. The study will be conducted among women without gestational diabetes who were members of the Kaiser Permanente Medical Care Program of Northern California between 1995 and 1998.

## Pregnancy and Child Health (cont.)

### **Drinking Water and Spontaneous Abortion**

Source of Funding: Sequoia Foundation  
Total Project Period: January 2000 – January 2002  
Principal Investigator: De-Kun Li, MD, PhD  
Goals/Objectives: This study will determine whether drinking tap water during pregnancy increases a woman's risk of spontaneous abortion.

### **Estimating Ectopic Pregnancy Prevalence and Treatment Choices**

Source of Funding: Centers for Disease Control and Prevention  
Total Project Period: October 1999 – September 2000  
Principal Investigator: Stephen K. Van Den Eeden, PhD  
Goals/Objectives: To estimate the prevalence and treatment of ectopic pregnancy within Kaiser Permanente, Northern California Region .

### **Feasibility Study of Staged Tailored Reproductive Health Counseling for Adult Women Obtaining a Pregnancy Tests in a Managed Care Setting**

Source of Funding: Centers for Disease Control and Prevention  
Total Project Period: December 1999 – October 2001  
Principal Investigator: Annette Aalborg, PhD  
Goals/Objectives: To test the feasibility and effectiveness of providing reproductive health counseling in a managed care setting for adult women who are at risk for unintended pregnancy and/or STD/HIV infection. In-person counseling and telephone follow-up will be available at the point of obtaining a pregnancy test for women who receive a negative pregnancy test and do not want to be pregnant. Effectiveness will be measured by assessing short-term behavioral changes related to preventing unintended pregnancy and/or STD/HIV infection.

### **Home Versus Group Visits After Early Postpartum Discharge**

Source of Funding: Maternal and Child Health Bureau  
Garfield Memorial Fund  
Kaiser Foundation Hospitals, Innovation Program  
Total Project Period: October 1997 – October 2000  
Principal Investigators: Tracy A. Lieu, MD, MPH  
Gabriel J. Escobar, MD  
Goals/Objectives: To compare the clinical outcomes, patient satisfaction and costs associated with home visit versus group clinic visit follow-up for mothers and infants who experience early postpartum hospital discharge.

### **How Much Does She Really Drink? An HMO Intervention**

Source of Funding: National Institute of Alcoholism and Alcohol Abuse  
Total Project Period: September 1999 – June 2000  
Principal Investigator: Gabriel J. Escobar, MD  
Goals/Objectives: This 5 year RCT will compare perinatal outcomes among women who use alcohol in pregnancy and who are randomized to: a) usual substance abuse rehabilitation, or b) a special intervention on alcohol use.

## Pregnancy and Child Health (cont.)

### **Individual, Family and Societal Outcomes of Infertility**

Source of Funding: National Institute of child Health and Human Development  
Total Project Period: October 1999 – June 2001  
Principal Investigator: De-Kun Li, MD, PhD  
Goals/Objectives: This retrospective cohort study will examine whether pregnancies occurring in infertility patients are at higher risk for adverse outcomes, including pregnancy complications, labor and delivery complications, neonatal and pediatric outcomes, as compared to pregnancies conceived by fertile women.

### **Infant Sleep Position and Sudden Infant Death Syndrome (SIDS) Risk**

Source of Funding: National Institutes of Child Health and Human Development  
Total Project Period: February 1995 - February 2002  
Principal Investigator: De-Kun Li, MD, PhD  
Goals/Objectives: This population-based multi-center case-control study is intended to 1) determine the risk of SIDS associated with sleeping in the prone or side positions relative to supine position in the Northern and Southern California population, 2) identify any factors that exacerbate the association of sleeping position with the risk of SIDS, 3) establish baseline information on the prevalence of each sleeping position, and 4) evaluate the potential impact of the Aback-to-sleep® campaign on the prevalence of sleeping positions.

### **Is Maternal Impaired Glucose Metabolism Associated with Increased Risk of Infant Prematurity**

Source of Funding: Kaiser Foundation Research Institute  
Total Project Period: January 2000 – December 2000  
Principal Investigator: Assiamira Ferrara, MD, PhD  
Goals/Objectives: To investigate whether the risk of infant prematurity increases across a spectrum of maternal glucose tolerance categories during pregnancy.

### **Maternal - Fetal HLA Sharing and the Risk of Preterm Delivery**

Source of Funding: Kaiser Foundation Research Institute  
Total Project Period: January 2000 – December 2000  
Principal Investigator: De-Kun Li, MD, PhD  
Goals/Objectives: The purpose of this study is to conduct a population-based sib-matched case-control study to examine whether maternal-fetal sharing of human leukocyte antigens is associated with risk of preterm delivery.

### **Prospective Epidemiologic Study of Spontaneous Abortion and Electromagnetic Field (EMF) Exposure**

Source of Funding: California Public Health Foundation  
Total Project Period: May 1996 – June 2001  
Principal Investigator: De-Kun Li, MD, PhD  
Goals/Objectives: To 1) determine whether exposure to an EMF increases the risk of spontaneous abortion of a clinically confirmed pregnancy, 2) determine whether prenatal EMF exposure increases the risk of spontaneous abortion in a susceptible subgroup of women who have a history of subfertility and/or multiple spontaneous abortions, 3) provide preliminary information on the relationship of prenatal EMF exposure with time to pregnancy and with the risk of other pregnancy outcomes including low birth weight, pre-term delivery and still birth, and 4) create a database and establish a well-defined study population for possible future study of the effect of EMF exposure on reproductive outcomes.

## Pregnancy and Child Health (cont.)

### Practice Standards for Newly Diagnosed ADHD

Source of Funding: Kaiser Foundation Research Institute  
Total Project Period: January 2000 – December 2000  
Principal Investigator: Laurel A. Habel, PhD  
Goals/Objectives: To examine the clinical management (including specialty care and pharmacologic treatment) of Kaiser Permanente health plan members under the age of 18 years who are newly diagnosed with ADHD.

### Rapid Retrieval of Intermediate Outcomes Data in Newborns: The Kaiser Permanente Neonatal Minimum Data Set (NMDS)

Source of Funding: Kaiser Foundation Health Plan  
Total Project Period: November 1993 - Ongoing  
Principal Investigator: Gabriel J. Escobar, MD  
Goals/Objectives: The NMDS is a wide area network linking 8 nurseries in Northern California. It is being used to 1) monitor neonatal outcomes and utilization 2) develop a simplified severity of illness scale, the Score for Neonatal Acute Physiology, version II (SNAP-II) in collaboration with Harvard University and the University of British Columbia at Vancouver and 3) serve as a test-bed for research on medical informatics.

### Risk Adjusted Pregnancy Outcomes in Northern California

Source of Funding: Kaiser Foundation Hospitals, Innovation Program  
Total Project Period: September 1997 – June 2000  
Principal Investigator: Gabriel J. Escobar, MD  
Goals/Objectives: To measure inter-facility variation in pregnancy outcomes in 1995-97 in the Kaiser Permanente Medical Care Program.

### SNAP-II

Source of Funding: Avandel Corporation  
Total Project Period: December 1999 – December 2001  
Principal Investigator: Gabriel J. Escobar, MD  
Goals/Objectives: Using the "Score for Neonatal Acute Physiology (SNAP)," Version II, the objective of this study is to develop a predictive model for resource consumption among newborns admitted to neonatal intensive care.

### Steppin' in Synch': Establishing a Research and Quality Improvement Partnership Between Colorado and Northern California

Source of Funding: Garfield Memorial Fund  
Total Project Period: May 1998 - June 2001  
Principal Investigator: Gabriel J. Escobar, MD  
Goals/Objectives: This study will 1) deploy the neonatal minimum data set database at the Exempla St. Joseph Hospital in Denver, 2) define what differences, if any, exist in neonatal rehospitalization rates between Colorado and Northern California, 3) define evidence-based strategies to decrease neonatal jaundice, severe neonatal dehydration and rehospitalization for jaundice and dehydration at all severity levels, and 4) assist the Kaiser Permanente Colorado Division in developing a research capability in maternal and child health.

## Pregnancy and Child Health (cont.)

### **Unstudied Infants: Low Risk Babies in a High Risk Place**

Source of Funding: Agency for Healthcare Research and Quality  
Total Project Period: August 2000 – July 2001  
Principal Investigator: Gabriel J. Escobar, MD  
Goals/Objectives: This project will study those infants who make up the majority of neonatal intensive care unit census: those who are 30-35 weeks gestation. It will measure in-hospital utilization and morbidity as well as post-discharge (to age 3 months) outcomes in these infants. The study sites are 12 birth facilities in Massachusetts and California.

WOMEN'S HEALTH (also see CANCER, Cardiovascular Disease, Diabetes, Health Services)

### **A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of an Ultralow Dose of Estradiol Given By Continuous Transdermal Administration in the Prevention of Osteoporosis**

Source of Funding: Berlex Laboratories  
Total Project Period: December 1999 – December 2002  
Principal Investigator: Bruce Ettinger, MD  
Goals/Objectives: This study will test the ability of a quarter strength estradiol patch to prevent bone loss in women aged 60 and older.

### **Assessing the Burden of Illness of Premenstrual Symptomology**

Source of Funding: MEDSTAT ( subcontract from Eli Lilly and Company)  
Total Project Period: June 1999 – July 2000  
Principal Investigator: Barbara Sternfeld, PhD  
Goals/Objectives: To describe relations of work productivity, health care utilization, and social role functions with severity of premenstrual symptoms.

### **Continuing Outcomes Relevant to Evista (CORE): A study of Raloxifene HCl and Placebo in the prevention of Invasive Breast Cancer in Postmenopausal Women with Osteoporosis**

Source of Funding: Eli Lilly Pharmaceuticals  
Total Project Period: November 1999 – October 2003  
Principal Investigator: Bruce Ettinger, MD  
Goals/Objectives: Title defines study.

### **Epidemiology of Physical Activity and Ovarian Function**

Source of Funding: National Institutes of Health  
Total Project Period: January 1999 – June 2002  
Principal Investigator: Barbara Sternfeld, PhD  
Goals/Objectives: To examine the influence of physical activity on characteristics of the menstrual cycle, reproductive hormonal patterns and hormone-related symptoms using three different data sets.

### **Evaluation of Osteoporosis in the Elderly**

Source of Funding: National Institute on Aging (subcontract from Dartmouth University)  
Total Project Period: July 1999 – June 2000  
Principal Investigator: Bruce Ettinger, MD  
Goals/Objectives: This is a telephone survey of women starting various osteoporosis treatments to assess reasons for starting and stopping and the effects of the drug on quality of life.



**Isoflavone Clover Extracts for Menopausal Hot Flashes**

Source of Funding: University of California San Francisco  
Total Project Period: May 1999 – April 2000  
Principal Investigator: Bruce Ettinger, MD  
Goals/Objectives: A comparison of two dietary supplements to placebo in postmenopausal women with hot flashes.

**Side Effects in the Treatment with Antidepressants Among Perimenopausal and Menopausal Women (STAMP)**

Source of Funding: Bristol-Myers Squibb  
Total Project Period: August 2000 – August 2002  
Principal Investigator: Elisabeth Gruskin, DrPH  
Goals/Objectives: The STAMP study is a clinical trial looking at the side effect profiles of antidepressants in older women with an emphasis on sexual side effects and sleep.

**Smoking and Lifestyle Risk Factors for Premenstrual Changes**

Source of Funding: Tobacco Related Disease Research Program  
Total Project Period: July 1998 - June 2000  
Principal Investigator: Barbara Sternfeld, PhD  
Goals/Objectives: To understand the effect of modifiable risk factors, such as active and passive smoking, diet and physical activity, on premenstrual physical and psychological symptoms.

**Study of Women's Health Across the Nation (SWAN)**

Source of Funding: National Institute on Aging (subcontract from University of California, Davis)  
Total Project Period: September 1994 – November 2002  
Principal Investigator: Barbara Sternfeld, PhD  
Goals/Objectives: A multi-site study to follow a large, multi-ethnic sample of premenopausal women through the menopausal transition in order to investigate the influence of biological and social/cultural factors on age at menopause, symptoms of menopause and change in disease risk factor status.

**Urinary Incontinence: Reproductive and Hormonal Risk Factors**

Source of Funding: National Institutes of Health (subcontract from Stanford University)  
Total Project Period: September 1998 – September 2002  
Principal Investigators: Stephen K. Van Den Eeden, PhD  
David H. Thom, MD, PhD  
Goals/Objectives: To evaluate reproductive risk factors including during labor and delivery e.g. prolonged labor, hysterectomy and use of exogenous hormones, as a risk factor for urinary incontinence in later life.

**Women's Health Initiative (WHI): Clinical Center**

Source of Funding: National Institutes of Health  
Total Project Period: September 1994 - September 2005  
Principal Investigator: Bette J. Caan, DrPH  
Goals/Objectives: The objectives of the clinical trial are to assess the effect of hormone replacement therapy, and dietary modification, and calcium and vitamin D supplementation on coronary heart disease, breast and colorectal cancers, osteoporotic fractures, and total mortality. The objectives of the observational study are to evaluate risk factors and biomarkers for these and other important disease outcomes for women in their postmenopausal years and to provide information complementary to that obtained from the clinical trial.

## Women's Health (cont.)

### **Women's Health Initiative - The Memory Study (WHIMS)**

Source of Funding: National Cancer Institute (subcontract from Wake Forest University School of Medicine)  
Total Project Period: June 1996 - May 2002  
Principal Investigator: Bette J. Caan, DrPH  
Goals/Objectives: To examine the effect of hormone replacement therapy on progression to Alzheimer's disease.

### OTHER

### **A Phase II Trial for the Treatment of Patients who are unable to tolerate Allopurinol**

Source of Funding: ILEX  
Total Project Period: September 2000 – December 2001  
Principal Investigator: Stephen Sidney, MD, MPH  
Goals/Objectives: A study of allopurinol prescribing habits of Kaiser Permanente physicians to determine the potential feasibility of clinical trial using oxypurinol in patients who are intolerant to allopurinol.

### **Accelerating the Cycle of Research Through a Network of integrated Delivery Systems**

Source of Funding: Agency for Healthcare Research and Quality  
Total Project Period: 2000 - Ongoing  
Principal Investigator: Joseph V. Selby, MD, MPH  
Goals/Objectives: A task order Agreement between AHRQ and the HMO Research Network, coordinated by DOR.

### **CRN Project 2 (DETECT) Supplement: Design, Implementation and Analysis of Clinician Survey**

Source of Funding: National Cancer Institute  
Total Project Period: January 2000 – December 2001  
Principal Investigator: Carol P. Somkin, PhD  
Goals/Objectives: To build a population laboratory for cancer research in HMO populations.

### **Characterization of DFNA1 in Inherited Hearing Loss**

Source of Funding: National Institutes of Health (subcontract from University of Washington)  
Total Project Period: May 1997 - December 2000  
Principal Investigator: Theodore R. Levin, MD  
Goals/Objectives: To develop a cohort of individuals with non-syndromic hearing loss diagnosed under the age of 40 years to evaluate the nature and frequency in inherited mutations in known deafness susceptibility genes.

### **Cohort Study of Medical Devices**

Source of Funding: Dow Corning Corporation  
Total Project Period: June 1996 – March 2000  
Principal Investigator: Lisa A. Herrinton, PhD  
Goals/Objectives: To investigate the potential role of silicone and non-silicone containing medical devices in the etiology of cancer, connective tissue disease, autoimmune disease, and neurological disease.

### **Dietary Supplement Use by Adult Members of Kaiser Permanente Medical Care Program of Northern California**

Source of Funding: Shaklee Corporation  
Total Project Period: March 2000 – April 2001  
Principal Investigator: Donna M. Schaffer, RD, MPH  
Goals/Objectives: A survey of the supplementation practices and health behaviors of respondents to the 1999 KP Member Health Survey.

**Factors Affecting Utilization of Preventive Services by Kaiser Adolescent Members**

Source of Funding: Kaiser Foundation Research Institute  
Total Project Period: January 2000 – December 2000  
Principal Investigator: Annette Aalborg, DrPH  
Goals/Objectives: This study will provide valuable information regarding "teen friendly" methods to improve utilization of primary preventive care for Kaiser teens.

**Frozen Serum**

Source of Funding: Orentreich Foundation for the Advancement of Science (OFAS)  
Total Project Period: July 1984 -Ongoing  
Principal Investigator: Gary D. Friedman, MD, MS  
Goals/Objectives: Collaborate with OFAS to use and maintain the large Kaiser-Orentreich collection of frozen serum for medical research.

**Health Education**

Source of Funding: Kaiser Foundation Hospitals  
Total Project Period: January 2000 – December 2000  
Principal Investigator: Nancy P. Gordon, ScD  
Goals/Objectives: The goal of this DOR research program area is to improve both Kaiser's and the community's (i.e. community agencies, Health Plan members, other health plans, academic/research community, etc.) knowledge of the need for and effectiveness, feasibility, and acceptability of different types of services aimed at improving the health of health plan members and/or different segments of the community. DOR staff provide consultation to regional and medical facility departments on the evaluation of programs and services targeting patients and clinicians and, in some cases, take on the responsibility for data collection, analysis, and reporting for these evaluations on a cost-sharing basis. Active involvement in program evaluations occurs only when there is an upfront agreement from the participants that results will be shared with the community through publications or presentations.

**Improvement of Wound Care Management by Teledermatology**

Source of Funding: The Permanente Medical Group Innovation Program  
Total Project Period: January 2000 – December 2001  
Principal Investigator: Joseph F. Terdiman, MD, PhD  
Goals/Objectives: To develop a portable teledermatology unit consisting of a digital camera and laptop computer that will be carried by a wound care nurse to patients' homes and nursing homes. Digital photographs of skin lesions and clinical data will be uploaded to the teledermatology website for review by wound care specialists.

**Income, Inequality, and Work and the Health of Californians**

Source of Funding: California Wellness Foundation  
Total Project Period: January 1999 – December 2000  
Principal Investigator: Carol P. Somkin, PhD  
Goals/Objectives: To provide a forum for clearer definition of the social capital and community factors that may contribute to health and will result in a set of measures which can be used and validated in subsequent studies.

**Innovative Approaches to Managed Care – School Partnerships: Evaluation of Kaiser Permanente Cares for Kids Demonstration Project**

Source of Funding: Robert Wood Johnson Foundation  
Total Project Period: May 1999 – December 2000  
Principal Investigator: Annette E. Aalborg, PhD  
Goals/Objectives: To evaluate implementation strategies and outcomes of two managed care-school health promotions projects: “Healthy Minds” and “Hearts of Power.” Recommendations will be developed that will assist KP and other health care providers to partner with schools to enhance the health of children.

**Kaiser-Middle School Wellness and Violence Prevention**

Source of Funding: Kaiser Foundation Hospitals, Direct Community Benefit Investment Program  
Total Project Period: January 2000 – December 2001  
Principal Investigator: Annette E. Aalborg, PhD  
Goals/Objectives: The aim of this project is to develop parent and youth peer leadership, decrease violence and improve safety in the school. Students’ perceptions of safety and incidents of fighting, cutting, and suspension are measured.

**Kaiser Permanente Adult Member Health Survey**

Source of Funding: Kaiser Foundation Hospitals, Direct Community Benefit Investment Program  
The Permanente Medical Group  
Total Project Period: 1990 - Ongoing  
Principal Investigator: Nancy P. Gordon, ScD  
Goals/Objectives: The Member Health Survey has been conducted every three years since 1990 (1990, 1993, 1996, and 1999). This survey provides information about the health status, health-related risks, needs and interests of adult health plan members. These results are used by Kaiser Permanente for service planning and quality monitoring and for conducting health services and epidemiologic research. They are also made available to community health agencies, other health plans, and academic researchers through presentations, journal articles, and directly upon request providing valuable information to non-Kaiser health service planners who do not have such information available on their own service populations.

**Looking for Trouble in All the Right Places: Electronic Decision Support for Human Error Reduction in a Large Managed Care Organization**

Source of Funding: Kaiser Foundation Hospitals, Innovation Program  
National Patient Safety Foundation of the American Medical Association  
Total Project Period: September 1998 – December 2001  
Principal Investigator: Gabriel J. Escobar, MD  
Goals/Objectives: To develop electronic mechanisms for identification of human error at three Kaiser Permanente facilities.

**Member Information Project**

Source of Funding: The Permanente Medical Group, Innovation Program  
Total Project Period: October 1999 – December 2000  
Principal Investigator: Nancy P. Gordon, ScD  
Goals/Objectives: This study will pilot test collection of demographic data from adult members in Oakland and Vallejo medical center service populations via questionnaire administered at the medical facility or by mail. Questionnaire data will be linked by medical record number (MRN) with data from Kaiser Permanente clinical and administrative databases to learn whether certain member subgroups are less likely to be getting recommended health care procedures, with special focus on the association of race/ethnicity, education level, and having a usual primary care provider with guideline-concordant receipt of preventive services.

**Pancreatitis: Predictors, Clinical Traits and Sequelae**

Source of Funding: Kaiser Foundation Research Institute  
Total Project Period: January 2000 – December 2000  
Principal Investigator: Arthur L. Klatsky, MD  
Goals/Objectives: The purpose of this study is to acquire new knowledge, in a large, defined Kaiser Permanente Medical Care Program (KPMCP) population about pancreatitis, a common serious condition.

**Sentinel Surveillance for Chronic Liver Disease**

Source of Funding: Centers for Disease Control and Prevention (subcontract from Public Health Foundation, Incorporated)  
Total Project Period: May 1998 – December 2001  
Principal Investigator: M. Michele Manos, PhD  
Goals/Objectives: To determine the incidence of physician-diagnosed chronic liver disease in a defined geographic area; the relative contribution of chronic HBV, HCV, and other etiologies to the burden of disease; the influence of etiologic agent(s) and other factors on morbidity and mortality; and to monitor the incidence of and mortality from chronic liver disease in a defined geographic area over time.

**Sociodemographic Database**

Source of Funding: Garfield Memorial Fund  
Total Project Period: July 2000 – June 2001  
Principal Investigator: Nancy P. Gordon, ScD  
Goals/Objectives: This study, being conducted with the Oakland and Vallejo medical facility service populations, seeks to assess the feasibility of collecting detailed sociodemographic information on all adults in a medical facility service population and to investigate the relationship of member race/ethnicity, education, and language preference to use of health services (especially preventive medicine) and health problems (as identified from Kaiser's ICD9-coded OSCR utilization database) in order to make recommendations to health plans and quality reporting of data that will be used to compare across health plans.

DOR INVESTIGATORS, THEIR AREAS OF EXPERTISE AND CURRENT PROJECTS

Annette E. Aalborg, DrPH



**Annette E. Aalborg, DrPH** ..... (510) 450-2369  
[aea@dor.kaiser.org](mailto:aea@dor.kaiser.org)

Child and adolescent development and health promotion in urban schools, partnership models for health science education in low-income and ethnic minority schools, empowerment and peer models of health promotion, violence prevention, issues relating to obesity and positive self-image and access to care, and evaluation/participatory research, cardiovascular health promotion for adolescents and families, reproductive health, prevention of unintended pregnancy and HIV/STD infection.

*Executive Work Group for Science Education Partnership Division of National Institutes of Health  
 Coordinator of Public Programs and Research, School of Public Health, University of California, Berkeley  
 Lecturer, School of Public Health, University of California Berkeley  
 Associate Researcher, School of Public Health, University of California, Berkeley*

**Projects:**

**Factors Affecting Utilization of Preventive Services by Kaiser Adolescent Members..... 31**

**Feasibility Study of Staged Tailored Reproductive Health Counseling for Adult Women Obtaining Pregnancy Test in a Managed Care Setting ..... 26**

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**Kaiser-Middle School Wellness and Violence Prevention ..... 32**

Lynn M. Ackerson, PhD



**Lynn M. Ackerson, PhD** ..... (510) 450-2386  
[lma@dor.kaiser.org](mailto:lma@dor.kaiser.org)

Biostatistics, longitudinal data analysis, design and analysis of clinical trials  
*Lecturer, Department of Epidemiology and Biostatistics, University of California, San Francisco*

**Projects:**

**Health-Related Quality of Life as a Predictor of Utilization Among Adults with Asthma in a Health Maintenance Organization..... 19**

**DOR Investigators (cont.)**

Mark Alexander, PhD



**Mark Alexander, PhD** ..... (510) 450-2104  
[mx@dor.kaiser.org](mailto:mx@dor.kaiser.org)

Cardiovascular and geriatric epidemiology  
*Assistant Director, Medical Effectiveness Research Center, University of California, San Francisco*

**Projects:**

**Evaluating Hypertensive Patients' Awareness of Blood Pressure** ..... 17

**Evaluating Pre-Hospital Delay Among Acute Myocardial Infarction Patients**..... 17

**Lipid Profiles of Kidney Transplant Recipient Patients in a Managed Care Setting** ..... 17  
Mary Anne Armstrong, MA



**Mary Anne Armstrong, MA** ..... (510) 450-2226  
[maa@dor.kaiser.org](mailto:maa@dor.kaiser.org)

Alcohol studies, perinatal health services research, biostatistics

**Projects:**

**Post-Partum Alcohol, Tobacco, and Other Drug Use: Impact of the Early Start Program** ..... 8  
Andrew L. Avins, MD



**Andrew L. Avins, MD** ..... (510) 450-2833  
[ala@dor.kaiser.org](mailto:ala@dor.kaiser.org)

Health care effectiveness, Health Services Research  
*Associate Director for Health Care Effectiveness, Division of Research*  
*Assistant Professor In-Residence, Department of Medicine and Department of Epidemiology and Biostatistics, University of California, San Francisco*  
*Staff Physician, General Internal Medicine Section, Medical Service, Veterans Affairs Medical Center, San Francisco*  
*Interim Director of Research, Osher Center for Integrative Medicine at UCSF, San Francisco*

**Projects:**

**Saw Palmetto Extract in Benign Prostatic Hyperplasia** ..... 12

Steven Black, MD



**Steven Black, MD**..... (510) 987-3501  
[steve.black@kp.org](mailto:steve.black@kp.org)

Evaluation of vaccine safety and efficacy  
*Associate Clinical Professor, Department of Pediatrics, University of California, San Francisco*

**Projects:**

**A Phase III Open Label Multicenter Study of the Safety and Immunogenicity of a Booster Dose of SmithKline Beecham Biological DTPA Vaccine (Infanrix) and Pasteur Merieux's HIB Conjugate Vaccine (OmniHIB) When Administered Intramuscularly as Separate Injections Between 12 and 18 Months of Age Following Primary Immunization at the Age of 2 Months, 4 Months, and 6 Months in the Study DTPA-HBV-027(CPMS NO 217744/027) ..... 22**

**Comprehensive Linked data Collection of Medical Events & Immunizations (Vaccine Safety and Development Datalink)..... 22**

**Postmarketing Evaluation of Prevnar Pneumococcal 7-Valent Conjugate Vaccine: Local and Systematic Reactogenicity of Prevnar Administered in Catch-Up Populations of Children Aged 7 to 11 months, 12 months to 2 years, 2 to 5 years, and 5 to 9 years ..... 22**  
 Bette J. Caan, Dr PH



**Bette J. Caan, Dr PH** ..... (510) 450-2116  
[bjc@dor.kaiser.org](mailto:bjc@dor.kaiser.org)

Nutritional epidemiology

**Projects:**

**California Men's Study (CMS): A prospective Cohort Study for Prostate Cancer ..... 12**

**Life After Cancer Epidemiology (LACE) ..... 9**

**Women’s Health Initiative (WHI): Clinical Center..... 30**

**Women’s Health Initiative – The Memory Study (WHIMS) ..... 30**

**Women’s Healthy Eating and Living (WHEL) Trial: A Randomized Controlled Trial of the Effect of a Plant-Based Diet on Breast Cancer Recurrence ..... 11**

**Women’s Intervention Nutrition Study (WINS): Low-Fat Diet in Localized Breast Cancer – Outcomes Trial ..... 11**



Chris J. Colby, PhD



**Chris J. Colby, PhD** ..... (510) 450-2332  
[cjc@dor.kaiser.org](mailto:cjc@dor.kaiser.org)

Medical economics and cost studies

**Projects:**

**Cost of Screening Sigmoidoscopy** ..... **20**  
Lisa Croen



**Lisa Croen** ..... (510) 450-2158  
[lac@dor.kaiser.org](mailto:lac@dor.kaiser.org)

Perinatal Research Unit, Clinical Epidemiology

Gerald N. DeLorenze



**Gerald N. DeLorenze** ..... (510) 450-2810  
[gnd@dor.kaiser.org](mailto:gnd@dor.kaiser.org)

HIV/AIDS epidemiology, biostatistical methods, reproductive epidemiology

**Projects:**

**Infectious Etiology of Multiple Sclerosis: A pilot study** ..... **22**

**HIV-1 Antiretroviral Treatment: Cost-Effectiveness of Triple Combination Therapy Vs Dual Therapy under a Markov Model** ..... **5**

**HIV-1 Virologic Response and Survival Patterns Associated with Highly Active Antiretroviral Therapy (HAART)** ..... **5**

Gabriel J. Escobar, MD



**Gabriel J. Escobar, MD**..... (510) 450-2128  
[gje@dor.kaiser.org](mailto:gje@dor.kaiser.org)

Perinatal health services research, informatics, guidelines development, critical care research, severity of illness scoring, outcome of high risk newborns, human error, assessment of prenatal care  
*Permanent non-voting member, Chiefs of OB/Gyn Quarterly Meeting, Nursery Directors' Quarterly Meeting, Perinatal Council Quarterly Meeting*  
*California Association of Neonatologists Quality Care Initiative, Database Committee*

**Projects:**

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**SNAP-II** ..... 28

**Steppin' in Synch: Establishing a Research and Quality Improvement Partnership Between Colorado and Northern California** ..... 28

**Unstudied Infants: Low Risk Babies in a High Risk Place** ..... 28

Bruce Ettinger, MD



**Bruce Ettinger, MD**..... (510) 450-2131  
[bxo@dor.kaiser.org](mailto:bxo@dor.kaiser.org)

Osteoporosis, kidney stones and calcium metabolism, hormones, menopause, pharmacoepidemiology  
*Clinical Professor of Medicine and Radiology, University of California, San Francisco*

**Projects:**

**A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of an Ultralow Dose of Estradiol Given By Continuous Transdermal Administration in the**

**DOR Investigators (cont.)**

**Prevention of Osteoporosis ..... 28**

**Corticosteroid-Induced Osteoporosis (CIO): Identification of Patients at Risk ..... 18**

**Continuing Outcomes Relevant to Evista (CORE): A study of Raloxifene HCl and Placebo in the prevention of Invasive Breast Cancer in Postmenopausal Women with Osteoporosis..... 29**

**Evaluation of Osteoporosis in the Elderly ..... 29**

**Isoflavone Clover Extract for Menopausal Hot Flashes..... 29**  
Assiamira Ferrara, MD, PhD



**Assiamira Ferrara, MD, PhD..... (510) 450-2706**  
[axf@dor.kaiser.org](mailto:axf@dor.kaiser.org)

Epidemiology of diabetes, cardiovascular disease, hormones, gestational diabetes and menopause

**Projects:**

**Does Pregnancy Glycemia Predict Perinatal Complications Among Women Without Gestational Diabetes Mellitus? ..... 25**

**Gestational Diabetes: Diagnostic Criteria and Outcomes ..... 16**

**Hormone Replacement Therapy and Cardiovascular Disease Risk in Type II Diabetics ..... 16**

**Is Maternal Impaired Glucose Metabolism Associated with Increased Risk of Infant Prematurity .. 27**

**Pilot Study of Trends and Risks in Gestational Diabetes ..... 17**

**Type 2 Diabetes among Children and Adolescents: Case Definitions Characteristics and Quality of Care..... 17**

Bruce H. Fireman, MA



**Bruce H. Fireman, MA ..... (510) 450-2137**  
[bhf@dor.kaiser.org](mailto:bhf@dor.kaiser.org)

Health services research, particularly small area variation studies

**Projects:**

**Evaluation of Centralized Call Centers in Kaiser Permanente Northern California and Colorado Regions..... 19**

**Evaluation of Care Manager Programs for Four Chronic Conditions ..... 21**

**Impact of the Adult Primary Care Redesign in Northern California on Quality, Cost, Patient Satisfaction and Physician Satisfaction..... 21**

**DOR Investigators (cont.)**

Gary D. Friedman, MD, MS



**Gary D. Friedman, MD, MS** ..... (510) 450-2129  
[gdf@dor.kaiser.org](mailto:gdf@dor.kaiser.org)

Epidemiology of cancer, cardiovascular disease, gallbladder disease, effects of smoking, alcohol and medicinal drugs  
*Consulting Professor, Department of Health Research and Policy, Stanford University School of Medicine*  
*Lecturer, Department of Biomedical and Environmental Health Sciences, University of California School of Public Health, Berkeley*  
*Lecturer, Department of Epidemiology and Biostatistics, University of California School of Medicine, San Francisco*

**Projects:**

**Cancer Epidemiology in a Large Health Care Plan (Outstanding Investigator Grant)** ..... 8  
**Frozen Serum** ..... 31  
 Alan S. Go, MD



**Alan S. Go, MD** ..... (510) 450-2382  
[axg@dor.kaiser.org](mailto:axg@dor.kaiser.org)

Cardiovascular health services research and clinical epidemiology management and outcomes of coronary heart disease, atrial fibrillation and stroke, screening and treatment of hyperlipidemia, electrocardiographic findings and outcomes in heart disease, prevention and treatment of end-stage renal disease  
*Assistant Professor, Departments of Epidemiology, Biostatistics, and Medicine, University of California School of Medicine, San Francisco*  
*Clinical Staff, General Internal Medicine Section, Veterans Affairs Medical Center, San Francisco*

**Projects:**

**Angiography in Angina (ANGINA) Study: Cardiac Procedure Use and Outcomes in New Onset Angina** ..... 13  
**Cardiovascular Disease Research Interest Group** ..... 13  
**Clinical and Genetic Predictors of Myocardial Infarction in Coronary Disease** ..... 14  
**Epidemiology of Anticoagulation in Atrial Fibrillation** ..... 14  
**Epidemiology, Practice, Outcomes and Cost of Heart Failure in Managed Care**..... 14  
**Patient-Clinician Factors Influencing Racial/Ethnic Variation in the Treatment of Coronary Disease** ..... 15

Nancy P. Gordon, ScD



**Nancy P. Gordon, ScD**..... (510) 450-2145  
[npg@dor.kaiser.org](mailto:npg@dor.kaiser.org)

Evaluation of health services (especially patient and provider education interventions aimed at improving chronic disease management and/or risk factor reduction), member health surveys (data about prevalence of chronic diseases, health risk factors such as smoking, quality of life and functional status issues among older members, etc., in the Kaiser adult membership), alternative therapy use among Kaiser members and primary care clinicians

**Projects:**

**Cancer Research Network Across Health Care Systems – Infrastructure, Screening, Breast Cancer, Tobacco**..... 9

**Health Education** ..... 32

**Improving Care of Depression**..... 23

**Kaiser Permanente Adult Member Health Survey**..... 33

**Member Information Project** ..... 33

**Sociodemographic Database** ..... 34

Elisabeth Gruskin, DrPH



**Elisabeth Gruskin, DrPH**..... (510) 450-2713  
[lpg@dor.kaiser.org](mailto:lpg@dor.kaiser.org)

Lesbian and bisexual women’s health research, sexuality research, depression and bipolar disorder, substance use, and breast cancer

*Lecturer, School of Public Health, University of California, Berkeley*  
*Fellow, Health Policy Institute, University of California, San Francisco*

**Projects:**

**Health Implications of Sexual Orientations** ..... 30

**Side Effects in the Treatment with Antidepressants Among Perimenopausal and Menopausal Women (STAMP)**..... 29

**DOR Investigators (cont.)**

Erica P. Gunderson, PhD



**Erica P. Gunderson, PhD**..... (510) 450-2193  
[epg@dor.kaiser.org](mailto:epg@dor.kaiser.org)

Perinatal and nutritional epidemiology

**Projects:**

**Life After Cancer Epidemiology (LACE)**..... **10**

Laurel A. Habel, PhD



**Laurel A. Habel, PhD**..... (510) 450-2328  
[lah@dor.kaiser.org](mailto:lah@dor.kaiser.org)

Etiology, detection, and prognosis of cancer, management of attention deficit disorder and the health effects of hormonal exposures

**Projects:**

**DCIS: Mammographic Fractures and Prognosis** ..... **9**

**Diabetes and Breast Cancer Risk** ..... **9**

**H. Pylori Phenotype and Stomach Cancer** ..... **8**

**Mammographic Density and Breast Cancer After DCIS**..... **10**

**Practice Standards for Newly Diagnosed ADHD** ..... **27**

**Tubal Sterilization and Breast Cancer Risk**..... **11**

Lisa J. Herrinton, PhD



**Lisa J. Herrinton, PhD**..... (510) 450-2149  
[ljh@dor.kaiser.org](mailto:ljh@dor.kaiser.org)

Cancer epidemiology, etiologic factors in hematologic malignancies, cancer care effectiveness  
*Lecturer, Department of Health Research and Policy, Stanford University School of Medicine*

**Projects:**

**Cancer Research Network Across Health Care Systems – Infrastructure, Screening, Breast Cancer, Tobacco**..... **9**

**Cohort Study of Medical Devices** ..... **31**

**DOR Investigators (cont.)**

**Preventative Oncology Academic Award ..... 10**  
 John Hsu, MD, MBA



**John Hsu, MD, MBA** ..... (510) 450-2820  
[jth@dor.kaiser.org](mailto:jth@dor.kaiser.org)

Health services research, medical decision making  
 Enid M. Hunkeler, MA



**Enid M. Hunkeler, MA** ..... (510) 450-2251  
[emh@dor.kaiser.org](mailto:emh@dor.kaiser.org)

Health services research in mental health, depression, domestic violence prevention, alcohol, smoking and drug abuse programs, behavioral health, hypertension, teens and adolescents

*Director, Inter-divisional Depression Initiative (funded by the Garfield Memorial Fund)*  
*Associate Fellow, the Epidemiology Council of the American Heart Association*  
*Member, the National Leadership Council and Quality Improvement Partnership Roundtable*  
*Consultant, THMOG Depression Shared Improvement Project*  
*Member, American Public Health Association*  
*Technical Advisor, AHCPR report evaluating new and old pharmacological treatment for depression*  
*Program Consultant, Care Management Institute*  
*Reviewer, Health Services Branch, NIMH*  
*Member, External Advisory Committee, setting protocol for STAR\*D (Sequenced Treatment Alternative to Relieve Depression)*

**Projects:**

**Can Trained Volunteers Provide Social Support and Increase Access and Health-Related Services for Functionally Disabled Adults..... 18**

**Depression Initiative ..... 23**

**Health Services Research ..... 18**

**The Efficacy of Nurse Telephone Follow-up and Peer Support in Treatment of Depression in Primary Care ..... 23**

**The Impact of Mental Health Problems on the Use of Non-Psychiatric Health Services in a Managed Care Setting..... 24**

**Treatment of Depression Among the Elderly ..... 18**

**DOR Investigators (cont.)**

Carlos Iribarren, MD, MPH, PhD



**Carlos Iribarren, MD, MPH, PhD** ..... (510) 450-2765

[cgi@dor.kaiser.org](mailto:cgi@dor.kaiser.org)

Cardiovascular epidemiology, cancer epidemiology, preventive medicine, asthma and liver function  
*Assistant Adjunct Professor, Department of Epidemiology and Biostatistics, University of California, San Francisco*

**Effects of Exposure to Secondhand Smoke** ..... **14**

**Glycemic Control and Congestive Heart Failure Among Diabetics Over 20 Years Old** ..... **15**

Andrew J. Karter, PhD



**Andrew J. Karter, PhD** ..... (510) 450-2059

[ajk@dor.kaiser.org](mailto:ajk@dor.kaiser.org)

Epidemiology of diabetes and cardiovascular disease

**Projects:**

**Myocardial Infarction and Antecedent Antibiotic Use Among Patients With Diabetes Mellitus**..... **16**

**Natural History of Glycemic Control Among Patients with Diabetes: The Northern California Kaiser Permanente Diabetes Registry** ..... **17**

**Population-Level Improvements in Glycemic Control Among Patients with Diabetes: A Real Individual-Level Effect or an Ecologic Fallacy** ..... **17**

Theodore R. Levin, MD



**Theodore R. Levin, MD** ..... (510) 450-2240

[trl@dor.kaiser.org](mailto:trl@dor.kaiser.org)

Health services and outcomes research related to colorectal cancer screening in average risk populations and in patients with a positive family history of colorectal cancer, outcomes research related to Gastroesophageal Reflux Disease and Dyspepsia  
*Assistant Clinical Professor of Medicine, University of California, San Francisco*

**Projects:**



**DOR Investigators (cont.)**

**A Study to Develop and Evaluate an Instrument to Predict Utilization and Costs for Patients with GERD..... 19**

**Adding New Fecal Occult Blood Tests to Sigmoidoscopy ..... 12**

**BAT-26 Mutations and Flexible Sigmoidoscopy Colorectal Cancer Screening ..... 21**

**Characterization of DFNA1 in Inherited Hearing Loss ..... 31**

**Evaluation of Risk Factors for Barrett's Esophagus ..... 10**

**Study of Sigmoidoscopy Complications ..... 22**

**Surveillance for Esophageal Carcinoma ..... 8**

De-Kun Li, MD, PhD



**De-Kun Li, MD, PhD ..... (510) 450-2255**

[dkl@dor.kaiser.org](mailto:dkl@dor.kaiser.org)

Reproductive, prenatal, and pediatric epidemiology, such as infertility, miscarriage, SIDS, and birth defects

**Projects:**

**Drinking Water and Spontaneous Abortion ..... 25**

**Individual, Family and Societal Outcomes of Infertility ..... 26**

**Induced Abortion and Breast Cancer Risk ..... 9**

**Infant Sleep Position and Sudden Infant Death Syndrome (SIDS) Risk ..... 27**

**Maternal - Fetal HLA Sharing and the Risk of Preterm Delivery ..... 27**

**Prospective Epidemiologic Study of Spontaneous Abortion and Electromagnetic Field (EMF) Exposure ..... 27**

M. Michele Manos, PhD, MPH

**M. Michele Manos, PhD, MPH ..... (510) 450-2348**

[mmm@dor.kaiser.org](mailto:mmm@dor.kaiser.org)

Etiology and prevention of cervical cancer, utility of human papillomavirus (HPV) testing and other new technologies to improve Pap screening, molecular epidemiology of cancers, women's reproductive health in minority populations, chronic liver disease

*Associate Adjunct Professor, Department of Epidemiology and Biostatistics, University of California, San Francisco*

*Steering Committee Member, National Cancer Institute, ALTS (ASCUS/LSIL Triage Study) Clinical Trial*

**Projects:**

**Cancer Research Network Across Health Care Systems – Infrastructure, Screening, Breast Cancer, Tobacco..... 9**

**Sentinel Surveillance for Chronic Liver Disease..... 34**

**DOR Investigators (cont.)**

**Towards Avoiding Cervical and Late-Stage Breast Cancers: A Program Project Award Increasing Effectiveness of Cancer Control Interventions: The HMO Research Network ..... 12**

Charles P. Quesenberry, Jr., PhD



**Charles P. Quesenberry, Jr., PhD..... (510) 450-2177**  
[cpq@dor.kaiser.org](mailto:cpq@dor.kaiser.org)

Biostatistical methods, survival analysis, cost of disease

**Projects:**

**Cost of Obesity Follow-up ..... 20**

**Obesity Registry Pilot study..... 20**

Catherine Schaefer, PhD

**Catherine Schaefer, PhD ..... (510) 450-2186**  
[cas@dor.kaiser.org](mailto:cas@dor.kaiser.org)

Psychosocial factors in disease, psychiatric epidemiology, early antecedents of adult chronic disease,  
 genetic epidemiology

**Projects:**

**Management Options for Women at Potential Risk for Inherited Breast Cancer in a Multiethnic Health Plan Population: A Randomized Control Trial ..... 10**

**Prenatal Determinants of Schizophrenia ..... 23**

**Recurrence and Survival Among Women Diagnosed with Breast Cancer While Pregnant ..... 10**

**Safety of Pregnancy After Breast Cancer ..... 10**

**Screening and Follow-Up for Postpartum Depression at Pediatric Well-Baby Visits ..... 23**

Donna M. Schaffer, RD, MPH



**Donna M. Schaffer, RD, MPH ..... (510) 450-2225**  
[dms@dor.kaiser.org](mailto:dms@dor.kaiser.org)

Diet and colorectal cancer, health consequences of dietary supplementation, maternal nutritional status in  
 the etiology of birth defects

**Projects:**

**Diet, Activity and Reproduction as Risks for Rectal Cancer ..... 12**

**Dietary Supplement Use by Adult Members of Kaiser Permanente Medical Care Program of Northern California ..... 31**

Joseph V. Selby, MD, MPH



**Joseph V. Selby, MD, MPH** ..... (510) 450-2106  
[jvs@dor.kaiser.org](mailto:jvs@dor.kaiser.org)

Epidemiology of diabetes, cardiovascular disease, and cancer; evaluation of screening tests; primary care enhancement, costs of care, impact of cost-sharing  
*Lecturer, Department of Epidemiology and Biostatistics, University of California School of Medicine, San Francisco*  
*Consulting Professor, Health Research and Policy, Stanford University School of Medicine*

**Projects:**

**A Cohort Study of the Incidence of Acute Hepatic Failure and Lesser Degrees of Liver Injury in Patients with Diabetes Mellitus** ..... 16

**A Case Control Study of Mammography** ..... 21

**Accelerating the Cycle of Research Through a Network of Integrated Delivery Systems** ..... 30

**Cardiac Arrhythmia Patient Outcomes Research Team** ..... 13

**Improving the Physician - Patient Match in HMO's** ..... 21

**Improving Quality of Care for Restructuring Provider Payments** ..... 20

**Increasing the Evidence Base for Retinopathy Screening Guidelines** ..... 16

**Insulin Resistance and Atherosclerosis Study(IRAS)** ..... 16

**Translational Research Centers for Diabetes Control Within Managed Care** ..... 17  
 Stephen Sidney, MD, MPH



**Stephen Sidney, MD, MPH** ..... (510) 450-2108  
[sxs@dor.kaiser.org](mailto:sxs@dor.kaiser.org)

Epidemiology of cardiovascular disease, oral contraceptives and cardiovascular disease, hormone replacement therapy and cardiovascular diseases, health effects of marijuana use  
*Consultant, Department of Epidemiology, University of California School of Public Health, Berkeley, CA*

**Projects:**

**A Phase II Trial for the Treatment of Patients who are unable to tolerate Allopurinol** ..... 30

**CARDIA Psychosocial Questionnaire** ..... 15

**Epidemiology: Oxidative Stress and Early Atherosclerosis** ..... 14

**DOR Investigators (cont.)**

**Epidemiology of Fractures in Persons Age 45 and Older ..... 18**

**Fat Redistribution and Metabolic Change in HIV Infection (FRAM)..... 5**

**Longitudinal Study of Coronary Heart Disease Risk Factors in Young Adults (CARDIA) ..... 15**

**Measuring Allostatic Load: A CARDIA Ancillary Study ..... 15**

**Oral Contraceptives and Thromboembolic Disease ..... 15**

**Predictors of Spontaneous Cerebral AVM Hemorrhage ..... 24**

**Visceral Fat, Metabolic Rate and CHD Risk in Young Adults ..... 15**

Krikor Soghikian, MD, MPH



**Krikor Soghikian, MD, MPH..... (510) 450-2132**

[kks@dor.kaiser.org](mailto:kks@dor.kaiser.org)

Health services research, gerontological research, hypertension  
*Clinical Professor of Medicine, University of California, San Francisco*  
*Visiting Professor, College of Health Sciences, American University of Armenia, Yerevan, Armenia*  
 Carol P. Somkin, PhD



**Carol P. Somkin, PhD ..... (510) 450-2194**

[cps@dor.kaiser.org](mailto:cps@dor.kaiser.org)

Health services research, breast cancer, cancer screening, sociodemographic factors and health,  
 participation in clinical trials  
*Member and Chair Public Education/Outreach Subcommittee, Breast and Cervical Cancer Advisory  
 Council, California Department of Health Services*  
*Member Scientific Advisory Board, Breast Cancer Action*

**Projects:**

**CRN Project 2 (DETECT) Supplement: Design, Implementation and Analysis of Clinician Survey. 30**

**Cancer Research Network Across Health Care Systems – Infrastructure, Screening, Breast Cancer,  
 Tobacco..... 9**

**Cancer Screening, Managed Care and the Underserved ..... 21**

**Income, Inequality, and Work and the Health of Californians ..... 32**

**Study of Tamoxifen and Raloxifene (STAR) ..... 11**

**Young Breast Cancer Survivors: A Population Based Cohort ..... 11**

Barbara Sternfeld, PhD



**Barbara Sternfeld, PhD** ..... (510) 450-2195  
[bxs@dor.kaiser.org](mailto:bxs@dor.kaiser.org)

Physical activity epidemiology, exercise and women's health, physical activity and cancer, cardiovascular disease, physical activity, physical function and aging

**Projects:**

- Assessing the Burden of Illness of Premenstrual Symptomolgy** ..... 28
- Epidemiology of Aging and Physical Function**..... 18
- Epidemiology of Physical Activity and Ovarian Function** ..... 29
- Smoking and Lifestyle Risk Factors for Premenstrual Changes** ..... 29
- Study of Women’s Health Across the Nation (SWAN)**..... 29

Joseph F. Terdiman, MD, PhD



**Joseph F. Terdiman, MD, PhD** ..... (510) 450-2107  
[ift@dor.kaiser.org](mailto:ift@dor.kaiser.org)

Medical informatics, technology assessment, cardiovascular epidemiology, cardiovascular and visual physiology

**Projects:**

- A New Assay for Cholesterol as a Predictor of Coronary Disease** ..... 13
- Establishing a Traumatic Brain Injury Registry and Tracking System** ..... 24
- Improvement of Wound Care Management by Tele dermatology**..... 32

Stephen K. Van Den Eeden, PhD



**Stephen K. Van Den Eeden, PhD** ..... (510) 450-2202  
[skv@dor.kaiser.org](mailto:skv@dor.kaiser.org)

Epidemiology of cancer, environmental and occupational diseases, Parkinson's Disease, aspartame, headaches, reproductive health

*Lecturer, Department of Health Research and Policy, Stanford University School of Medicine*

*Lecturer, Department of Epidemiology, University of California School of Public Health, Berkeley*

**Projects:**

DOR Investigators (cont.)

**Air Pollution and Morbidity and Mortality Among California Kaiser Permanente Members ..... 5**

**Air Pollution, Race, SES and Asthma Hospitalization Risk ..... 5**

**Case-Control Study of Prostate Cancer Screening and Mortality Feasibility Study for Prostate Cancer Screening ..... 12**

**Case-Crossover Analysis of Ambient Air Pollution and Cardiopulmonary Hospitalizations of Kaiser Members in Sacramento and Fresno Metropolitan Areas ..... 6**

**Epidemiology of Primary and Secondary Dystonia in a Multi-Ethnic Population: "A Pilot Planning Grant" ..... 24**

**Estimating Ectopic Pregnancy Prevalence and Treatment Choices..... 25**

**Explaining the Inverse Smoking Relation with Parkinson’s Disease ..... 24**

**Parkinson's Disease and Quality of Life, Utilization and Natural History 24**

**Particulate Air Pollution and Morbidity in the California Central Valley: A High Particulate Pollution Region..... 6**

**Risk of IHD Hospitalization Associated with exposure to Air Pollution..... 6**

**Urinary Incontinence: Reproductive and Hormonal Risk Factors ..... 30**

**Utilization, Quality of Life, and Direct Medical Costs Associated in Treated and Untreated Urinary Incontinence ..... 20**

**Veterans Affairs Prostate Specific Antigen Prostate Cancer Study ..... 22**  
Lawrence J. Walter, MA



**Lawrence J. Walter, MA ..... (510) 450-2203**  
[ljw@dor.kaiser.org](mailto:ljw@dor.kaiser.org)

Psychiatric and substance abuse treatment outcomes measurement, mental health services quality improvement, utilization and cost analysis, large scale database linkage

**Projects:**

**Follow-up Study of Medicaid Chemical Dependency Patients in a Private HMO: Do High Medical Costs Come Down Over Time?..... 6**

Constance M. Weisner, DrPH, MSW



Constance M. Weisner, DrPH, MSW (510) 450-2156

[cmw@dor.kaiser.org](mailto:cmw@dor.kaiser.org)

Drug and alcohol epidemiology, treatment outcomes, access and utilization of behavioral health care  
*Professor of Psychiatry, University of California San Francisco Department of Psychiatry, Langley Porter  
Psychiatric Institute*

**Projects:**

**Impact of Services on Trajectories..... 7**

**Integrated Drug and Medical Care: Cost and Effectiveness..... 20**

**Long-Term Impact of Day Treatment on Outcome and Cost ..... 7**

**Outcome and Cost of Day Hospital vs. Outpatient Care..... 7**

**Pathways to Substance Abuse Treatment in Adolescents in an HMO: Implications for Policy ..... 7**

**Primary Care Behavioral Health Risk Screening and Referral ..... 8**

ADJUNCT INVESTIGATORS, THEIR AREAS OF EXPERTISE AND CURRENT PROJECTS

<b>James E. Allison, MD, FACP</b> .....	(510) 450-2720
	<a href="mailto:jea@dor.kaiser.org">jea@dor.kaiser.org</a>
Screening for colorectal cancer, costs of H. pylori associated peptic ulcer disease, cost effective management of H. pylori associated peptic ulcer disease	
<i>Clinical Professor of Medicine, University of California, San Francisco</i>	
<i>Faculty, Gastroenterology Division, University of California, San Francisco General Campus</i>	
<i>Investigator, Division of Colorectal Cancer Research, Department of Gastroenterology, Veterans Administration Hospital, San Francisco</i>	
<b>Projects:</b>	
<b>Adding New Fecal Occult Blood Tests to Sigmoidoscopy – What Does It Add to Sigmoidoscopic Screening?</b> .....	<b>21</b>
<b>Stomach Study - Study of Management and Costs of Helicobacter Pylori Infection</b> .....	<b>19</b>
<b>Mark Eisner, MD</b> .....	(510) 450-2724
	<a href="mailto:mde@dor.kaiser.org">mde@dor.kaiser.org</a>
Pulmonology, asthma	
<b>S. Claiborne Johnston, MD</b> .....	(510) 450-2786
	<a href="mailto:scj@dor.kaiser.org">scj@dor.kaiser.org</a>
Neurology and neurologic disorders	
<b>Jennifer Kelsey, PhD</b> .....	(650) 725-6114
	<a href="mailto:kelsey@osiris.stanford.edu">kelsey@osiris.stanford.edu</a>
Epidemiology of osteoporosis, fractures, and falls	
<i>Professor of Health Research and Policy, Division of Epidemiology, Stanford University School of Medicine</i>	
<b>Arthur L. Klatsky, MD</b> .....	(510) 596-6538
	<a href="mailto:alk@dor.kaiser.org">alk@dor.kaiser.org</a>
Health effects of alcohol, coffee, cardiovascular epidemiology	
<b>Projects:</b>	
<b>A Study of the “Early Repolarization Normal Variant” ECG Pattern: A Common and Vexing Problem</b> .....	<b>13</b>
<b>Alcoholic Beverage Choice and Mortality</b> .....	<b>6</b>
<b>Alcohol Drinking and Risk of Cerebrovascular Disease</b> .....	<b>6</b>
<b>Pancreatitis: Predictors, Clinical Traits and Sequelae</b> .....	<b>33</b>
<b>Nancy Krieger, PhD</b> .....	(617) 432-1571
	<a href="mailto:nkrieger@hsph.harvard.edu">nkrieger@hsph.harvard.edu</a>
Epidemiology of social inequalities in health, cancer, hypertension	
<i>Assistant Professor, Department of Health and Social Behavior, Harvard University School of Public Health</i>	



**Adjunct Investigators (cont.)**

**Tracy A. Lieu, MD, MPH** ..... (617) 421-6218  
[Tracy.Lieu@hphc.org](mailto:Tracy.Lieu@hphc.org)  
 Medical decision-making, cost-effectiveness analysis, and pediatric primary care delivery, including immunizations and asthma, and perinatal services  
*Associate Professor, Department of Ambulatory Care, Harvard Pilgrim Health Care and Harvard Medical School*

**Projects:**  
**Asthma Care Quality in Varying Managed Medicare Plans** ..... **19**  
**Home Versus Group Visits After Early Postpartum Discharge** ..... **26**

**Lorraine Midanik, PhD** ..... (510) 642-7974  
[lmidanik@uclink4.berkeley.edu](mailto:lmidanik@uclink4.berkeley.edu)  
 Alcohol and drug epidemiology, health services research, measurement issues in research  
*Professor, School of Social Welfare, University of California, Berkeley*  
*Senior Program Consultant, Robert Wood Johnson Foundation, Substance Abuse Policy Research Program*

**Lorene Nelson, PhD** ..... (650) 723-6854  
[nelson@osiris.stanford.edu](mailto:nelson@osiris.stanford.edu)  
 Epidemiology of neurologic disorders, epidemiology of autoimmune diseases, epidemiologic methods  
*Assistant Professor, Department of Health Research and Policy, Stanford University School of Medicine*

**Tom Newman, MD, MPH**..... (415) 476-6457  
[tbn@dor.kaiser.org](mailto:tbn@dor.kaiser.org)  
 Pediatrics  
*Professor of Epidemiology and Biostatistics, Pediatrics, and Laboratory Medicine, University of California, San Francisco*

**Projects:**  
**5 Year Outcome of Severe Neonatal Jaundice & Dehydration**..... **25**

**Henry R. Shinefield, MD** ..... (415) 202-6295  
[henry.shinefield@kp.org](mailto:henry.shinefield@kp.org)  
 Evaluation of vaccine safety and efficacy  
*Clinical Professor, Department of Pediatrics, Department of Dermatology, University of California School of Medicine, San Francisco*

**David H. Thom, MD, PhD** ..... (650) 725-2912  
[dthom@leland.stanford.edu](mailto:dthom@leland.stanford.edu)  
 Primary care issues, patient-physician interactions, Chlamydia pneumoniae, and urinary incontinence  
*Assistant Professor of Medicine, Stanford University Medical School*  
*Director of Stanford Geriatric Education University, Stanford University*  
*Adjunct Assistant Professor, University of California, San Francisco Medical School*

**Projects:**  
**Urinary Incontinence: Reproductive and Hormonal Risk Factors** ..... **29**

## DOR Research Clinics

### **Facilities:**

The Division of Research supports observational studies and clinical trials that require the collection of high quality clinical data. The clinical research setting is distinguished by its multi-functional capabilities designed to provide an efficient and pleasant setting for participants and staff. A total of 10,000 square feet on two floors of the DOR is available for clinical research. The main clinic on the 9<sup>th</sup> floor has a reception area, participant changing rooms and bathrooms, blood processing laboratory, six interview rooms and two examination rooms. There are designated rooms for bone densitometry as well as an expanded JACHO accredited monitoring and medical procedures room. The 9th floor supplemental clinic also provides a blood processing laboratory and five interview rooms to support busier clinic days. The 8th floor clinic space is devoted to the Women's Health Initiative, and includes study records room and ECG room as well as examination rooms. All three clinic areas have blood processing laboratories, each with at least one refrigerated centrifuge, small refrigerator, and interim freezer storage space. A dedicated freezer room on the 9th floor contains four -70°C freezers, five -20°C freezers and one refrigerator for short and long-term storage of biological specimens.

### **Activities in 2000:**

Thirteen studies utilized the research clinics during the year 2000. Nearly 6,000 clinic visits were made by study participants. The total annual budget of the studies utilizing the clinics was \$3,546,387, representing approximately 14% of the total annual budget of the DOR.

Observational studies included the following: Allostatic Load Study; Coronary Artery Risk Development in Young Adults (CARDIA); Fat Redistribution and Metabolic Change in HIV Infection (FRAM); Genetics and Epidemiology of Motor Neuron Disorders (GEM); Jaundice and Infant Feeding Study (JIFEE); Liver Disease Surveillance Study; Study of Women's Health Across the Nation (SWAN); Visceral Fat and Metabolic Rate in Young Adults (VIM).

Clinical trials included the following: Isoflavone Clover Extract (ICE); Continuing Outcomes of Raloxifene Evaluation (CORE); Study of Tamoxifen and Raloxifene (STAR); Women's Healthy Eating and Living Trial (WHEL); and Women's Health Initiative (WHI).

## SERVICES PROVIDED AND STUDIES CONDUCTED FOR KAISER PERMANENTE IN 2000

### **THE PERMANENTE MEDICAL GROUP (TPMG) - FUNDED RESEARCH ACTIVITIES**

In addition to the peer-reviewed externally and internally funded projects detailed in this report, Division of Research (DOR) investigators conduct studies and maintain a number of disease registries with direct funding through core support from The Permanente Medical Group (TPMG) or with funding from Kaiser Foundation Hospitals (KFH). DOR investigators provide additional services to the organization through teaching, consultation, and committee memberships.

#### **Cardiac Services**

We completed evaluation of temporal trends between 1996 and 2000 in the use of invasive cardiac procedures (i.e. coronary angiography, percutaneous coronary interventions, and coronary artery bypass surgery) among the Kaiser Permanente of Northern California (KPNC) adult population as well as among targeted subgroups of patients with coronary heart disease (acute myocardial infarction and newly diagnosed angina). While the total number of coronary angiography procedures has increased with the growing membership, the rate of coronary angiography has remained stable over the past 4 years. Consistent with nationwide practices, the use of percutaneous interventions (especially intra-coronary stenting) has risen dramatically among patients undergoing angiography with an associated decrease in use of coronary artery bypass surgery. Invasive procedures are utilized more frequently following a heart attack compared with a new angina diagnosis, and there is now little variation across the referral cardiac service areas in their use of these procedures.

The risk of adverse outcomes following acute myocardial infarction appears to be decreasing over time, but there remains significant opportunity to improve the management of LDL-cholesterol levels in patients with myocardial infarction and especially among outpatients with angina for the secondary prevention of cardiac events and death.

#### **HIV/AIDS Database**

The DOR staff contributes to our organization's response to the AIDS epidemic by participating in the Northern California Regional HIV/AIDS Committee. At the request of the Regional HIV/AIDS Committee, DOR developed and maintains an HIV/AIDS Database and tracking/reporting system. This HIV/AIDS Database, managed by Leo Hurley, is now the definitive resource for HIV prevalence and incidence information in KP Northern California (see <http://dor-ent1.kaiser.org/>, Research Projects, AIDS/HIV Annual Report). DOR uses the HIV/AIDS Database primarily for assisting in resource allocation for and evaluation and support of HIV care delivery, as well as for recruiting members for HIV clinical trials, and for conducting epidemiological and health services research as initiated by KP clinicians and DOR investigators. Dr. Stephen Sidney and Leo Hurley are members of the Regional HIV/AIDS Committee.

#### **The KP-Northern California Cancer Registry**

The DOR has maintained research databases containing cancer incidence data since 1960. In 1994, through an award from the Innovation Program, the Kaiser Permanente Northern California Cancer Registry (KPNCRR) was established, providing the first complete regionwide cancer data, and structured utilizing the standards of common practice among cancer registries. The KPNCRR focuses on data quality and outcomes reporting using standard measures such as incidence, stage at diagnosis, and survival, and publishes a complete annual report summarizing key internal statistics with comparisons to external benchmarks. The KPNCRR Project Director consults with, and responds to, requests for data from multiple sources including providers (TPMG), administrators, managers and investigators. This research-based cancer registry is heavily utilized to support our numerous research endeavors.

## **TPMG – Funded Research Activities (cont.)**

### **Colon Cancer Prevention Program (CoCaP)**

In 1993 Kaiser Permanente funded the CoCaP program to deliver cost-effective colorectal cancer screening. The CoCaP guideline calls for flexible sigmoidoscopy every ten years for all health plan members beginning at age 50 (with the exception of higher risk members who require colonoscopy). The CoCaP Program was described in a 1997 publication by Dr. Albert Palitz et al in HMO Practice. Based on previous studies conducted at the DOR, it was expected that CoCaP would eventually reduce the occurrence of colorectal cancer through removal of pre-malignant polyps found at sigmoidoscopy. More than 400,000 members have been screened with sigmoidoscopy since CoCaP began. According to the 1999 Member Health Survey, 67% of Kaiser Permanente members aged 50-79 years now report having had a sigmoidoscopy in the past 10 years. This is approximately twice the level of screening in the non-Kaiser population, and is higher than rates reported anywhere in the United States. A proposal has been submitted to the California Cancer Registry and the National Cancer Institute to compare incidence patterns within Kaiser Permanente over the past 7 years to those for the rest of Northern California. DOR staff built a database that includes reports on the first 180,000 sigmoidoscopies performed in CoCaP, along with subsequent pathology and colonoscopy reports. This database has been used to evaluate and refine the CoCaP screening guidelines. These data formed the basis for a 1999 publication in JAMA by Dr. T.R. Levin et al on the need for colonoscopy after discovery of tiny adenomas at sigmoidoscopy. Another publication, detailing the remarkably low sigmoidoscopy complication rate in CoCaP has been submitted for publication. In addition, current studies are examining the potential gains from combining a highly sensitive fecal occult blood test with sigmoidoscopy screening and the occurrence of interval cancers following negative sigmoidoscopy examinations. It is the aim of DOR and the Chiefs of Gastroenterology to ensure that Kaiser Permanente continues to search for improved methods of colorectal screening, while maintaining the highly effective CoCaP screening in the meantime.

#### **PUBLICATIONS:**

Selby JV. Explaining recent declines in colorectal cancer incidence: was it the sigmoidoscope? Am J Med 2000;109(4):332-4.

### **Kaiser Permanente Northern California Region (KPNC) Diabetes Registry**

The Regional Diabetes Registry was originally funded by an award from the Innovation Program. The registry was first constructed in October 1993 and has been updated annually since then. In the intervening years, DOR investigators have obtained funding from a variety of sources, including the Centers for Disease Control, the American Diabetes Association, the American Heart Association, the National Institutes of Diabetes and Digestive and Kidney Disease, and from several pharmaceutical companies to maintain and conduct research in the registry. The registry has been adapted by the Department of Quality and Utilization for quarterly reports on the progress of KPNC's Chronic Care Management Program for diabetes. A total of 11 papers have been published from registry data. These include papers on the costs of care for diabetes, the impact of metformin on glycemic control, the effects of self-monitoring of blood glucose (SMBG) on glycemic control, the effect of copayments on SMBG practice, the association of hormone replacement therapy on glycemic control, predictors of high risk status for diabetes complications, and an evaluation of cluster visits for treatment of diabetes. The DOR continues to participate in the CDC-funded TRIAD (Translating Research Into Practice for Diabetes) Study, which is evaluating the effectiveness of various managed care strategies on the health and quality of life of enrolled members with diabetes in ten U.S. health plans and more than 50 provider groups. Other ongoing studies include an evaluation of criteria for diagnosing gestational diabetes (Dr. Ferrara), recent changes in LDL measurement and control in diabetes (Dr. Selby), and an evaluation of the impact of the legislative mandate to provide glucose monitoring equipment to all patients with diabetes (Dr. Karter).

### **Early Neonatal Discharge**

In light of the recent political controversy regarding length of stay and follow-up services after normal childbirth, DOR (under the leadership of Drs. Tracy Lieu and Gabriel Escobar) conducted a randomized controlled trial to compare home visits vs. individual clinic visits on the 4th postpartum day for mothers and infants receiving early postpartum discharge in Sacramento. Outcomes included urgent clinic visits, breastfeeding success rates,

## TPMG – Funded Research Activities (cont.)

rehospitalization, and patient satisfaction. The study found that all health outcomes were comparable, with no differences between groups in rehospitalization rates, breast feeding failures, or any other clinical outcome. However, patient satisfaction was significantly and substantially higher in the home visit group. A cost analysis suggests that home visits are more expensive than pediatric clinic visits, but they are also longer and include attention to the mother not provided at a clinic visit. Thus, if a clinic visit for the mother were required in addition to a clinic visit for the newborn, the excess costs of a home visit would be minimal.

### PUBLICATIONS:

Lieu TA, Braveman PA, Escobar GJ, Fischer AF, Jensvold NG, Capra AM. A randomized comparison of home and clinic follow-up visits after early postpartum hospital discharge. *Pediatrics* 2000; 105:1058-65.

### Other Perinatal Studies

Dr. Gabriel Escobar and his associates continued their efforts to expand our Region's perinatal research capability. Work on two new studies accelerated in 1998. The "Piecing the Perinatal Puzzle" study began developing strategies to link two key Regional databases (the Pre-Term Birth Prevention Program and the Neonatal Minimum Data Set, or NMDS) with administrative and laboratory databases. The "Steppin' in Synch" study began deployment of the NMDS database in Denver, Colorado. As work ended on the the "Watchful Waiting vs. Antibiotics A.S.A.P." project, which characterized the neonatal "sepsis work-up," the emphasis in this area shifted to the development of a Regional guideline using study results. Work continued using the NMDS database for 1) continued outcomes monitoring at the six level III NICU's 2) analyzing post-NICU rehospitalization patterns 3) validating a simplified neonatal severity of illness score with Harvard University and the University of British Columbia at Vancouver and 4) characterizing the frequency and duration of neonatal assisted ventilation. Work also continued on two population-based case control studies focusing on severely jaundiced and severely dehydrated infants.

## KAISER FOUNDATION HOSPITALS (KFH) - FUNDED RESEARCH ACTIVITIES

### Health Services Research and Evaluation Activities - Direct Community Benefit Investment (DCBI) Program

*Evaluation and Consultation Services to KPCMP and the Community.* Funds from Kaiser's DCBI Program support Dr. Nancy Gordon and her staff in providing program evaluation and research consultation services to KPMCP departments and clinicians engaged in DCBI-funded program areas (e.g., Health Education, KP Cares for Kids, KFRI-funded research, community health partnership programs), to community agencies, and academic institutions. In 2000, program evaluations/needs assessments were conducted in the following topic areas: behavioral health/mind-body medicine psychoeducation classes; prenatal education, pediatric preventive care systems; use of group appointments for medical care; long-term care (projects funded by the KP Inter-Regional Council on Aging); and Kaiser Permanente Cares for Kids Child Health Plan. Consultation services are also provided to many Kaiser Permanente clinicians and program managers and to non-Kaiser Permanente researchers regarding the development and implementation of clinical and health services research and evaluation projects.

*1999 Adult Member Health Survey.* Headed by Dr. Gordon, DOR has conducted a large-scale mailed survey of a stratified random sample of adult Health Plan members in Northern California every three years since 1990. Support for these surveys has come from both DCBI and TPMG. This is the only survey of that links self-reported health and functional status, behavioral risk factors, preventive service use, and satisfaction, and also with KPMCP administrative and clinical databases. The survey enables Kaiser to compare its service population to the general insured population (e.g., based on National Health Interview Survey and California Behavioral Risk Factor Survey). Profiles of the adult health plan membership in the region and for each of the 18 medical center service populations are made available to health education departments and external affairs managers for needs assessment purposes. Data are also made available to community and government agencies, academic researchers, and other health plans through scientific presentations, publications, and special reports generated upon request.

## KFH – Funded Research Activities (cont.)

In addition to the core set of questions, the 1999 survey collected information on use of 19 alternative/complementary therapies and selected vitamins and herbal supplements during the past 12 months, psychosocial stresses such as physical or sexual assault, robbery, and harassment/discrimination during the past 12 months; member preferences for different methods of receiving health information, and member access to personal computers and the internet. A Member Health Survey website has been created to make it possible for anyone with access to the KP Intranet to download copies of the reports and survey questionnaire (<http://www.dor.kaiser.org/dor/mhsnet/index.html>).

*Member Information Project.* DCBI support in Year 2000 helped to continue a pilot project to test the collection of sociodemographic information from adult members in two Kaiser Permanente Northern California medical facilities (Vallejo and Oakland). The Member Information Project has three main goals: (1) to evaluate the feasibility and acceptability of a population-based member sociodemographic data collection, (2) to study whether traditionally underserved member subpopulations (based on race/ethnicity, education, and language barriers) are just as likely as the non-disadvantaged population to receive guideline-concordant preventive and chronic disease management services when financial barriers to these services are almost totally removed, and (3) to analyze the role of education and language barriers as mediating factors if race/ethnic differences in services received are observed.

*Children with Medi-Cal Managed Care: Utilization, Costs, Health Status and Access to Care.* DCBI funds were used to augment a study originally led by Dr. Tracy Lieu which aimed to describe the access to care of Medicaid children in the Kaiser Permanente Medical Care Program in Northern California and any differences between them and commercially-insured children. A paper, which covers the results of the access to care analyses augmented by the DCBI-funded utilization piece, "A comparison of health care experiences for Medicaid and commercially insured children in a large nonprofit HMO", was accepted by *Ambulatory Pediatrics*.

*Mental Health.* During the year 2000, DCBI funds were also used to support eight continuing projects and two new ones related to mental health under the direction of Enid Hunkeler, MA. Three of the projects are now completed (Efficacy of Nurse Telehealth Care and Peer Support in Augmenting Treatment of Depression in Primary Care, Beyond Screening for Domestic Violence: A Systems-model Approach in a Managed Care Setting, and Alcohol Consumption Patterns and Health Care Costs in an HMO). There were five articles submitted for publication stemming from these projects. The Community on Patrol for Safety (COPS) project has received a \$25,000 award for recognition of outstanding community service from Eli Lilly and Company and was featured on Channel 4 news after the Columbine tragedy. Following is a listing of the articles published, those accepted for publication, and those still under review.

Articles:

Hunkeler EM, Meresman JF, Hargreaves WA, Fireman B, Berman WH, Kirsch AJ, Groebe J, Hurt SW, Braden P, Getzell M, Feigenbaum PA, Peng T, Salzer M. Efficacy of Nurse Telehealth Care and Peer Support in Augmenting Treatment of Depression in Primary Care. *Archives of Family Medicine*. 2000; 9:700-708.  
McCaw B, Bauer HM, Berman WH, Moone L, Holmberg M, Hunkeler EM. Women Referred For On-site Domestic Violence Services in a Managed Care Organization. *Women in Health*, June 2001  
Hunkeler EM, Hung YY, Rice DP, Weisner C, Hu TW. Alcohol Consumption Patterns and Health Care Costs in an HMO. *Drug and Alcohol Dependence* (in press).  
McCaw B, Berman WH, Syme L, Hunkeler EM. Beyond Screening For Domestic Violence: A Systems-model Approach in a Managed Care Setting. *American Journal Preventive Medicine* (Submitted 12/01)

### **Mental Health and Chemical Dependency Quality Improvement Studies (jointly funded with TPMG)**

During the decade of the 1990s, the provision of accessible and effective mental health and chemical dependency (MH/CD) services have been seen as an increasingly vital component of health care. A wide range of internally-funded research and evaluation activities at DOR have paralleled the dramatic expansion of KP's MH/CD programs during this period. A series of clinical outcome studies in psychiatric clinics and the Chemical Dependency Recovery Programs (CDRPs) examined patient characteristics, patterns of treatment received, and patient outcomes

## **KFH – Funded Research Activities (cont.)**

such as symptom reduction, increased functioning, abstinence from alcohol or illicit substances and patient satisfaction. Other studies have examined the impact of mental health and chemical dependency treatment on medical utilization, new models of psychiatric case-management for high risk Medi-Cal patients, the impact of on-site mental health providers in the emergency department, and trends in provider satisfaction. During the year 2000, DOR researchers were actively involved in the development of consistent standards for data collected at chemical dependency intake visits, an evaluation of cognitive-behavioral depression groups conducted by telephone for frail elders, the testing of a new brief multipurpose depression scale, the development of a patient satisfaction questionnaire for psychiatric inpatients, and an analysis of trends in suicide rates. Additionally, DOR staff regularly serve on Regional oversight committees and workgroups in the MH/CD area, and provide consultation and other assistance to many Regional projects.

### **OTHER SERVICES**

#### **Administration**

The Division of Research provides comprehensive administrative services to DOR personnel as well as to other KP researchers seeking assistance with federal grant and contract research proposal submissions. The administration team is comprised of research administrators, accountants, procurement specialists, information technology specialists, human resource professionals, administrative assistants and administrative managers. Additional support services include a medical record analyst unit, data entry services and library support. The administrative staff members are responsible for grant and contract proposal development and submission in tandem with principal investigators, pre- and post-award financial administration, purchasing, space allocation, payroll, personnel, accounts payable, building operations, and computer support for our extensive local area network.

#### **Breast Cancer Task Force**

Dr. Carol Somkin has been an active member of this task force since its inception in 1992. She advises the Task Force on research methods generally as well as policy implications of data on breast cancer incidence, survival, mortality and other aspects of epidemiology that could affect breast cancer care at Kaiser Permanente. Consultations have also been provided in the area of screening guideline development. In 1995, Dr. Somkin directed a major survey of patient satisfaction with breast care in Kaiser Permanente. The results from this survey served as the baseline for a follow-up survey (in 1997) to monitor the effectiveness of improvements made in breast cancer care and services since the first survey, and to identify ways to further improve the breast cancer care and services KP provides to members. In 2000, Dr. Somkin worked with the Task Force to plan the 2001 survey. It is anticipated that the breast cancer patient survey will continue to be conducted on an ongoing basis.

#### **Consultation to Kaiser Permanente Departments, Committees, Investigators, Clinicians**

Members of the DOR staff provide consultation to many departments and individuals throughout the Northern California Region. This usually takes the form of assistance to individual TPMG clinicians in selecting a study design or planning sample size for proposals, or of statistical analyses or data interpretation after studies are funded and underway. Each month one of DOR's four biostatisticians takes responsibility for receiving initial requests for statistical consultation. Two DOR staff members, Dr. Barbara Sternfeld and Mary Anne Armstrong, serve on the Central Research Committee that reviews internally generated research proposals throughout the year. DOR investigators serve as members of a number of regional and inter-regional committees and task forces and maintain working relationships with TPMG chiefs' groups and with regional committees related to their research areas. Working relationships currently exist with the Chiefs of Medicine, Gastroenterology, Obstetrics/Gynecology, Neonatology, Mental Health, Chemical Dependency, Cardiology, and Endocrinology. DOR investigators and analysts also report regularly to the Regional Diabetes Steering Group and the Psychiatry Coordinating Committee, and the Breast Cancer Advisory Council. These relationships provide insights to DOR investigators on the practical questions faced by health plan and clinician groups and allow the medical group and health plan to take advantage of the presence of a research department within the HMO.

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