# Permanente Abstracts

We are pleased to highlight six abstracts authored by Kaiser Permanente (KP) clinicians and researchers. The abstracts are taken from articles published in leading scientific and medical research journals in recent months. Addressing the mounting interest in rigorously testing alternative therapies, Cherkin et al conducted a randomized clinical trial testing the effectiveness of chiropractic manipulation compared with physical therapy and provision of an educational booklet for patients experiencing low back pain. They found that for all outcomes, there were no significant differences between the physical therapy and chiropractic groups.

In another randomized clinical trial, Williams et al found that a touch-sensitive computer-based system for preventive services can contribute to an improvement in completion of screening mammography and clinical breast exams in women 50 years of age and older. This was particularly true of patients who had a health maintenance exam (HME) during the study year.

In this issue, Kaiser Permanente databases and registries demonstrate their value as resources for retrospective studies in several clinically important areas. Managed care has been criticized for early discharge of women who have uncomplicated vaginal deliveries, because this might be correlated with a higher risk of rehospitalization. In a retrospective cohort study, Meikle et al used the Colorado Kaiser Permanente Perinatal Database, administrative databases, billing records and inpatient charts to determine whether length of stay was correlated with rehospitalization or increased outpatient contacts for woman after vaginal delivery. This study emphasized the importance of a flexible discharge policy managed by the attending physician.

Diabetes care is a focal area of research and implementation of disease management strategies in Kaiser Permanente. Brown et al used the KP Northwest Division's integrated laboratory information system and the KPNW Regional Diabetes Registry to examine the impact of the new American Diabetes Association criteria for diagnosis of type II diabetes. This study shows the value of having sensitive and specific databases for determining appropriate treatment, forecasting, and planning for increases in demand and ability to quickly contact and inform patients.

The national Vaccine Adverse Event Reporting System (VAERS) provided the passive surveillance data for a case series and Kaiser's Vaccine Safety Datalink (VSD), the computerized record linkage system to compare the postmarketing safety experience of two recombinant hepatitis B (HepB) vaccines licensed for infants and children in the US. The study, by Niu et al, revealed that more serious adverse events were reported in children who received a specific brand of recombinant HepB vaccine. This underscores the importance of using independent data sets (VSD) for postmarketing assessment of vaccine safety profiles.

Robbins et al compared the stage-specific prostate cancer survival of black and white male members and nonmembers of the KP San Francisco Bay region. Population-based cancer registry data show that black men with prostate cancer have poorer stage-specific survival outside of equal access health care systems. These findings support the hypothesis that tumor virulence is higher in blacks. ❖

*– Mary Durham, PhD, Associate Editor*

## A Comparison of Physical Therapy, Chiropractic Manipulation, and Provision of an Educational Booklet for the Treatment of Patients With Low Back Pain

*Cherkin DC; Deyo RA; Battie M; Street J; Barlow W. N Engl J Med 1998;339:1021-9.*

**Background and Methods:** There are few data on the relative effectiveness and costs of treatments for low back pain. We randomly assigned 321 adults with low back pain that persisted for seven days after a primary care visit to the McKenzie method of physical therapy, chiropractic manipulation, or a minimal intervention (provision of an educational booklet). Patients with sciatica were excluded. Physical therapy or chiropractic manipulation was provided for one month (the number of visits was determined by the practitioner but was limited to a maximum of nine); patients were followed for a total of two years. The bothersomeness of symptoms was measured on an 11-point scale, and the level of dysfunction was measured on the 24-point Roland Disability Scale.

**Results:** After adjustment for baseline differences, the chiropractic group had less severe symptoms than the booklet group at four weeks (P=0.02), and there was a trend toward less severe symptoms in the physical therapy group (P=0.06). However, these differences were small and not significant after transformations of the data to adjust for their non-normal distribution. Differences in the extent of dysfunction among the groups were small and approached significance only at one year, with greater dysfunction in the booklet group than in the other two groups (P=0.05). For all outcomes, there were no significant differences between the physical therapy and chiropractic groups and no significant differences among the groups in the number of days of reduced activity or missed work or in recurrences of back pain. About 75 percent of the subjects in the therapy groups rated

their care as very good or excellent, compared with about 30 percent of the subjects in the booklet group (P<0.001). Over a two-year period, the mean costs of care were $437 for the physical-therapy group, $429 for the chiropractic group, and $153 for the booklet group.

**Conclusions:** For patients with low back pain, the McKenzie method of physical therapy and chiropractic manipulation had similar effects and costs, and patients receiving these treatments had only marginally better outcomes than those receiving the minimal intervention of an educational booklet. Whether the limited benefits of these treatments are worth the additional costs is open to question.

## A Patient-Initiated System for Preventive Health Care: A Randomized Trial in Community-Based Primary Care Practices

*Williams RB; Boles M; Johnson RE. Arch Fam Med 1998;7:338-45.*

**Objective:** To test the effectiveness of a patient-initiated, touch-sensitive computer system (TSCS) for improving screening rates for cancers of the breast, cervix, colon and rectum, and oral cavity.

**Design:** One-year, randomized controlled trial with primary care practice as the unit of analysis.

**Setting:** Sixty primary care practices, randomly recruited from 329 nonteaching practices in a southeastern state.

**Subjects:** Random sample of the medical records of 50 male and female adult patients before intervention, and 50 adult patients after intervention in each practice, and a random sample of 507 TSCS users.

**Interventions:** Touch-sensitive computer system and a registered nurse who served as liaison to the study practices. The TSCS provided patient-specific preventive service recommendations and facilitated work flow to increase the completion of these interventions.

**Main Outcome Measures:** Average change, adjusted for health maintenance examination (HME) and use of the TSCS, in the proportion of eligible patients undergoing screening mammography, clinical breast examination, digital rectal examination, fecal occult blood test, flexible sigmoidoscopy, Papanicolaou smear, and oral cavity examination.

**Results:** We observed a significant increase in the completion of screening mammography (6.6%;P≤.05) and clinical breast examination (6.1%;P≤.01) in women 50 years of age and older, particularly for those who had an HME during the study year.

**Conclusions:** Patients who have HMEs are more likely to receive cancer screening; however, a computer-based system for preventive services can contribute to improvement in screening. Among those patients who did not have an HME, TSCS users had higher rates of breast cancer screening than nonusers.

## Rehospitalizations and Outpatient Contacts of Mothers and Neonates after Hospital Discharge after Vaginal Delivery

*Meikle SF; Lyons E; Hulac P; Orleans M.Am J Obstet Gynecol 1998 Jul;179(1):166-71.*

**Objective:** Our purpose was to determine whether length of hospital stay after vaginal delivery as determined by the discharging physician is associated with rehospitalizations or increased outpatient contacts by mothers and neonates and to assess the impact of home health care visits.

**Study Design:** An inception cohort study of all rehospitalizations and outpatient contacts of mothers and neonates after vaginal delivery at St. Joseph Hospital, Denver, Colorado, was done from January 1, 1994, to September 30, 1995. All Kaiser Permanente mother-neonate pairs in which the delivery was vaginal (excluding those with multiple gestations or birthweight <2500 g) were included. Length of initial hospital stay was divided into three time periods: ≤ 24 hours, 25 to 48 hours, and > 48 hours. The Colorado Kaiser Permanente Perinatal Database was used to identify perinatal and demographic factors that might have increased health care use. Additional information was sought in administrative databases, bill records, and inpatient charts. Mothers were followed up for 6 weeks and neonates for 28 days after delivery. Home care visits were provided to more than half the mothers and neonates by means of a standardized protocol. The main outcome measures were rehospitalizations and outpatient visits for mothers and neonates, controlling for home care visits.

**Results:** A total of 4323 mother-neonate pairs were identified. For mothers, a longer initial hospital stay (> 48 hours) was significantly associated with both readmission (P < .01) and increased outpatient care use (P = .01) in the 6-week postpartum period. Thirty-five mothers (.81%) were rehospitalized by 6 weeks. Maternal factors associated with increased outpatient contacts were preeclampsia, preterm delivery, and instrument delivery. Sixty-seven neonates (1.55%) were readmitted to the hospital. Home care visits reduced the need for both readmissions and outpatient visits.

**Conclusions:** For mothers in this cohort, a longer initial hospital stay was significantly associated with hospital readmission and increased outpatient care in the postpartum period. Further analysis revealed that mothers with recognized potential and observed problems were rarely discharged in ≤ 24 hours. We did not find statisti-

cally significant problems among neonates that were related to the length of their initial hospital stay. Those neonates receiving home care were less likely to require hospital readmission and less likely to seek outpatient care. It is unlikely that a single discharge policy will be appropriate for all mothers and neonates.

### Impact on a Population-Based Registry of Changing Diagnostic Thresholds for Diabetes

*Brown J; Glauber H; Nichols G. Diabetes Care 1998 21(8):1374-5.*

**Background:** In an effort to simplify the process of detecting type 2 diabetes and to better align the results of oral glucose tolerance testing (OGTT) with fasting plasma glucose (FPG) concentration, the American Diabetes Association recently proposed a new diagnostic threshold for type 2 diabetes: [a] a confirmed fasting plasma glucose (FPG) ≥ to 126 mg/dL or [b] a confirmed nonfasting plasma glucose (non-FPG) ≥ 200 mg/dL. Recent publications indicate that adopting the new diagnostic criterion would increase the number of persons with diagnosed diabetes from 7.9% to 9.9% of adults aged 40-74 years if all undiagnosed members of a population were screened. We examined this question in the highly sensitive and specific databases of Kaiser Permanente Northwest Division's Regional Diabetes Program.

**Methods:** In 1996, our diabetes registry contained 16,597 members with diabetes and at least one month of health plan eligibility (4.12% of total membership). A single integrated laboratory information system in use since 1993 recorded all outpatient and most inpatient laboratory test on health plan members.

**Results:** We identified 7899 members who had either a confirmed FPG 126-140mg/dL or a confirmed non-FPG>200 mg/dL between January 1, 1993 and December 31, 1996. Of this number, 6081 were already in the diabetes registry. Of the remaining 1818, 752 subsequently entered the registry by the end of 1996. Therefore, over the three year interval studied, adoption of the new ADA diagnostic threshold would have identified 1066 members who would not otherwise have entered the diabetes registry by the end of 1996, increasing the registry size at the end of 1996 by 6.4%.

**Discussion:** Although we cannot precisely predict what will happen as the new ADA threshold achieves acceptance and as results in the 126-139 mg/dL range are followed up more aggressively, our analysis suggests that in a large, stable, integrated group-model HMO, lowering the diagnostic threshold for type 2 diabetes to FPG≥126 mg/dL would increase the number of persons diagnosed with diabetes by approximately 6.4%.

### Comparative Safety of Two Recombinant Hepatitis B Vaccines in Children: Data From the Vaccine Adverse Event Reporting System (VAERS) and Vaccine Safety Datalink (VSD)

*Niu MT; Rhodes P; Salive M; Lively T; Davis DM; Black S; Shinefield H; Chen RT; Ellenberg SS. J Clin Epidemiol 1998 Jun;51(6):503-10.*

**Background:** Preliminary review of data from the Vaccine Adverse Event Reporting System (VAERS), 1991-1994, revealed that more serious adverse events were reported in children who received a specific brand of recombinant hepatitis B (HepB) vaccine.

**Objective:** To compare the postmarketing safety experience of the two recombinant HepB vaccines licensed for use in infants and children in the United States.

**Design:** Review of a case series derived from passive surveillance data in the national VAERS. A retrospective cohort study using data from one health maintenance organization participating in Vaccine Safety Datalink (VSD), a computerized record linkage system.

**Populations Studied:** U.S. children, ages birth-10 years, for whom adverse events after HepB vaccine were reported to VAERS, 1991-1994. Children, ages birth-6 years, who received HepB vaccine at Kaiser Permanente Medical Care Program, Northern California, 1991-1994.

**Main Outcome Measures:** VAERS reporting rates for each vaccine by manufacturer were calculated from the numbers of reported events occurring within 30 days of HepB vaccination and the number of doses distributed by the manufacturers. VSD event rates for each vaccine were calculated from the numbers of hospitalization or emergency room visits within 30 days of HepB vaccination and the number of vaccine doses administered to the cohort.

**Results:** In VAERS, higher rates of serious events (ie, life-threatening or resulting in hospitalization or permanent disability) were reported in children who received Vaccine A vs. Vaccine B (relative risk [RR]: 3.13-8.18, P<0.01), particularly by those vaccinated in the private (RR: 7.62-28.58, P<0.01) but not public sector (RR: 2.12, P=0.19). Similar types of events were reported in recipients of both vaccines. In contrast, analysis of VSD data showed no significant difference in rates of hospitalization or ER visits in children who received either HepB vaccine (RR: 0.96-1.25, P>0.05).

**Conclusions:** Our investigation reveals that it is unlikely there is a true difference between rates of

serious events temporally associated with the two HepB vaccines in children. This study demonstrates the dual roles played by VAERS and VSD in providing a more complete picture of the postmarketing safety profile of childhood vaccines and underscores the importance of using other analytic studies to evaluate findings from passive surveillance systems of adverse events.

### Race, Prostate Cancer Survival, and Membership in a Large Health Maintenance Organization

*Robbins AS; Whittemore AS; Van Den Eeden SK. J Natl Cancer Inst 1998 Jul;90(13):986-90.*

**Background:** Population-based cancer registry data have shown that black men with prostate cancer have poorer stage-specific survival than white men, while studies in equal-access health care systems have not found racial differences in stage-specific survival. This study was designed to test the hypothesis that black men and white men with prostate cancer have equal stage-specific survival in equal-access health care systems.

**Methods:** We conducted a cohort study using cancer registry data from all incident cases of prostate cancer occurring in a five-county San Francisco Bay Area region. Incident cases occurred among members (5263 cases, from January 1973 through June 1995) and nonmembers (16,019 cases, from January 1973 through December 1992) of the Kaiser Permanente (KP) Medical Care Program, a large health maintenance organization. Death rate ratios (DRRs, black men versus white men) for KP members and nonmembers were computed for all stages combined (adjusting for age and stage) and for each stage (adjusting for age).

**Results:** Among KP members, adjusted DRRs comparing black men with white men were as follows: all stages combined, 1.28 (95% confidence interval [CI] = 1.14-1.44); local stage, 1.23 (95% CI = 1.01-1.51); regional stage, 1.30 (95% CI = 0.97-1.75); and distant stage, 1.27 (95% CI = 1.07-1.50). Corresponding DRRs for nonmembers were as follows: all stages combined, 1.22 (95% CI = 1.14-1.30); local stage, 1.24 (95% CI = 1.09-1.41); regional stage, 1.48 (95% CI = 1.29-1.68); and distant stage, 1.01 (95% CI = 0.91-1.12).

**Conclusions:** These results show poorer prostate cancer survival for black men compared with white men in an equal-access medical care setting. The findings are most consistent with the hypothesis of increased tumor virulence in blacks.

We are guests in our patients' lives; and we are their hosts when they come to us. Why should they, or we, expect anything less than the graciousness expected by guests and from hosts at their very best. Service is quality.

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