

Annual Report 2001



Division of
Research



*The Kaiser Permanente Medical Center, Inc. and
Kaiser Permanente Research Institute*

Division of Research

2000 Broadway, Oakland, Ca 94612

3505 Broadway, Oakland, Ca 94611

<http://www.dor.kaiser.org>

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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.

A MESSAGE FROM DOR'S DIRECTOR EMERITUS



FOREWORD

The Division of Research (DOR) under the able leadership of Dr. Joe V. Selby continues to carry forward the important goals of DOR to provide clinical, epidemiological, and health services research to Kaiser Permanente (KP) and to the nation. DOR was an integral part of the vision of the KP founders, Sidney R. Garfield and Henry J. Kaiser. They recognized that research directed to improving the quality of patient care and member services was essential for the recognition, development, and promulgation of best medical practices. These founders believed that the integration of a research division in the KP medical care program was the most effective method of applying medical research to medical practice. The Division of Research (DOR) was established in 1961 (originally called the Department of Medical Methods Research). Its annual reports have shown a continuing growth of DOR in size, in funding, in the acquisition of experienced investigators, and in the number of peer-reviewed publications. In addition, DOR has acquired a growing national reputation for producing a high quality of medical research; and it currently ranks as one of the premiere medical research centers in the country.

Morris F. Collen, MD, Director Emeritus

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

I am delighted to present the 2001 Annual Report of the Division of Research. Its primary aim is to familiarize you with DOR's 40 research scientists, with their achievements, and with the more than 200 projects they currently have underway.

Conducting research at Kaiser Permanente continues to be an exciting and productive endeavor. The size of the Kaiser Permanente member population and the richness of its clinical databases provide unique opportunities to carry out important research projects. DOR's and Kaiser Permanente's most valuable research contributions, including studies in cardiovascular disease, vaccine safety and effectiveness, cancer control and many other areas, are the direct result of our ability to conduct studies of a size and level of accuracy not possible elsewhere. In all of this work, we are guided by Kaiser Permanente's Institutional Review Board, which reviews and approves each project, ensuring that risks to study subjects, including risks to privacy, are minimized and that the potential benefits of the study outweigh those risks.

Many of our projects involve collaboration with co-investigators who are The Permanente Medical Group (TPMG) clinicians or Kaiser Permanente operations staff members. The opportunities for collaboration among these three groups are another unique strength of Kaiser Permanente, enriching our research portfolio, improving TPMG's clinical practice, and refining the organization's policies and operations. A growing number of our studies feature collaboration with researchers from other regions of Kaiser Permanente. Most of these inter-regional projects are funded by federal sources, the NIH, the CDC, and AHRQ. However, Kaiser Permanente, through the Garfield Memorial Fund, plays an increasingly important role in sponsoring inter-regional research activities that address questions of importance to both the organization and the community. The intent to publish results in the scientific literature remains a constant in all of this work.

2001 was distinguished by the arrival of Dr. Lawrence Kushi as our new Associate Director for Etiology and Prevention Research. Larry is an internationally known and respected epidemiologist who specializes in the study of nutritional effects on health. He joins us from the faculty of Columbia University. With his arrival, DOR's scientific leadership is now at full strength. Also joining the research scientific staff in 2001 is Dr. Rachel Whitmer. Rachel is a WHISPR (Women's Health Interdisciplinary Scholarship Program for Research) Scholar, who completed a Ph.D. program in Human Development at the University of California, Davis in 2000 and a postdoctoral traineeship in cardiovascular epidemiology at the University of California Berkeley in 2002. Her work and interest are focused primarily in the area of aging.

As always, we thank our organizational sponsors within The Permanente Medical Group and Kaiser Permanente for their steady and manifold support, and we acknowledge our collaborators from government, academia, and industry for sharing their insights, for their hard work, and for the pleasure of their company during the past year.

Joe V. Selby, MD, MPH
Director

**DIVISION OF RESEARCH FUNDING
1994 - 2001**

	1994	1995	1996	1997	1998	1999	2000	2001
INTERNAL FUNDING								
KFH/KFHP								
Community Services/Direct Community Benefit Investment Program								
Clinical Research	\$601,007	\$522,910	\$635,690	\$494,770	\$533,070	\$587,118	\$713,907	\$665,091
Health Services	589,000	530,100	504,000	501,158	501,158	475,950	475,949	513,637
Other	192,550	355,680	267,500	234,845	266,748	371,384	400,000	466,950
TPMG Research								
Innovations	278,994	776,677	1,084,818	1,425,386	753,243	370,976	178,911	0
Non-physician Personnel	1,069,042	1,638,246	1,607,044	1,714,440	1,001,426	1,635,093	1,401,221	1,384,505
Physician Personnel ¹	1,155,531	1,555,531	915,967	1,151,030	1,834,536	636,416	780,154	838,950
Non-personnel	138,352	154,718	137,346	190,822	145,370	149,290	266,551	281,988
EXTERNAL FUNDING								
Federal	5,521,996	7,213,852	6,650,807	7,707,446	10,229,350	10,632,450	12,226,190	13,062,229
Pharmaceutical	3,575,533	2,457,792	3,026,857	3,351,721	3,964,573	3,203,072	3,613,583	3,196,257
Other ²	2,178,725	1,637,567	2,320,279	2,494,133	2,281,495	2,889,410	4,685,608	5,938,016
TOTAL	\$15,300,730	\$16,443,073	\$17,060,308	\$19,445,751	\$21,510,996	\$20,931,159	\$24,742,074	\$26,347,623
EMPLOYEES								
	1994	1995	1996	1997	1998	1999	2000	2001
Total Number	230	228	268	310	330	310	333	393
Full Time Equivalents ³	166	164	193	245	247	242	266	229

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

² Includes foundations, subcontract from universities

³ Estimates

CURRENT RESEARCH PROJECTS IN 2001

AIDS/HIV

Fat Redistribution and Metabolic Change in HIV Infection (FRAM)

Primary Funding Source: Northern California Institute for Research Education

Total Project Period: October 1999 – August 2001

Principal Investigator: Stephen Sidney, MD, MPH

Description: This cross-sectional study will examine 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

Primary Funding Source: Pharmacia

Total Project Period: February 1999 – June 2001

Principal Investigator: Gerald N. DeLorenze, PhD

Description: This study will 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)

Primary Funding Source: University-wide AIDS Research

Total Project Period: July 1999 – June 2001

Principal Investigator: Gerald N. DeLorenze, PhD

Description: The purpose of this study is three-fold, 1)to estimate rates of maximum virologic response and virologic treatment failure in HIV patients under HAART, 2)to determine the distribution of time to AIDS diagnosis and the time to death after initiation of HAART, and 3)to measure health care usage trends both pre- and post HAART.

Renal Insufficiency Among HIV-1 Patients in a Large Health Maintenance Organization

Primary Funding Source: Gilead Sciences

Total Project Period: May 1999 – December 2001

Principal Investigator: Gerald N. DeLorenze, PhD

Description: This study will determine the incidence of renal insufficiency among Northern California KPMCP HIV-1 patients following the introduction of highly active antiretroviral therapy (HAART).

AIR POLLUTION

Air Pollution and Morbidity and Mortality Among California Kaiser Permanente Members

Primary Funding Source: Environmental Protection Agency

Total Project Period: October 1995 – September 2001

Principal Investigator: Stephen K. Van Den Eeden, PhD

Description: This study will 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

Primary Funding Source: National Institute of Environmental Health Sciences
Total Project Period: August 2000 – July 2002
Principal Investigator: Stephen K. Van Den Eeden, PhD
Description: This case-crossover study will assess the risk of asthma hospitalization 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

Primary Funding Source: American Lung Association
Total Project Period: December 2000 – November 2001
Principal Investigator: Stephen K. Van Den Eeden, PhD
Description: 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.

Economic Value Hospitalizations Associated with Particular and Ozone Air Pollution

Primary Funding Source: Air Resources Board
Total Project Period: June 2000 – June 2002
Principal Investigator: Stephen K. Van Den Eeden, PhD
Description: This study will use the results of the Kaiser Permanente South Coast Air Quality Management District Study of Particulate Air Pollution and Cardiopulmonary Hospitalizations to model the economic consequences of air pollution exposure.

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

Primary Funding Source: California Air Resources Board
Total Project Period: November 1997 – February 2001
Principal Investigator: Stephen K. Van Den Eeden, PhD
Description: This study will examine the association of particulate matter air pollution morbidity among Kaiser Permanente members in the California Central Valley.

ALCOHOL AND OTHER DRUGS (also see HEALTH SERVICES)

Alcoholic Beverage Choice and Mortality

Primary Funding Source: Wine Institute
Total Project Period: July 2000 – December 2001
Principal Investigator: Arthur L. Klatsky, MD
Description: This is 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.

Environmental Tobacco Smoke Exposure and Adult Asthma

Primary Funding Source: Tobacco Related Disease Research Program
Total Project Period: July 2001 – June 2004
Principal Investigator: Carlos Iribarren, MD PhD MPH
Description: The goal of this project is to study whether environmental tobacco smoke (ETS) exposure has harmful effects on adults with asthma by determining how common ETS exposure is in adults with severe asthma, and by examining the impact of ETS exposure on asthma severity, quality of life, and future asthma attacks that require hospitalization.

Alcohol and Other Drugs (cont.)

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

Primary Funding Source: Robert Wood Johnson Foundation
Total Project Period: November 1998 – October 2001
Principal Investigator: Lawrence J. Walter, MA
Description: This study will 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.

Hepatocellular Carcinoma: A Cross-Sectional Study of Attributable Cause

Primary Funding Source: Northern California Cancer Center
Total Project Period: January 2001 – December 2001
Principal Investigator: Michele Manos, PhD, MPH
Description: This study will determine the frequencies of alcoholic cirrhosis, hepatitis-B virus (HBV) and hepatitis-C virus (HCV) viral genome presence, and hemochromatosis gene polymorphisms in the tumors of persons with hepatocellular carcinoma (HCC) in the greater Bay Area.

Impact of Services on Trajectories

Primary Funding Source: National Institute on Alcohol Abuse and Alcoholism
Total Project Period: August 1994 – June 2004
Principal Investigator: Constance M. Weisner, DrPH, MSW
Description: The aims of this 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

Primary Funding Source: National Institute on Drug Abuse
Total Project Period: September 1993 – August 2004
Principal Investigator: Constance M. Weisner, DrPH, MSW
Description: 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.

Medical Comorbidity in Alcoholics: Service Implications

Primary Funding Source: National Institute on Alcohol Abuse and Alcoholism
Total Project Period: June 2000 – May 2005
Principal Investigator: Charles Moore, MD
Description: This study examines pre-treatment medical services utilization, medical conditions and medications, and their impact on medical services utilization and outcome at one year as well as longer-term (7 year) trajectories among substance abuse treatment program. It will examine whether high pre-treatment utilization (inpatient and ER) and chronic co-morbid medical conditions are related to a) shorter stays in index treatment; and b) rates of abstinence and numbers of days abstinent post-treatment.

Methamphetamine Dependence and the Risk of HIV infection

Primary Funding Source: National Institute on Drug Abuse

Total Project Period: February 2001 – August 2004

Principal Investigator: Charles Moore, MD

Description: This study attempts to measure the long term burden of medical and psychiatric comorbidity in patients with methamphetamine dependence. The major focus of medical concern is the likelihood of having or developing HIV related illness. Two populations are being recruited for the study- an in-treatment and an out-of-treatment group. Our program is referring patients for the in-treatment arm of the study. Patients will receive baseline and follow-up diagnostic interviews and lab work, but there is no specific clinical intervention involved in this project.

Outcome and Cost of Day Hospital vs. Outpatient Care

Primary Funding Source: National Institute of Alcoholism and Alcohol Abuse

Total Project Period: December 1994 – May 2004

Principal Investigator: Constance M. Weisner, DrPH, MSW

Description: 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

Primary Funding Source: Robert Wood Johnson Foundation

Total Project Period: November 1999 – October 2002

Principal Investigator: Constance M. Weisner, DrPH, MSW
Stacy Sterling, MSW MPH

Description: 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.

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

Primary Funding Source: Kaiser Foundation Research Institute

Total Project Period: January 2000 – December 2001

Principal Investigator: Mary Anne Armstrong, MA

Description: This study will 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

Primary Funding Source: Robert Wood Johnson Foundation

Total Project Period: August 1998 – February 2001

Principal Investigator: Constance M. Weisner, DrPH, MSW

Description: 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 Care Outcomes Research and Surveillance (CanCORS)

Primary Funding Source: National Cancer Institute

Total Project Period: September 2001 – August 2002

Principal Investigator: Lisa Herrinton, PhD

Description: This award supports population based research in the areas of access to care, patterns of care, and prognosis of lung and colorectal cancer.

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

Primary Funding Source: National Cancer Institute

Total Project Period: June 1989 – March 2001

Principal Investigator: Gary D. Friedman, MD, MS

Description: This is 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.

Cancer Surveillance in HMO Administrative Data

Primary Funding Source: National Cancer Institute

Total Project Period: April 2001 – March 2002

Principal Investigator: Charles Quesenberry, PhD

Description: The purpose of this study is to identify the existence and extent of biases associated with HMO electronic and claims-type encounter data when they are used to characterize patterns of care and to analyze the relationship between treatment and outcomes of breast and cervical cancers.

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

Primary Funding Source: National Cancer Institute

Total Project Period: January 2000 – December 2001

Principal Investigator: Carol P. Somkin, PhD

Description: The purpose of this study is to build a population laboratory for cancer research in HMO populations.

Evaluation of Risk Factors for Barrett’s Esophagus

Primary Funding Source: National Institute of Diabetes and Digestive and Kidney Diseases
Total Project Period: September 2000 – August 2001
Principal Investigator: Douglas Corley, MD, MPH
Description: 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.

Massage Therapy for Cancer-Related Fatigue

Primary Funding Source: National Center for Complementary and Alternative Medicine
Total Project Period: April 2001 – March 2003
Principal Investigator: Andrew L. Avins, MD MPH
Description: This study is a randomized pilot trial of a massage therapy intervention for the treatment of fatigue in patients with cancer undergoing chemotherapy, with a focus on the development of valid methodology for studying the efficacy of bodywork therapies for highly subjective outcomes.

Preventive Oncology Academic Award

Primary Funding Source: National Cancer Institute
Total Project Period: May 1996 – April 2001
Principal Investigator: Lisa J. Herrinton, PhD
Description: This award will support 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.

Breast Cancer

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

Primary Funding Source: National Cancer Institute
Total Project Period: January 1999 – December 2002
Principal Investigators: Lisa J. Herrinton, PhD
M. Michele Manos, PhD, MPH
Nancy P. Gordon, ScD
Carol Somkin, PhD
Description: 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

Primary Funding Source: National Cancer Institute

Total Project Period: May 1999 – February 2004

Principal Investigator: Laurel A. Habel, PhD

Description: Among Kaiser Permanente members diagnosed with DCIS from 1990 to 1997 and treated with breast-conserving surgery, this study will determine whether mammographic features of the breast at diagnosis predict risk of subsequent ipsilateral breast cancer.

Life After Cancer Epidemiology (LACE)

Primary Funding Source: National Cancer Institute

Total Project Period: May 1999 – February 2004

Principal Investigators: Bette J. Caan, DrPH
Erica P. Gunderson, PhD

Description: 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

Primary Funding Source: National Cancer Institute

Total Project Period: July 1999 – June 2001

Principal Investigator: Laurel A. Habel, PhD

Description: This study seeks 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 B-17 clinical trial.

Study of Tamoxifen and Raloxifene (STAR)

Primary Funding Sources: National Surgical Adjuvant Breast and Bowel Project
National Cancer Institute

Total Project Period: October 1998 – planned to be 10-15 year study

Co-Principal Investigator: Carol P. Somkin, PhD

Description: This multi-site randomized controlled trial will 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.

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

Primary Funding Source: National Cancer Institute

Total Project Period: September 1993 – December 2001

Principal Investigator: Bette J. Caan, DrPH

Description: This study will 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

Primary Funding Source: National Cancer Institute

Total Project Period: December 1997 – November 2001

Principal Investigator: Bette J. Caan, DrPH

Description: This study will 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

Primary Funding Source: National Cancer Institute
Total Project Period: September 1998 – September 2002
Principal Investigator: Carol P. Somkin, PhD
Description: This project will 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

Primary Funding Source: National Cancer Institute
Total Project Period: January 1999 – December 2002
Principal Investigator: M. Michele Manos, PhD, MPH
Description: This study seeks to understand the failure (in screening, detection, and follow-up) that accounts 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

Primary Funding Source: National Cancer Institute
Total Project Period: May 1997 – April 2001
Principal Investigator: Theodore R. Levin, MD
Description: This study will 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

Primary Funding Source: National Cancer Institute
Total Project Period: August 1997 – July 2002
Principal Investigator: Donna Schaffer, RD, MPH
Description: This study will examine the environmental and genetic risk factors for rectal cancer and the interactive effects of these risks.

Insulin Resistance and Adenomas of the Colorectum (IRAsC)

Primary Funding Source: National Cancer Institute
Total Project Period: April 2001 – March 2004
Principal Investigator: Theodore R. Levin, MD
Description: This study will test the hypothesis that colorectal neoplasia risk is increased substantially by factors related to insulin resistance and to examine the biologic mechanisms whereby that risk is increased.

Interval Screening for Colorectal Cancer by Flexible Sigmoidoscopy

Primary Funding Source: Kaiser Foundation Research Institute

Total Project Period: January 2001 – December 2001

Principal Investigator: Theodore R. Levin, MD

Description: This study proposes to calculate the incidence rates of cancer following screening for colorectal cancer by flexible sigmoidoscopy in two groups: 1) those who screened negative for adenomas, and 2) those who have adenomas diagnosed and removed upon screening. The relative incidences of CRC for different time intervals following screening should offer some insight into recommending an appropriate interscreen interval for each of these groups.

SEER Special Study: Population Effects of a Colorectal Cancer Screening Program

Primary Funding Source: National Cancer Institute

Total Project Period: August 2001 – July 2002

Principal Investigator: Joe V. Selby, MD, MPH

Description: This study tests the hypothesis that a large flexible sigmoidoscopy screening program has reduced the incidence of advanced distal colorectal cancer by comparing site and stage-specific incidence patterns for colorectal cancer over the past 6 years in a large HMO population with patterns in the remaining adult population from the same geographic area.

Prostate Cancer

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

Primary Funding Source: California Department of Health Services

Total Project Period: June 2000 – May 2002

Principal Investigator: Bette J. Caan, DrPH

Description: 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

Primary Funding Source: Centers for Disease Control and Prevention

Total Project Period: September 1998 – December 2001

Principal Investigator: Stephen K. Van Den Eeden, PhD

Description: This case-control study will assess the efficacy of PSA screening to reduce prostate cancer mortality.

Saw Palmetto Extract in Benign Prostatic Hyperplasia

Primary Funding Source: National Institute of Diabetes and Digestive and Kidney Diseases

Total Project Period: August 1999 – July 2002

Principal Investigator: Andrew L. Avins, MD MPH

Description: 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 (also see Women's Health)

A Nested Case-Control Study of Lipoprotein-Associated Phospholipase A2 (Lp-PLA2) and Subclinical Cardiovascular Disease among Young Adults

Primary Funding Source: Smithkline Beecham Company
Total Project Period: September 2001 – May 2002
Principal Investigator: Carlos Iribarren, MD PhD MPH
Description: This study seeks to describe the distribution of lp-PLA2 in young adults, its correlation with traditional and new risk factors and its association with coronary artery calcification.

A New Assay for Cholesterol as a Predictor of Coronary Disease

Primary Funding Source: Otsuka Pharmaceutical Company
Total Project Period: June 1996 – December 2001
Principal Investigator: Joseph F. Terdiman, MD, PhD
Description: This retrospective case-control study is to examine 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.

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

Primary Funding Source: The Permanente Medical Group
Total Project Period: July 1998 - Ongoing
Principal Investigator: Alan S. Go, MD
Description: 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.

Asymmetric Dimethyl-Arginine (ADMA), Coronary Risk Factors and Subclinical Disease in Young Adults

Primary Funding Source: American Heart Association
Total Project Period: January 2001 – December 2004
Principal Investigator: Carlos Iribarren, MD, PhD, MPH
Description: This study will examine the distribution of a novel risk marker of endothelial function, asymmetric dimethyl-arginine, and its relation to coronary risk factors and subclinical coronary artery disease (CAD) among young adults enrolled in the CARDIA Study. This study may provide atherosclerosis and CAD and may identify new strategies for the prevention of CAD.

CARDIA Psychosocial Questionnaire

Primary Funding Source: MacArthur Foundation
Total Project Period: April 2000 – June 2001
Principal Investigator: Stephen Sidney, MD, MPH
Description: These funds support a supplementary battery of psychosocial questionnaires for participants in the CARDIA study.

Cardiovascular Disease (cont.)

Cardiovascular Disease Research Interest Group

Primary Funding Source: Merck & Company, Incorporated
TAP
Total Project Period: November 2000 – December 2002
Principal Investigator: Alan S. Go, MD
Description: This award supports the development and growth of cardiovascular research at the Division of Research.

Characterization of Asthma Drug Exposures and Development of an Algorithm for Identification of Patients with Churg-Strauss Syndrome

Primary Funding Source: Glaxo Wellcome Company
Total Project Period: December 2000 – January 2002
Principal Investigator: Alan S. Go, MD
Description: This pilot study is a collaborative effort among HMO network members who are currently part of the Centers for Education and Research on Therapeutics (CERTs). This project will characterize asthma drug exposures among asthmatic adults and examine better systematic ways of identifying patients with Churg-Strauss Syndrome based on automated database approaches. The goal is to assess the feasibility of further study into estimation of the true incidence of and risk factors for the condition.

Clinical and Genetic Predictors of Myocardial Infarction in Coronary Disease

Primary Funding Source: Reynolds Foundation
Total Project Period: October 2000 – September 2001
Principal Investigator: Alan S. Go, MD
Description: This study will 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

Primary Funding Source: Tobacco-Related Disease Research Program
Total Project Period: July 1999 – June 2001
Principal Investigator: Carlos Iribarren, MD, PhD, MPH
Description: This project will study the relationship between exposure to environmental tobacco smoke and several long-term health outcomes including cardiovascular disease, smoking-related cancers and respiratory diseases.

Epidemiology of Anticoagulation in Atrial Fibrillation

Primary Funding Source: National Heart, Lung, and Blood Institute
Total Project Period: September 1997 – August 2003
Principal Investigator: Alan S. Go, MD
Description: This longitudinal cohort study involves 17,124 patients will 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

Primary Funding Source: G.D. Searle & Company, Incorporated

Total Project Period: May 2000 – April 2002

Principal Investigator: Alan S. Go, MD

Description: 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

Primary Funding Source: National Heart, Lung, and Blood Institute

Total Project Period: April 2000 – June 2001

Principal Investigator: Stephen Sidney, MD, MPH

Description: This study will describe the distribution and correlation of oxidative damage and test the association between oxidative damage and clinical CHD (define) in a cohort of 3500 black and white young men and women.

Evaluating Hypertensive Patients' Awareness of Blood Pressure

Primary Funding Source: Bristol Myers Squibb

Total Project Period: June 2000 – October 2001

Principal Investigator: Mark Alexander, PhD

Description: 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.

Genetic Epidemiology of Atherosclerotic Heart Disease: Advanced Strategies for Prevention and Therapy

Primary Funding Source: Reynolds Foundation

Total Project Period: October 2000 – September 2002

Principal Investigator: Carlos Iribarren, MD PhD MPH

Description: The study's short term goal is to develop insights into the pathophysiology of coronary disease based on genetics and non-genetic risk markers. Our long term goal is to use these new genetic risk factors or risk modifiers to improve diagnosis and risk stratification.

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

Primary Funding Source: National Heart, Lung, and Blood Institute

Total Project Period: December 1983 – November 2003

Principal Investigator: Stephen Sidney, MD, MPH

Description: This study will 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

Primary Funding Source: MacArthur Research Network on Socioeconomic Status

Total Project Period: April 2000 – June 2001

Principal Investigator: Stephen Sidney, MD, MPH

Description: This study will collect 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.

Cardiovascular Disease (cont.)

Trends in the Cost of Care for Four Chronic Conditions: Coronary Heart Disease, Heart Failure, Diabetes, and Asthma

Primary Funding Source: Care Management Institute
Total Project Period: January 2001 – December 2001
Principal Investigator: Bruce Fireman MA
Description: This study will 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.

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

Primary Funding Sources: Agency for Healthcare Research and Quality
Center for Disease Control and Prevention
Total Project Period: August 2000 – August 2004
Principal Investigator: Alan S. Go, MD
Description: This study will examine the variation in the presentation to care and treatment received across race/ethnic groups with heart disease, and 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

Primary Funding Source: National Heart, Lung, and Blood Institute
Total Project Period: September 1995 – March 2003
Principal Investigator: Stephen Sidney, MD, MPH
Description: This study will determine whether there are race and gender differences in visceral adipose tissue and resting energy expenditure, and 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

Primary Funding Source: Parke-Davis Pharmaceuticals
Total Project Period: August 1999 – February 2001
Principal Investigator: Joe V. Selby, MD, MPH
Description: This retrospective cohort study of diabetic patients will 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

Primary Funding Source: National Institute of Diabetes and Digestive and Kidney Diseases
Total Project Period: September 2000 – August 2001
Principal Investigator: Assiamira Ferrara, MD, PhD
Description: This 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.

Increasing the Evidence Base for Retinopathy Screening Guidelines

Primary Funding Source: American Diabetes Association
Total Project Period: July 2000 – June 2002
Principal Investigator: Joe V. Selby, MD, MPH
Description: 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)

Primary Funding Source: National Heart, Lung, and Blood Institute
Total Project Period: September 1991 - August 2001
Principal Investigator: Joe V. Selby, MD, MPH
Description: This is a 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.

Pilot Study of Trends and Risks in Gestational Diabetes

Primary Funding Source: Centers for Disease Control and Prevention
Total Project Period: September 1999 – September 2001
Principal Investigator: Assiamira Ferrara, MD, PhD
Description: 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.

Probability of Treating-to-Target: Type 2 Diabetes Patients from the Northern California Kaiser Permanente Diabetes Registry Starting New Anti-Hyperglycemic Therapies

Primary Funding Source: Pfizer Incorporated
Total Project Period: January 2001 – December 2001
Principal Investigator: Andrew Karter, PhD
Description: The primary aim of this epidemiologic study is to evaluate the proportion of patients with type 2 diabetes who are switched to new diabetes therapies that reach and maintain glycemic control targets (<7% HbA1c).

Translational Research Center for Diabetes Control Within Managed Care

Primary Funding Source: Centers for Disease Control and Prevention
Total Project Period: November 1998 – November 2003
Principal Investigator: Joe V. Selby, MD, MPH
Description: This study aims 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

Primary Funding Source: Centers for Disease Control and Prevention
Total Project Period: September 1999 – March 2001
Principal Investigator: Assiamira Ferrara, MD, PhD
Description: 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.

GENETIC RESEARCH

Health Plan Members' Attitudes toward Participation in Genetic Research

Primary Funding Source: Kaiser Foundation Research Institute
Total Project Period: January 2001 – December 2001
Principal Investigator: Catherine Schaefer, PhD
Description: This study will examine the attitudes and concerns of Kaiser Permanente health plan members toward genetic research through conducting focus groups and a mailed survey.

HEALTH AND HEALTH CARE IN THE ELDERLY

Bone Effects of Subcutaneous rDNA Teriparatide Following Discontinuation of Raloxifene or Alendronate Women with Postmenopausal Osteoporosis

Primary Funding Source: Parexcel
Total Project Period: July 2001 – December 2002
Principal Investigator: Bruce Ettinger, MD
Description: This clinical trial will assess the efficacy of PTH daily injections in women with osteoporosis who have used either raloxifene or alendronate for 18-36 months prior.

Continuation of Hormone Replacement Therapy (HRT) in women over 65 years of age

Primary Funding Source: Eli Lilly and Company
Total Project Period: February 1997 – July 2001
Principal Investigator: Bruce Ettinger, MD
Description: The purpose of this study was to examine reasons how and why elderly (65 years and older) begin and stop using HRT and to contrast them with women 50-55 years of age.

Epidemiology of Aging and Physical Function

Primary Funding Source: National Institute of Aging
Total Project Period: June 1998 – March 2002
Principal Investigator: Barbara Sternfeld, PhD
Description: The purpose of this study was 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

Primary Funding Source: National Institute of Arthritis and Musculoskeletal and Skin Diseases
Total Project Period: May 1996 – April 2001
Principal Investigator: Stephen Sidney, MD, MPH
Description: This case-control study examined 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.

Health and Health Care in the Elderly (cont.)

Treatment of Depression Among the Elderly

Primary Funding Source: California Healthcare Foundation
Total Project Period: January 1999 – December 2002
Principal Investigator: Enid M. Hunkeler, MA
Description: This study compared 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)

Cost/Cost-Effectiveness Studies

Co-payments and Access to Care: The Patient Perspective

Primary Funding Source: Kaiser Foundation Research Institute
Total Project Period: January 2001 – December 2001
Principal Investigator: John Hsu, MD, MBA, MSCE
Description: This cross-sectional study will evaluate patients' perceptions of co-payments, and assess their underlying preferences for access to care.

Cost-Effectiveness of an HMO Based Colorectal Cancer Screening Program Using the MISCAN-COLON Simulation Model

Primary Funding Source: National Cancer Institute
Total Project Period: August 2000 – August 2001
Principal Investigator: Theodore R. Levin, MD
Joe V. Selby, MD, MPH
Description: In this project, data from the Kaiser Permanente, Northern California, CoCaP program will be collected and shared with the National Cancer Institute for use in their cost-effectiveness model for colorectal cancer screening.

Safety and Financial Ramifications of Emergency Department (ED) Copayments

Primary Funding Source: Agency for Healthcare Research and Quality
Total Project Period: July 2001 – June 2003
Principal Investigator: John Hsu, MD, MBA, MSCE
Description: The goal of this study is to assess the impact of ED co-payments on patient clinical outcomes and treatment costs in the Northern California Kaiser Permanente member population.

The Cost-Effectiveness of Pneumococcal Conjugate Vaccine

Primary Funding Source: Center for Disease Control and Prevention
Total Project Period: September 2000 – September 2001
Principal Investigators: Steven Black, MD
G. Tom Ray, MBA
Description: This project will revise a previously developed cost-effectiveness model of the pneumococcal conjugate vaccine. In this revision, we will incorporate national assumptions and monetary values for the benefits of the vaccine derived from community-based surveys on parents' willingness-to-pay to avoid pneumococcal-related health conditions.

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

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

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

Disease Management

Asthma Care Quality in Varying Managed Medicare Plans

Primary Funding Sources: American Association of Health Plans Foundation
Agency for Health Care Research and Quality
Total Project Period: July 1998 - March 2001
Principal Investigator: Tracy A. Lieu, MD, MPH
Description: This study will 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

Primary Funding Source: Kaiser Permanente (Operation Support Services)
Total Project Period: March 2000 – December 2001
Principal Investigator: Bruce Fireman, MA
Description: This study seeks 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?

Primary Care

Accelerating the Cycle of Research through a Network of integrated Delivery Systems

Primary Funding Source: Agency for Healthcare Research and Quality
Total Project Period: September 2000 - Ongoing
Principal Investigator: Joe V. Selby, MD, MPH
Description: This award is for a Master Task Order agreement between AHRQ and the HMO Research Network coordinated by DOR.

Centers for Education and Research Therapeutics (CERT)

Primary Funding Source: Agency for Healthcare Research and Quality
Total Project Period: September 2000 – August 2002
Principal Investigator: Alan Go, MD
Description: The purpose of these centers is to develop a collaborative research network among nine HMO's to study the prescribing patterns of therapeutic agents and the determinants of their use, their effectiveness and safety in usual clinical care, patient adherence to medications, and the relative costs and cost-effectiveness of these agents. Dr. Go's project relates to the use and dosing of angiotensin-converting enzyme inhibitors for patients with heart failure and its impact on hospital readmissions within managed care.

Health Services – Primary Care (cont.)

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

Primary Funding Source: Kaiser Permanente Garfield Memorial Fund
Total Project Period: October 1999 – October 2001
Principal Investigator: Bruce Fireman, MA
Description: This study will 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.

Information Technology Ramifications for Communication

Primary Funding Source: Kaiser Permanente Garfield Memorial Foundation
Total Project Period: May 2001 – May 2002
Principal Investigator: John Hsu, MD, MBA, MSCE
Description: The goal of this study is to assess how clinical information systems, e.g. an electronic medical record, affects the topics, duration, and quality of communication between patients and their primary care providers, in the setting of an integrated managed care organization.

Screening

Cancer Screening, Managed Care, and the Underserved

Primary Funding Source: National Cancer Institute
Total Project Period: February 1998 – November 2003
Principal Investigator: Carol P. Somkin, PhD
Description: This multi-site program project aims to increase breast and cervical cancer screening and improve follow-up among low-income multi-ethnic women. The study team will 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 attribution.

BAT-26 Mutations and Flexible Sigmoidoscopy Colorectal Cancer Screening

Primary Funding Source: EXACT Laboratories
Total Project Period: October 2000 – August 2001
Principal Investigator: Theodore R. Levin, MD
Description: This study is an evaluation of the potential value of BAT-26 mutations and microsatellite instability in the detection of colorectal cancers not detected by sigmoidoscopy alone.

INFECTIOUS DISEASES AND VACCINES, EXCLUDING AIDS/HIV

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

Primary Funding Source: Centers for Disease Control and Prevention
Total Project Period: September 1995 – September 2001
Principal Investigators: Steven Black, MD
Henry R. Shinefield, MD
Description: This project expands and maintains 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 Diseases and Vaccines, Excluding AIDS/HIV (cont.)

Clinical Immunization Safety Assessment (CISA) Centers

Primary Funding Source: Centers for Disease Control and Prevention
Total Project Period: September 2001 – September 2002
Principal Investigator: Steven Black, MD
Description: The CISA center is a consortium headed by Kaiser Permanente, Northern California, including Stanford University and Vanderbilt University. The goal of these centers is to improve understanding of clinically significant adverse events following immunization. Through clinical assessments and specialized laboratory investigations, genetic or other risk factors that predispose to adverse events will be determined.

Expanded Phase II and Phase IV Vaccine Trials in Humans

Primary Funding Source: National Institute of Allergy and Infectious Diseases
Total Project Period: November 2001 – October 2006
Principal Investigator: Steven Black, MD
Description: Using the clinical trials capabilities of KPNC, these studies enroll subjects and provide services for the conduct of government funded Phase II and IV clinical trials in infants, children and adults, and to use the laboratory expertise of investigators at Stanford and Vanderbilt Universities to measure the immune responses to vaccines.

Infectious Etiology of Multiple Sclerosis: A pilot study

Primary Funding Source: National Multiple Sclerosis Foundation
Total Project Period: July 2000 – June 2001
Principal Investigator: Gerald N. Delorenze, PhD
Description: This pilot study of diagnostic confirmation of Multiple Sclerosis (MS) among patients with frozen serum specimens from Multiphasic exams. The results will contribute to a larger study of the infectious etiology associated with MS.

Long Term Safety and Efficacy of Varicella Vaccine

Primary Funding Source: Merck & Company, Incorporated
Total Project Period: January 1995 – December 2001
Principal Investigator: Steven Black, MD
Description: This study is a Phase IV study of the Merck varicella vaccine and has two components. The first component evaluated the safety of the vaccine in 89,000 children and adults through linkage with medical utilization databases. The goal of the second components of the study is to evaluate the long-term effectiveness of the vaccine. For this purpose, telephone interviews are being conducted on a prospectively identified cohort of 8,000 children who are being interviewed every six months for fifteen years.

Sentinel Surveillance for Chronic Liver Disease

Primary Funding Source: Centers for Disease Control and Prevention
Total Project Period: May 1998 – December 2001
Principal Investigator: M. Michele Manos, PhD, MPH
Description: This study will 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.

MENTAL HEALTH

eCare License and Development

Primary Funding Source: Eli Lilly & Company
Total Project Period: September 2001 – August 2002
Principal Investigator: Enid Hunkeler, MA
Description: This study seeks to develop and evaluate, through a randomized clinical trial, an internet-based disease management program for patients with bipolar affective disorder and recurrent depression.

Glycemic Control in Patients with Depression and Diabetes Mellitus: Impact of Treatment for Depression

Primary Funding Source: Robert Wood Johnson Foundation
Total Project Period: October 1999 – September 2002
Principal Investigator: Enid M. Hunkeler, MA
Description: This study will determine the effects of collaborative care for depression on diabetes self-management in a large national sample of patients with major depression and co-existent diabetes mellitus.

Mood and Depression

Primary Funding Source: Solvay
Total Project Period: September 2001 – August 2002
Principal Investigator: Enid M. Hunkeler, MA
Description: This study compares the incidence of suicide attempts and completed suicides, patient compliance, adverse events and need for supplemental antidepressant medication among bipolar patients treated with lithium (extended and immediate release) or Depakote in a managed care setting.

Pharmacogenetics of Membrane Transporters

Primary Funding Source: National Institute of General Medical Sciences
Total Project Period: April 2000 – March 2005
Principal Investigator: Catherine Schaefer, PhD
Description: This is a multidisciplinary, collaborative study aims to identify genetic variants, characterize selected genes, and examine relationships between genetic variants and clinical phenotypes of genes in the membrane transporter class, which are the targets for common pharmacologic agents such as antidepressants and digoxin.

The Depression Initiative II

Primary Funding Sources: Garfield Memorial Fund
Eli Lilly and Company
SmithKline Beecham Company
Pfizer
Kaiser Foundation Hospitals, Direct Community Benefit Investment Program
Total Project Period: September 1997 - Ongoing
Principal Investigator: Enid M. Hunkeler, MA
Description: This 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

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

Total Project Period: September 1997 - January 2001

Principal Investigator: Enid M. Hunkeler, MA

Description: This study evaluates 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 Prevalence, Costs, and Characteristics of Patients with Depression and Chronic Pain, Singly or Together

Primary Funding Source: Eli Lilly and Company

Total Project Period: November 2001 – October 2002

Principal Investigator: Enid Hunkeler, MA

Description: The prevalence (both detected and undetected) of depression alone, depression and chronic pain together, and chronic pain alone, in a population of patients recently seen in the primary care setting of a managed care organization.

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

Primary Funding Sources: DuPont Merck Pharmaceuticals
Agency for Healthcare Research and Quality

Total Project Period: May 1998 - May 2005

Principal Investigator: Enid M. Hunkeler, MA

Description: This study is 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

Center of Excellence for Autism Epidemiology

Primary Funding Source: Centers for Disease Control and Prevention

Total Project Period: July 2001 – September 2006

Principal Investigator: Lisa Croen, PhD

Description: This program project is designed to investigate a broad range of environmental factors contributing to the incidence and severity of childhood autism.

Environmental Epidemiology of Autism

Primary Funding Source: National Institute of Environmental Health Sciences

Total Project Period: July 2001 – June 2006

Principal Investigator: Lisa Croen, PhD

Description: This case-control study is the first large-scale epidemiological study to examine autism in relation to a broad array of environmental exposures and endogenous susceptibility factors.

Neurological Disease (cont.)

Epidemiology of Primary and Secondary Dystonia in a Multi-Ethnic Population: “A Pilot Planning Grant”

Primary Funding Source: Parkinson’s Institute

Total Project Period: April 2000 – March 2002

Principal Investigator: Stephen K. Van Den Eeden, PhD

Description: 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

Primary Funding Source: Kaiser Permanente Innovation Program

Total Project Period: January 2000 – December 2001

Principal Investigator: Joseph F. Terdiman, MD, PhD

Description: This project will 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)

Primary Funding Source: Tobacco-Related Disease Research Program

Total Project Period: July 1999 – June 2002

Principal Investigator: Stephen K. Van Den Eeden, PhD

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

Genetic and Environmental Risks for ALS

Primary Funding Source: National Institute of Environmental Health Sciences

Total Project Period: September 1996 – August 2001

Principal Investigator: Stephen Van Den Eden, PhD

Description: To estimate the risk of Amyotrophic Lateral Sclerosis (ALS) associated with exposure to selected putative neurotoxins and genetic polymorphisms of the SOD 1 gene. Seek to estimate incidence of the disease in this population and determine how it may vary by age and gender.

Neurodevelopmental Effects of Antiepileptic Drugs

Primary Funding Source: National Institutes of Health

Total Project Period: September 2000 – August 2001

Principal Investigator: Stephen K. Van Den Eeden, PhD

Description: The primary objective of this study is to differentiate the relative risks/benefits of three major AEDs in the treatment of women with epilepsy in terms of their children’s neurobehavioral development after in utero exposure.

Parkinson’s Disease and Quality of Life, Utilization and Natural History

Primary Funding Source: Pharmacia & Upjohn Company

Total Project Period: September 1999 – March 2001

Principal Investigator: Stephen K. Van Den Eeden, PhD

Description: 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.

Pre-diagnostic Markers of Infection and Risk of Multiple Sclerosis (MS)

Primary Funding Source: National Institute of Neurological Disorders and Stroke

Total Project Period: August 2001 – July 2002

Principal Investigator: Gerald N. Delorenze, PhD

Description: Specific hypotheses to be addressed by this study are: 1) that risk of MS is increased among individuals infected with EBV, as determined by the presence of specific serum antibodies. 2) that among individuals who are seropositive for EBV infection, those with higher serum levels of antiviral capsid antigen (VCA) and anti-Epstein-Barr nuclear antigen (EBNA) have an increased risk of MS. 3) that risk of MS is increased among individuals seropositive for Chlamydia pneumoniae (Cpn) infection, and positively associated with the serum concentration of anti-Cpn antibodies.

Predictors of Spontaneous Cerebral AVM Hemorrhage

Primary Funding Source: National Institute of Neurological Disorders and Stroke

Total Project Period: February 2000 – August 2002

Principal Investigator: Stephen Sidney, MD, MPH

Description: This study examines the natural history of cerebral arteriovenous malformations (AVMs) including the incidence, prevalence, treatment, and hemorrhage rates.

PATIENT SAFETY

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

Primary Funding Sources: 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

Description: This project seeks develop electronic mechanisms for identification of human error at three Kaiser Permanente facilities.

The CERT Prescribing Safety Program: Quality Improvement Intervention

Primary Funding Source: Agency for Healthcare Research and Quality

Total Project Period: September 2001 – August 2002

Principal Investigator: Joe V. Selby, MD, MPH

Description: The goal of this study is to improve the detection of medication prescribing errors in the ambulatory setting, and to develop new uses of this information to improve care.

PREGNANCY AND CHILD HEALTH

A Perinatal Health Services Research Laboratory Pilot

Primary Funding Source: Agency for Healthcare Research and Quality

Total Project Period: September 2000 – September 2001

Principal Investigator: Gabriel J. Escobar, MD

Description: This project will 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.

Pregnancy and Child Health (cont.)

Chorioamnionitis and Risk of Cerebral Palsy in Infants \geq 2000 grams

Primary Funding Source: United Cerebral Palsy Foundation
Total Project Period: January 2001 – December 2001
Principal Investigator: Gabriel J. Escobar, MD
Description: Chorioamnionitis is a treatable condition associated with severe consequences to newborns in the immediate neonatal period. This study seeks to determine whether it is also associated with long term consequences (cerebral palsy) and whether such consequences are affected by maternal treatment with intrapartum antibiotics.

Drinking Water and Spontaneous Abortion

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

Ethnic Disparities in Perinatal Outcomes

Primary Funding Source: Agency for Healthcare Research and Quality
Total Project Period: September 2000 – August 2005
Principal Investigator: Gabriel J. Escobar, MD
Description: The overall goal of this study is to delineate the elements of communication, expectations, values, and interpersonal relationships that characterize the delivery, use, and outcomes of health care services for patients of different race/ethnicity.

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

Primary Funding Source: Centers for Disease Control and Prevention
Total Project Period: December 1999 – October 2001
Principal Investigator: Annette Aalborg, PhD
Description: This study will 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.

High Risk Women Refusing Substance Abuse Intervention During Prenatal Care

Primary Funding Source: National Institute on Alcohol Abuse and Alcoholism
Total Project Period: July 2001 – June 2003
Principal Investigator: Gabriel J. Escobar, MD
Description: Working with women refusing substance abuse intervention during prenatal care, this project will bring these women into the care system, ensuring that they remain in the system, and provide specialized counseling with respect to alcohol and other substance use during pregnancy tailored to their specific problem.

Individual, Family, and Societal Outcomes of Infertility

Primary Funding Source: National Institute of Child Health and Human Development
Total Project Period: October 1999 – June 2001
Principal Investigator: De-Kun Li, MD, PhD
Description: 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.

Pregnancy and Child Health (cont.)

Induced Abortion and Breast Cancer Risk

Primary Funding Source: National Cancer Institute
Total Project Period: August 1998 – May 2002
Principal Investigator: De-Kun Li, MD, PhD
Description: This project will study the effectiveness of prophylactic mastectomy in women at an increased risk of breast cancer.

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

Primary Funding Source: National Institute of Child Health and Human Development
Total Project Period: February 1995 – February 2002
Principal Investigator: De-Kun Li, MD, PhD
Description: 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 back-to-sleep campaign on the prevalence of sleeping positions.

Longitudinal Maternal Health and Adverse Birth Outcomes

Primary Funding Source: National Institute of Child Health and Human Development
Total Project Period: July 2000 – June 2003
Principal Investigator: Gabriel J. Escobar, MD
Description: This study will assess the effects of pre-conceptual health status on perinatal outcomes in a multi-center, multi-ethnic cohort from the San Francisco Bay Area.

New Approaches to Improving Quality of Kaiser Permanente Obstetric Care

Primary Funding Source: Kaiser Permanente Garfield Memorial Foundation
Total Project Period: June 2001 – May 2003
Principal Investigator: Gabriel J. Escobar, MD
Description: The goal of this project is to identify operational deficiencies and assist Kaiser Permanente Quality Departments in their review of high-risk events in obstetrics.

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

Primary Funding Source: California Public Health Foundation
Total Project Period: May 1996 – June 2001
Principal Investigator: De-Kun Li, MD, PhD
Description: This study will 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.)

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

Primary Funding Source: Kaiser Foundation Health Plan
Total Project Period: November 1993 - Ongoing
Principal Investigator: Gabriel J. Escobar, MD
Description: 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.

SNAP-II

Primary Funding Source: Avandel Corporation
Total Project Period: December 1999 – December 2001
Principal Investigator: Gabriel J. Escobar, MD
Description: 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

Primary Funding Source: Kaiser Permanente Garfield Memorial Fund
Total Project Period: May 1998 - June 2001
Principal Investigator: Gabriel J. Escobar, MD
Description: 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.

Unstudied Infants: Low Risk Babies in a High Risk Place

Primary Funding Source: Agency for Healthcare Research and Quality
Total Project Period: August 2000 – July 2001
Principal Investigator: Gabriel J. Escobar, MD
Description: 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.

Use of Linked Database to Assess Selected Quality Indicators for Maternal Health

Primary Funding Source: Agency for Healthcare Research and Quality
Total Project Period: October 2001 – September 2002
Principal Investigator: Lisa Croen, PhD
Description: This project will examine whether there are variations in the patterns of maternal health care among sub-populations (maternal age, race/ethnicity, education) and will assess the potential usefulness of selected maternal health care quality indicators in predicting health outcomes for pregnant women and children at birth, one year after delivery, and 3-5 years after delivery.

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

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

Analysis of HRT use

Primary Funding Source: Proctor & Gamble Pharmaceuticals, Incorporated
Total Project Period: November 1996 – December 2001
Principal Investigator: Bruce Ettinger, MD
Description: The major aim of this study is to determine whether continuation of hormone treatment is different between women who initiated therapy using a pill (Premarin) versus those who initiated therapy with a transdermal patch (Estraderm). A secondary aim of the study was to determine the rate of gynecologic procedures for abnormal bleeding in these two groups.

Calculating Risk: How Women Decide Whether or Not to Participate in the STAR Trial

Primary Funding Source: Kaiser Foundation Research Institute
Total Project Period: January 2001 – December 2001
Principal Investigator: Carol Somkin, PhD
Description: This study will examine how women assess their personal risk of breast cancer versus the risks and benefits of participating in the STAR Trial (Study of Tamoxifen and Raloxifene).

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

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

Database Survey of Alendronate Users for Adverse Upper Gastrointestinal Events and Discontinuation

Primary Funding Source: Novartis Pharmaceuticals
Total Project Period: August 1996 – December 2001
Principal Investigator: Bruce Ettinger, MD
Description: The purpose of this study is to determine the tolerability, compliance with patients' instructions regarding use, and continuation of Alendronate therapy among women initiating this osteoporosis treatment. Also, to evaluate incidence of acid-related disorders and symptoms among women using Alendronate.

Epidemiology of Physical Activity and Ovarian Function

Primary Funding Source: National Institute on Aging
Total Project Period: January 1999 – June 2002
Principal Investigator: Barbara Sternfeld, PhD
Description: This study will examine the influence of physical activity on characteristics of the menstrual cycle, reproductive hormonal patterns and hormone-related symptoms using three different data sets.

Gastric & Duodenal PUBs in Women with Osteoporosis

Primary Funding Source: Merck & Company, Incorporated

Total Project Period: November 1998 – June 2001

Principal Investigator: Bruce Ettinger, MD

Description: This study will determine if there is an increased risk of gastric and duodenal abnormalities among patients with osteoporotic fractures.

Human Prenatal Exposure of Organochlorines and Fecundability

Primary Funding Source: National Institute of Environmental Health Sciences

Total Project Period: January 2001 – June 2001

Principal Investigator: Assiamira Ferrara, MD, PhD

Description: This study will provide the first inter-generational investigation of the relation of organochlorine exposure to reproductive performance and endocrine function in two generations of women.

Influence of Physical Activity on Body Composition and Resting Energy Expenditure During the Menopause Transition

Primary Funding Source: American Heart Association

Total Project Period: September 2000 – August 2003

Principal Investigator: Barbara Sternfeld, PhD

Description: This study will examine whether physical activity can prevent or attenuate the changes in body composition and resting metabolic rate that occur in midlife women as a result of aging and/or hormonal change.

Low-Cycle, Low-Dose, Progestin-Estrogen Replacement Therapy

Primary Funding Source: Solvay

Total Project Period: April 1998 – September 2001

Principal Investigator: Bruce Ettinger, MD

Description: This study will evaluate safety and efficacy of hormone therapy composed of half-strength estrogen combined with every 6-month cycles of progestin.

Mammographic Practices & Performance in the Population

Primary Funding Source: National Cancer Institute

Total Project Period: April 1998 – March 2002

Principal Investigator: Bruce Ettinger, MD

Description: This study will develop a large registry of mammograms and assess quality of reporting, measure mammographic density, and relate these to various outcomes including breast cancer and osteoporosis.

Oral Contraceptives and Thromboembolic Disease

Primary Funding Source: National Heart, Lung, and Blood Institute

Total Project Period: September 1997 – August 2001

Principal Investigator: Stephen Sidney, MD, MPH

Description: This study will 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.

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

Primary Funding Source: Bristol-Myers Squibb Company
Total Project Period: August 2000 – August 2002
Principal Investigator: Elisabeth Gruskin, DrPH
Description: 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.

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

Primary Funding Source: National Institute on Aging
Total Project Period: September 1994 – November 2002
Principal Investigator: Barbara Sternfeld, PhD
Description: This multi-site study will 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

Primary Funding Source: National Institute of Diabetes and Digestive and Kidney Diseases
Total Project Period: September 1998 – September 2002
Principal Investigators: Stephen K. Van Den Eeden, PhD
David H. Thom, MD, PhD
Description: This study will 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 later in life.

Women's Health Initiative (WHI): Clinical Center

Primary Funding Source: National Heart, Lung, and Blood Institute
Total Project Period: September 1994 - September 2005
Principal Investigator: Bette J. Caan, DrPH
Description: The objectives of this clinical trial study are to assess the effect of hormone replacement therapy, dietary modification, 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 Initiative - The Memory Study (WHIMS)

Primary Funding Source: National Cancer Institute
Total Project Period: June 1996 - May 2002
Principal Investigator: Bette J. Caan, DrPH
Description: This study examines 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

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

Asthma Health Outcomes Following Intensive Care

Primary Funding Source: National Heart Lung and Blood Institute
Total Project Period: February 2000 – January 2001
Principal Investigator: Mark Eisner, MD MPH
Description: This study is designed to assemble a prospective cohort of adults with life-threatening asthma exacerbation, as indicated by ICU admission. The purpose is to elaborate risk factors for adverse health outcomes over time.

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

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

Family Health for Schools and Science Centers

Primary Funding Source: National Center for Research Resources
Total Project Period: September 2000 – August 2003
Principal Investigator: Annette Aalborg, DrPH
Description: This model program will disseminate interactive health science materials and practices to schools and science centers in the western region and nationally. The overarching goals of the program are to increase student, parent and teacher knowledge of health issues and increase their participation in health and science education programs.

Frozen Serum

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

Implementation-Nurse Telecare

Primary Funding Source: Kaiser Permanente Garfield Memorial Fund
Total Project Period: January 2001 – December 2002
Principal Investigator: Enid Hunkeler, MA
Description: This award supports the implementation of PC3/Nurse Telecare Model of Care.

Improvement of Wound Care Management by Teledermatology

Primary Funding Source: The Permanente Medical Group Innovation Program
Total Project Period: January 2000 – December 2001
Principal Investigator: Joseph F. Terdiman, MD, PhD
Description: This study seeks 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.

Kaiser – Middle School Wellness and Violence Prevention

Primary Funding Source: Kaiser Foundation Hospitals, Direct Community Benefit Investment Program
Total Project Period: January 2000 – December 2001
Principal Investigator: Annette E. Aalborg, PhD
Description: 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

Primary Funding Source: Kaiser Foundation Hospitals, Direct Community Benefit Investment Program
The Permanente Medical Group
Total Project Period: 1990 - Ongoing
Principal Investigator: Nancy P. Gordon, ScD
Description: 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.

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

Primary Funding Source: Novartis Pharmaceuticals
Total Project Period: June 2000 – June 2001
Principal Investigator: Mark Alexander, PhD
Description: 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.

OSCR Database

Primary Funding Source: University of California at San Francisco
Total Project Period: February 2000 – January 2001
Principal Investigator: Mark Eisner, MD MPH
Description: In a cohort of adults with asthma, to project will validate self-reported health care utilization for asthma using KP computerized databases. In addition, the project will validate self-reported asthma medication use by using PIMS data.

Sociodemographic Database

Primary Funding Source: Kaiser Permanente Garfield Memorial Fund
Total Project Period: July 2000 – June 2001
Principal Investigator: Nancy P. Gordon, ScD
Description: 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.

Study of the Care and Outcomes of Renal Insufficiency (SCORE)

Primary Funding Source: National Institute of Diabetes and Digestive and Kidney Diseases
Total Project Period: September 2001 – August 2008
Principal Investigator: Alan Go, MD
Description: This study will establish a joint San Francisco Bay Area Clinical Center between KPNC and USCF to contribute to the NIDDK sponsored cohort of 3000 patients with mild-to-moderate chronic renal insufficiency.

DOR INVESTIGATORS, THEIR AREAS OF EXPERTISE AND CURRENT PROJECTS



Annette E. Aalborg, DrPH..... (510) 891-3498
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*

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Lynn M. Ackerson, PhD (510) 891- 3556
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



Mark Alexander, PhD.....(510) 891-3550
mx@dor.kaiser.org

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

Projects:

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DOR Investigators (cont.)



Mary Anne Armstrong, MA (510) 891-3501
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 11



Andrew L. Avins, MD MPH (510) 891-3557
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:

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Massage Therapy for Cancer-Related Fatigue 13



Steven Black, MD (510) 987-3501
steve.black@kp.org

Evaluation of vaccine safety and efficacy

Associate Clinical Professor, Department of Pediatrics, University of California, San Francisco

Projects:

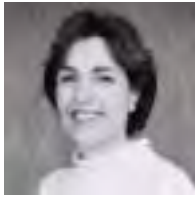
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Bette J. Caan, Dr PH (510) 891-3719
bjc@dor.kaiser.org

Nutritional epidemiology

Projects:

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Lisa Croen, PhD (510) 891-3463
lac@dor.kaiser.org

Perinatal Research Unit, Clinical Epidemiology

Projects:

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Use of Linked Database to Assess Selected Quality Indicators for Maternal Health 33



Gerald N. DeLorenze, PhD (510) 891-3586
gnd@dor.kaiser.org

HIV/AIDS epidemiology, biostatistical methods, reproductive epidemiology

Projects:

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Gabriel J. Escobar, MD (510) 891-3502
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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Bruce Ettinger, MD (510) 891-3253
bx@dor.kaiser.org

DOR Investigators – B. Ettinger (cont.)

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 Prevention of Osteoporosis 34

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Assiamira Ferrara, MD, PhD (510) 891- 3588
axf@dor.kaiser.org

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

Projects:

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Type 2 Diabetes among Children and Adolescents: Case Definitions Characteristics and Quality of Care..... 22



Bruce H. Fireman, MA (510) 891-3459
bhf@dor.kaiser.org

Health services research, particularly small area variation studies

Projects:

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Gary D. Friedman, MD, MS..... (510) 891-3542
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) 12

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Alan S. Go, MD..... (510) 891-3553
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:

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Study of the Care and Outcomes of Renal Insufficiency (SCORE) 38



Nancy P. Gordon, ScD..... (510) 891-3587
npg@dor.kaiser.org

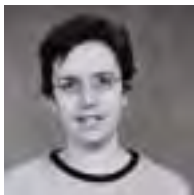
Evaluation of health services (especially patient and provider education interventions aimed at improving chronic disease management and/or risk factor reduction), member health surveys (data about prevalence of chronic diseases, health risk factors such as smoking, quality of life and functional status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

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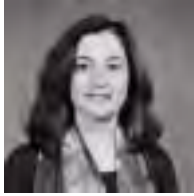
Elisabeth Gruskin, DrPH..... (510) 891-3552
lpg@dor.kaiser.org

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:

Side Effects in the Treatment with Antidepressants Among Perimenopausal and Menopausal Women (STAMP)..... 36



Erica P. Gunderson, PhD..... (510) 891-3497
epg@dor.kaiser.org

Perinatal and nutritional epidemiology

Projects:

Life After Cancer Epidemiology (LACE) 14



Laurel A. Habel, PhD..... (510) 891-3715
lah@dor.kaiser.org

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

Projects:

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Lisa J. Herrinton, PhD..... (510) 891-3714
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:

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John Hsu, MD, MBA, MSCE (510) 891-3601
jth@dor.kaiser.org

Health services research, medical decision making

Projects:

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Enid M. Hunkeler, MA, FAHA(510) 891-3462
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)

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

Ad hoc Reviewer, Health Services Branch, NIMH

*Member, External Advisory Committee, setting protocol for STAR*D (Sequenced Treatment Alternative to Relieve Depression)*

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Carlos Iribarren, MD, PhD, MPH (510) 891-3554
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

Projects:

A Nested Case-Control Study of Lipoprotein-Associated Phospholipase A2 (Lp-PLA2) and Subclinical Cardiovascular Disease Among Young Adults 17

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Andrew J. Karter, PhD (510) 891-3716
ajk@dor.kaiser.org

Epidemiology of diabetes and cardiovascular disease

Projects:

Probability of Treating-to-Target: Type 2 Diabetes Patients from the Northern California Kaiser Permanente Diabetes Registry Starting New Anti-Hyperglycemic Therapies 21



Theodore R. Levin, MD..... (510) 891-3460
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:

Adding New Fecal Occult Blood Tests to Sigmoidoscopy 15

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De-Kun Li, MD, PhD (510) 450-2255
dki@dor.kaiser.org

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

Projects:

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Prospective Epidemiologic Study of Spontaneous Abortion and Electromagnetic Field (EMF) Exposure 32

M. Michele Manos, PhD, MPH..... (510) 891-3464
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 (CRN) Across Health Care Systems – Infrastructure, Screening, Breast

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Charles P. Quesenberry, Jr., PhD (510) 891-3752
cpq@dor.kaiser.org

Biostatistical methods, survival analysis, cost of disease

Projects:

Cancer Surveillance in HMO Administrative Data 12



Catherine Schaefer, PhD..... (510) 891-3751
cas@dor.kaiser.org

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

Projects:

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Pharmacogenetics of Membrane Transporters..... 27



Donna M. Schaffer, RD, MPH (510) 891-3247
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 15

Dietary Supplement Use by Adult Members of Kaiser Permanente Medical Care Program of Northern California 37



Joe V. Selby, MD, MPH (510) 891-3407
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 20

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Stephen Sidney, MD, MPH (510) 891-3753
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 36

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Krikor Soghikian, MD, MPH (510) 891-3551
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 (510) 891-3555
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:

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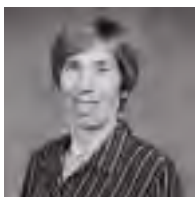
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Barbara Sternfeld, PhD (510) 891-3717
bxs@dor.kaiser.org

Physical activity epidemiology, exercise and women’s health, physical activity and cancer, cardiovascular

disease, physical activity, physical function and aging

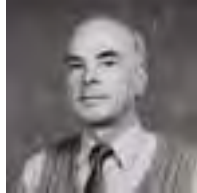
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Joseph F. Terdiman, MD, PhD..... (510) 891-3814
jft@dor.kaiser.org

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

Projects:

A New Assay for Cholesterol as a Predictor of Coronary Disease 17

Establishing a Traumatic Brain Injury Registry and Tracking System..... 29

Improvement of Wound Care Management by Teledermatology..... 37



Stephen K. Van Den Eeden, PhD (510) 891-3718
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:

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Lawrence J. Walter, MA..... (510) 891-3499

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:

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Constance M. Weisner, DrPH, MSW (510) 891-3599

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*

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DOR Investigators – C. Weisner (cont.)



Rachel Whitmer, PhD (510) 891-3461
raw@dor.kaiser.org

Women’s health interdisciplinary research, cardiovascular epidemiology, human development, biopsychology

ADJUNCT INVESTIGATORS, THEIR AREAS OF EXPERTISE AND CURRENT PROJECTS

James E. Allison, MD, FACP (510) 450-2724
jea@dor.kaiser.org

Screening for colorectal cancer, costs of H. pylori associated peptic ulcer disease, cost effective management of H. pylori associated peptic ulcer disease

Clinical Professor of Medicine, University of California, San Francisco

Faculty, Gastroenterology Division, University of California, San Francisco General Campus

Investigator, Division of Colorectal Cancer Research, Department of Gastroenterology, Veterans Administration Hospital, San Francisco

Douglas Corley, MD MPH (510) 891-3811
dac@dor.kaiser.org

Gastroenterology, Medicine, Epidemiology

Assistant Clinical Professor of Medicine, University of California, San Francisco

Projects:

Evaluation of Risk Factors for Barrett’s Esophagus **13**

Mark Eisner, MD MPH (510) 891-3881
mde@dor.kaiser.org

Pulmonology, asthma

Projects:

Asthma Health Outcomes Following Intensive Care **37**

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S. Claiborne Johnston, MD (510) 891-3768
scj@dor.kaiser.org

Neurology and neurologic disorders

Jennifer Kelsey, PhD (650) 725-6114
kelsey@osiris.stanford.edu

Epidemiology of osteoporosis, fractures, and falls

Professor of Health Research and Policy, Division of Epidemiology, Stanford University School of Medicine

Arthur L. Klatsky, MD (510) 891-3241
alk@dor.kaiser.org

Health effects of alcohol, coffee, cardiovascular epidemiology

Projects:

Alcoholic Beverage Choice and Mortality **9**

Adjunct Investigators (cont.)

Nancy Krieger, PhD (617) 432-1571
nkrieger@hsph.harvard.edu

Epidemiology of social inequalities in health, cancer, hypertension
Assistant Professor, Department of Health and Social Behavior, Harvard University School of Public Health

Tracy A. Lieu, MD, MPH (617) 421-6218
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 **24**

Lorraine Midanik, PhD (510) 642-7974
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

Charles D. Moore, PhD (916) 482-1132
charlie.moore@kp.org

Medical Informatics, Biology
Subregional Chief of Mental Health and Chemical Dependency Services

Projects:

Medical Comorbidity in Alcoholics: Service Implications **10**

Methamphetamine Dependence and the Risk of HIV infection **11**

Lorene Nelson, PhD (650) 723-6854
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

Pediatrics
Professor of Epidemiology and Biostatistics, Pediatrics, and Laboratory Medicine, University of California, San Francisco

Henry R. Shinefield, MD (415) 202-6295
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

Projects:

Comprehensive Linked Data Collection of Medical Events and Immunization (Vaccine Safety and Development Datalink) **25**

David H. Thom, MD, PhD **Adjunct Investigators (cont.)**
(650) 725-2912
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 36

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 24,000 square feet on two floors of the DOR is available for clinical research. The main clinic on the 9th 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 2001:

Thirteen studies utilized the research clinics during the year 2001. Nearly 5300 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 2001

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.

Utilization of Cardiac Services & Management of Coronary Heart Disease **Within KPNC: 1996-2000**

Dr. Alan Go 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 adjusted risk of in-hospital mortality following acute myocardial infarction has decreased by 27% between 1994 - 2000, consistent with the increased use of evidence-based therapies (e.g., thrombolytic therapy, aspirin, beta-blockers, ACE inhibitors). However, there remains significant opportunity to improve the management of dyslipidemia in patients with myocardial infarction and especially among outpatients with angina for the secondary prevention of cardiac events and death.

HIV/AIDS Database

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 Committee, DOR developed and maintains an HIV/AIDS Database. The Database continues to be managed by Leo Hurley at DOR, and is the definitive resource for HIV incidence and prevalence reporting in KP Northern California (see <http://dor-ent1.kaiser.org/>, Research Projects, AIDS/HIV Annual Report). The HIV/AIDS Database is accessible to only three staff at DOR and patient identifiers are encrypted. The Database is used primarily to support and evaluate HIV care delivery in Northern California and in resource allocation decisions. The database is also used for recruiting members for Northern California HIV clinical trials, and for conducting epidemiological and health services research as initiated by KP clinicians and DOR investigators, and as approved by the Institutional Review Board and the Regional HIV/AIDS Committee. Dr. Stephen Sidney and Leo Hurley are members of the Regional HIV/AIDS Committee.

Services Provided and Studies Conducted for Kaiser Permanente in 2001 – TPMG (cont.)

The Kaiser Permanente 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 (KPNCCR) was established, providing the first complete region wide cancer data, and structured utilizing the standards of common practice among cancer registries. The KPNCCR 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 KPNCCR 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 DOR's numerous research endeavors.

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.

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

Services Provided and Studies Conducted for Kaiser Permanente in 2001 – TPMG (cont.)
equipment to all patients with diabetes (Dr. Karter).

Home visits versus group visits following early postpartum discharge

In 2001, the DOR Perinatal Research Unit (PRU) completed a randomized clinical trial at the Santa Clara facility. This trial compared individual home visits by a nurse to group neonatal visits (“the Newborn Club”) and individual clinic visits. No differences in outcomes were found, although patient satisfaction was higher in the home visit group.

Kaiser Permanente Neonatal Minimum Data Set (NMDS) (Joint TPMG/KFHP funding)

The NMDS database project was originally funded by an Innovation Program grant in 1991. The database now consists of a wide area network linking all 6 level III intensive care nurseries in Northern California (Hayward, Oakland/Alta Bates, Sacramento, San Francisco, Santa Clara, and Walnut Creek) as well as two smaller units (Santa Teresa and Vallejo). The NMDS database serves as the principal database for the DOR Perinatal Research Unit and continued to generate high quality outcomes data which are employed for internal purposes as well as for the generation of pilot data for grant proposals. Major developments in the year 2001 were: 1) completion of the SNAP-II project to define a new neonatal severity of illness score; and 2) increased output of reports to clinicians, including a new outcomes report and development of a capability to report to two projects that have regulatory implications, the California Perinatal Quality Care Collaborative and generating data to meet California Children’s Services reporting requirements. In addition to these activities, the NMDS infrastructure and data outputs continued to be used to support several Federal and internally-funded projects.

Looking for Trouble in All the Right Places (Jointly funded by TPMG and the National Patient Safety Foundation)

Work on this project continued in 2001, and results from it were employed to support two new projects funded by the Garfield Memorial Fund. The first of these was “New Approaches to Improving Quality of Kaiser Permanente Obstetric Care,” which aimed to take these techniques into a more operational context, and the second was “The Perinatal Patient Safety Project,” which aimed to decrease human error in obstetrics at 3 pilot sites (since expanded to 4 in 2002).

Early Start

This project provides confidential counseling to women at risk for substance abuse during pregnancy. Originally funded as a pilot study by the Garfield Fund in 1990, the program now operates in 19 of the 32 obstetrics outpatient clinics in Northern California, screening approximately 24,000 women each year. During the year 2001, the DOR PRU having completed an analysis of the effectiveness of the Program as well as a business case, worked with the Chiefs of Obstetrics and Gynecology to continue expanding the program in Northern California.

Other projects

The DOR PRU continued providing regular reports on obstetrics outcomes and utilization as well as providing consultation support to KP clinicians and administrators. Three projects continued in active data collection (the *Unstudied Infants: Low Risk Babies in a High Risk Place*, which focuses on premature infants 30-34 6/7 weeks gestation; the *5 year outcome of severe neonatal jaundice and dehydration* project; and a case control study focusing on the relationship between cerebral palsy and chorioamnionitis). One large new project was funded and began developing data collection tools, the *Infant Functional Status and Discharge Management* project, which aims to define appropriate criteria for discharge of premature 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. Dr. Nancy Gordon and her staff provide

Services Provided and Studies Conducted for Kaiser Permanente in 2001 – KFH (cont.)

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). In 2001, program evaluations or needs assessments were conducted in the following topic areas: behavioral health/mind-body medicine psychoeducation classes; 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.

1999 and 2002 Adult KP Member Health Surveys. With support from both DCBI and TPMG, Dr. Gordon conducts a large mailed survey of a random sample of adult Health Plan members in Northern California every three years since 1990. The Member Health Survey (MHS) is the only regional source of information linking self-reported health and functional status, behavioral risk factors, preventive service use, and satisfaction. These survey data can also be linked with KPMCP administrative and clinical databases. The MHS enables Kaiser to compare its membership with the general insured population (e.g., based on National Health Interview Survey and California Behavioral Risk Factor Survey) from the same geographic area.

Regional and medical center-specific profiles of the adult health plan membership are made available to health education departments and external affairs managers for needs assessment purposes. 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>).

Data may also be made available to community and government agencies, academic researchers, and other health plans upon special request.

A particular focus of both the 1996 and 1999 surveys was the use of complementary and alternative (CAM) medicines. During 2001, two presentations at a national Complementary and Alternative Medicine conference reported on trends in use of different CAM modalities in 1996 and 1999, with special focus on the increase in herbal use, and on use of herbals and other types of supplements among respondents who were also taking drugs with a narrow therapeutic index.

During the latter part of 2001, planning commenced for the 2002 MHS.

Member Information Project. DCBI and Garfield Memorial Fund support in Year 2001 helped to fund this pilot project which tests a method of collecting sociodemographic information from adult members in two Kaiser Permanente medical facilities (Vallejo and Oakland). The Member Information Project also aims to study whether traditionally underserved member subpopulations (based on race/ethnicity, education, and language barriers) are as likely as the non-disadvantaged population to receive guideline-concordant preventive and chronic disease management services within Kaiser Permanente and to analyze the possible role of education and language barriers as mediating factors if differences in services received are observed.

Evaluating Knowledge and Awareness of Blood Pressure Among Hypertensive Patients. DCBI funding was used along with funding from Bristol-Myers-Squibb for this survey of 2500 KPMCP patients with hypertension. The major aims of this project were to assess patient awareness of personal levels and recommended levels of systolic and diastolic blood pressure. Preliminary results of the project were presented by Dr. Mark Alexander at the American Heart Association Scientific Sessions, November 2001.

During the year 2001, DCBI funds were used to support ten projects and a graduate student intern from the University of California, Berkeley, School of Social Welfare. The graduate student played a major role in the development of a booklet for flight attendants dealing with trauma in response to the events of September 11. The booklet was a combined effort of Kaiser Permanente, The Depression and Bipolar Support Alliance (formerly the Depressive and Manic-depressive Association), the Association of Flight Attendants and the U.S Department of Health and Human Services Substance Abuse and Mental Health Services Administration. The pamphlet was distributed to over 48,000 flight attendants at 26 carriers worldwide, including over 11,000 furloughed flight attendants. The pamphlet has been read by the Office of National Drug Control Policy (ONDCP) with the Executive Office, provided to them by Health and Human Services. We are now working on a second printing of the flight

Services Provided and Studies Conducted for Kaiser Permanente in 2001 – KFH (cont.)

attendant booklet and developing a similar booklet for airline pilots.

Of the ten projects, two of the projects are now completed (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). Four of the projects (Efficacy of Nurse Telehealth Care and Peer Support in Augmenting Treatment of Depression in Primary Care, Comorbid Psychiatric Symptoms, Associated Role dysfunction and Non-psychiatric Medical Care Cost in a Managed Care Setting, Community on Patrol for Safety (COPS) and Can Trained Volunteers Provide Social Support and Increase Access to Social and Health-related Services for Functionally Disabled Adults?) have completed work in the field and we are now writing articles about them. In addition to the manuscript for the Efficacy of Nurse Telehealth Care and Peer Support in Augmenting Treatment of Depression in Primary Care project, twenty (20) nurses in Southern California have been trained to provide nurse telehealth care. Two of the projects (Evaluating the Effectiveness of a Disease Management Model of the Treatment of Depression Among Elderly Primary Care Patients in a Managed Care Setting -aka IMPACT and Glycemic Control in Patients with Depression and Diabetes Mellitus: Impact for Depression) are currently active still in the field. One project (A Managed Care and Managed Housing Survey to Assess How the Elderly and Disabled Adults Perceive Their Social and Health-related Needs) is in the data analysis phase. There is one new project (Suicide Attempt and Completed Suicide among Kaiser Permanente Members in Northern California, 1994-1999: Time Trends, Area Variation and Association with Psychiatric Conditions and Modality of Care). There were three articles accepted for publication and five presentations made at various conferences.

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

The Mental Health/Chemical Dependency Interest Group continued to meet monthly during the year 2001. The meeting format usually included a formal presentation with a DOR guest speaker (i.e., “Implementation of Parity in Kaiser Permanente”, presenter- Robin Dea, MD, Regional Chief of Psychiatry Chiefs in Northern California and “Persons with Depression and the Treatment they Receive: Comparison of Primary Care Physicians and Psychiatrists”, presenter David Pingatore, PhD, UCSF Mental Health Investigator), a discussion of projects in development, updates from DOR and Regional Committees, such as the Dual Diagnosis Best Practices Committee, and announcements of relevant conferences and events.

DOR researchers and staff continue to regularly serve on Regional oversight committees and workgroups in the MH/CD area, and provide consultation and other assistance to several Regional projects. During the report period DOR Investigators were actively involved in eighteen research projects related to mental health or chemical dependency. A mental health and chemical dependency database was created and is maintained on a regular basis.

OTHER SERVICES

Administration

The Division of Research provides comprehensive administrative services to DOR personnel as well as to other KP/TPMG 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 can provide assistance with 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.

Biostatistical Support

The Division of Research (DOR) provides short-term biostatistical consulting services to clinicians. More specifically, DOR Biostatisticians offer a wide range of biostatistical expertise and service, including:

- 1) advice on statistical methods, 2) interpretation of results and 3) recommendations for revising biostatistical

Other Services (cont.)

methodology sections in publication drafts. The Division of Research Biostatisticians have all completed formal training at either the Doctorate or Master's level and are very experienced researchers.

Breast Cancer Task Force

Dr. Carol Somkin has been an active member of the Breast Cancer 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. The survey was conducted for the third time in 2001. 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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