3-Year Follow-up from a Cluster-Randomized Trial of a Primary Care Informatics-Based System for Breast Cancer Screening

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BACKGROUND: We sought to increase screening for breast cancer in eligible women within one primary care (PC) practice-based research network (PBRN) through a novel system of integrated population-based surveillance that linked patients to primary care providers (PCPs) and used an informatics tool to let providers review overdue patients and initiate outreach for those selected for contact.

METHODS: We randomized 12 PC practices (4 community health centers and 8 affiliated practices) to intervention (n=6) or usual care (n=6). Women 42 to 69 years of age without prior bilateral mastectomy were eligible and linked to a specific PCP or practice (if not PCP linked). Patients overdue for screening included 1) those who had not had a mammogram in the two years prior to the start of the trial (prevalent overdue) or 2) those who became two years overdue in the year after the study start date (incident overdue). In intervention practices, PCPs (for PCP-linked patients) and case managers (CMs, for practice-linked patients) received three periodic emails during the one year trial with a direct link to a web-based informatics tool that listed their overdue patients. Providers could select patients for contact or defer patients and provide a reason. Patients selected for contact received an automatically-generated letter with information about the value of screening and how to schedule a mammogram. The tool then transferred these patients to practice delegates who called patients to schedule tests or document exclusions. After the one year study period, the informatics tool remained active, though no reminder emails were sent and the original population was not updated. We examined time to mammography completion over a 3-year follow-up period in all overdue patients and in prevalent and incident overdue populations using Kaplan-Meier curves and Cox proportional hazards regression controlling for baseline covariates and physician/practice clustering.

RESULTS: Among 32,688 eligible women, baseline mammography screening rates in intervention and control groups did not differ (79.5% vs. 79.3%, p=0.73). Overall, 9795 women were overdue for mammograms including 6697 at the start of the study (prevalent overdue: 3045 in intervention and 3652 in control practices) and 3098 during the one year trial period (incident overdue: 1442 in intervention and 1656 in control practices). Intervention patients were younger, more likely to be non-Hispanic white, and have health insurance. Most intervention PCPs (59 of 64, 92%) and all CMs (6 of 6) used the tool. Action was taken in 3415 (76.1%) intervention patients (2865 [84%] contacted and 550 [16%] deferred). Over three years of follow-up, intervention patients were more likely to have a mammogram than control patients (hazard ratio: 1.19, 95% CI: 1.10-1.29, p<0.001).

CONCLUSION: We developed a novel system for breast cancer screening that included a non-visitbased informatics tool for providers to screen their overdue list for contact and follow-up by practice delegates. Over three years of follow-up, intervention patients were more likely to complete mammography screening.
Evaluation of Rilonacept for Prevention of Gout Flares During Initiation of Urate-Lowering Therapy: Results of a Phase 3, Randomized, Double-Blind, Placebo-Controlled Trial

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BACKGROUND: While attaining serum uric acid levels <6.0 mg/dL is critical to the long-term management of gout, gout flares (GFs) are often precipitated as serum uric acid levels fall during the initial months of urate-lowering therapy (ULT). This phase 3 study evaluated the efficacy and safety of rilonacept, an interleukin-1 (IL-1) blocker, for the prevention of GFs during initiation of ULT with allopurinol.

METHODS: This multicenter trial included adults with gout (1977 ARA preliminary criteria), uric acid levels ≥7.5 mg/dL, and self-reported history of 2 or more GFs in the previous year. Eligible patients were initiated on allopurinol 300 mg daily (or lower dose in those with renal dysfunction) with subsequent titration to achieve uric acid <6 mg/dL and randomized to receive treatment (Tx) with weekly subcutaneous (SC) injections of placebo (Pbo; n=80), rilonacept 80 mg (R80; n=80), or rilonacept 160 mg (R160; n=81) (loading dose on Day 1). GFs were reported by the patient via interactive voice response diary; GFs were treated, as appropriate, with NSAIDs or oral glucocorticoids while continuing weekly SC injections and allopurinol Txs. The primary endpoint was the mean number of GFs over the 16 week Tx period. Other endpoints included the percent of patients with 1 or more GFs, and the number of GFs during each 4 week Tx period through week 16. Safety and tolerability were also assessed.

RESULTS: Baseline characteristics were similar among treatment groups; 92.9% were male, the mean (SD) age was 52.3 (12.6) years, and the number of flares reported in the prior year was 4.6 (3.3). By week 2 median serum uric acid levels decreased to 6.0 mg/dL in the R groups and 6.2 mg/dL in the Pbo group. Through week 16, the mean number of GFs per patient (primary endpoint) was significantly lower in both R groups relative to Pbo: 1.06 for Pbo; 0.29 for R80 (95% CI, 0.20 to 0.60; p=0.0003 vs Pbo), and 0.21 for R160 (95% CI, 0.14 to 0.41; p<0.0001 vs Pbo). From day 1 to week 16, the proportion of patients who experienced one or more GFs was 46.8% Pbo (95% CI, 35.5 to 58.4) vs 18.8% R80 (95% CI, 10.9 to 29.0) vs 16.3% R160 (95% CI, 8.9 to 26.2; p<0.0001 for both comparisons), resulting in an 60% and 65% reduction in the respective R groups. The number of GFs per Tx period is shown in table 1.

The overall incidence of adverse events (AE) was similar between Pbo (60.8%) and rilonacept (63.4%). Injection site reactions (generally mild) were the most frequent AE with rilonacept compared with placebo (1.3% Pbo, 8.8% R80, 19.8% R160). Other common AEs included respiratory infections, musculoskeletal system disorders, and headache, and rates were similar among the treatment groups. Three patients in each group experienced serious AEs; no rilonacept-related SAEs, deaths, or serious infectious AEs were reported.

CONCLUSION: This phase 3 trial confirmed that IL-1 blockade with rilonacept markedly reduced the occurrence of gout flares during initiation of urate-lowering therapy. Rilonacept demonstrated an acceptable safety and tolerability profile.
Activating Patients to Improve Glycemic Control: The Reducing Racial/Ethnic Disparities in Diabetes with Coached Care (R2D2C2) Project Sherrie H. Kaplan 1; Dara H. Sorkin 1; John Billimek 1; Quyen Ngo-Metzger 1; Sheldon Greenfield1. 1University of California, Irvine, Irvine, California. (Proposal ID # 10795)

BACKGROUND: The Coached Care intervention, aimed at increasing patient involvement in treatment decisions, has been shown to improve the health outcomes of patients with chronic diseases. In order to assess its effectiveness in reducing disparities in diabetes care among diverse patient groups, we modified the intervention to use community-based coaches with diabetes drawn from outpatient clinics of a university teaching hospital.

METHODS: We conducted a stratified, randomized controlled cluster trial at all 6 outpatient clinics of a university teaching hospital. We stratified by clinic and three ethnic groups: Non-Hispanic white, Mexican-American, and Vietnamese. Patients are randomized to enroll in either the Coached Care intervention or the control group and are followed for two years. Patients enrolled in the Coached Care intervention are each paired with an ethnically and linguistically matched "coach", who meets with the patient for 20 minutes before every diabetes-related medical visit during the study period. The coaches, who themselves also have diabetes, were recruited from the community and trained to teach patients skills to negotiate treatment decisions with their providers. Patients randomized to the control group complete 20-minute standardized diabetes education sessions with a research assistant before each visit.

To date, 677 patients have been enrolled in the study. All study patients completed baseline and follow-up surveys. Other key study variables were collected from medical records, laboratory and administrative databases. The primary outcome was change in hemoglobin A1c from baseline to one-year follow-up. Multiple regression was used to test intervention effects on glycemic control over the observation period.

RESULTS: To date, 288 patients (79% Mexican American, 8% Vietnamese, 13% Non-Hispanic white) have completed the one-year observation point. The majority of patients (53%) had a median annual household income below $20,000; 66% had limited proficiency in English. There were no significant differences between the Coached Care group (mean[SD]=9.1[1.4]) and control group (9.2[1.6]; p=.52) in baseline HbA1c values. At one year, patients in the Coached Care intervention group had a significantly lower HbA1c (8.6[1.8]) compared to controls (9.2[1.9]; p<.05). This difference persisted after adjustment for baseline HbA1c, age, gender, race/ethnicity, duration of diabetes and regimen intensity (adjusted mean difference[95%CI]=−0.38[-0.75,-0.02]; p<.05).

CONCLUSION: Coached Care appears to improve glycemic control in a socioeconomically and ethnically diverse patient sample. Further research will address whether for similar access to care, Coached Care is effective in reducing racial disparities.
BACKGROUND: Despite high rates of post-deployment psychosocial problems in Iraq and Afghanistan veterans, mental health and social services are under-utilized. We sought to evaluate whether a new Department of Veterans Affairs (VA) Integrated Care (IC) clinic (established in April 2007), offering an initial three-part primary care, mental health and social services visit, improved psychosocial services utilization in Iraq and Afghanistan veterans compared to Usual Care (UC), a standard primary care visit with referral for psychosocial services as needed.

METHODS: This was a retrospective study using VA administrative data to compare clinical outcomes of UC after 2007 to both UC before 2007 and IC after 2007. The study population included 526 Iraq and Afghanistan veterans initiating primary care at a VA medical center between April 1, 2005 and April 31, 2009. Multivariable models compared the independent effects of primary care type on VA mental health and social services utilization.

RESULTS: Compared to UC patients before April 2007, veterans presenting to UC after April 2007, were significantly more likely to have had an initial mental health evaluation (25% versus 59%, p After April 2007, there were further increases in initial mental health evaluations in the IC versus UC primary care clinic (92% versus 59%, p In particular, female veterans, younger veterans, and those with positive mental health screens were independently more likely to have had mental health and social services evaluations if seen in the IC versus UC clinic. Among veterans who screened positive for ≥ 1 mental health disorder(s), there was a median of 1 follow-up specialty mental health visit within the first year in both the UC and IC clinics.

CONCLUSION: Among Iraq and Afghanistan veterans new to primary care, an integrated primary care visit further improved the likelihood of an initial mental health and social services evaluation, but did not improve retention in specialty mental health services. Future studies can test interventions targeted at enhancing mental health services retention in combat veterans.
The Access Partnership: A model to improve access to specialty care for the uninsured? Lauren Block 1; Sai Ma 2; Matthew Emerson 3; Anne Langley 3; Desiree de la Torre 3. 1Johns Hopkins Hospital, Baltimore, Maryland; 2Johns Hopkins School of Public Health, Baltimore, Maryland; 3Johns Hopkins Medical Institution, Baltimore, Maryland. (Proposal ID # 11282)

BACKGROUND:
A patchwork of access to primary care exists for the uninsured across the U.S., but meeting the specialty care needs of this population remains a challenge, particularly as 25% of primary care visits end with a specialty referral. The Access Partnership (TAP) is a novel cooperative program between primary care and specialty physicians at an academic medical center program designed to provide access to needed specialty care for uninsured and underinsured patients. Providers refer patients from designated zip codes to needed specialty care and diagnostics. If the medical director agrees as to medical necessity, patients pay a nominal fee to enter the program, and a care coordinator schedules the appointment and any needed follow-up, including imaging and procedures, without any additional charges. We sought to evaluate program impact by examining patient satisfaction, perceived access to care, follow-through rates at specialty appointments, and emergency department utilization before and after initiation of the TAP program.

METHODS:
A program evaluation survey was created using a RAND questionnaire and administered via phone by trained interviewers. Answers were graded using Likert scales and positive answers grouped and tallied. Visit and claims data were analyzed for the first year of program activity. We then selected Medicaid patients from the same zip codes with matched specialty care referrals during the same period and surveyed 248 of these patients.

RESULTS:
Between May 2009 and April 2010, 726 specialty referrals were made for 336 patients, 309 patients had approved referrals, and 214 of these patients chose to enter the program. Of those patients who entered the program, we reached 136 (63%) by phone. Analysis of administrative data revealed that 89% of referrals for patients who entered the program were completed, which is comparable to specialty care show rates found in the literature. Referrals to diagnostic tests and specialty physicians were more likely to be completed than referrals to ancillary care and pain management providers. 21% of patients surveyed reported completing specialty referrals in the year prior to joining TAP (pre-TAP), compared with 88% in the time since joining TAP (post-TAP) (p<0.001). Patient-reported access to care increased significantly after TAP, with 33% of patients reporting access to care pre-TAP, and 87% of patients reporting access to care post-TAP (p<0.001). Patient satisfaction with healthcare increased significantly after TAP, with 41% of patients reporting satisfaction with care before TAP, and 91% reporting satisfaction with care after TAP (p<0.001). 86% of patients reported a financial barrier to specialty care pre-TAP, compared with 18% post-TAP (p<0.001). Reported ED visit rate per month was lower post-TAP, with 0.09 reported visits per month compared with 0.18 visits per month pre-TAP (p<0.001). Administrative data showed that while the total number of ED visits did not vary after TAP, the total number of patients who used the ED decreased. We then used difference-in-difference models to compare TAP and Medicaid patients, controlling for age and gender. Our preliminary results show that compared with Medicaid patients, TAP patients reported significantly decreased ED use and significantly increased access to specialty care during the same period.

CONCLUSION:
TAP enrollment was associated with significantly increased access to and satisfaction with care. Patient-reported ability to complete specialty referrals and decreased ED utilization correlated with administrative data. Limitations include recall bias and lack of comparison group visit and claims data. Future work will evaluate financial, administrative, and patient outcomes through comparison of administrative data with the matched cohort of Medicaid patients.
Utilization of Services in Medicare Advantage and Traditional Medicare: A National Comparison

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BACKGROUND: Relative to traditional Medicare (TM), clinically integrated health plans that participate in Medicare Advantage (MA) may be able to treat a given patient more efficiently, using fewer resources with equal or superior quality, through their flexibility in benefit structure, network contracting, and ability to coordinate and manage care. Little prior research, however, has compared the utilization of services within MA and TM, largely because standardized utilization measures, such as available through HEDIS, are not available for the unmanaged TM population. This issue has become even more salient since the passage of the Medicare Modernization Act of 2003, which increased payment rates to MA plans and resulted in a doubling of MA enrollment over the ensuing years as well as a large increase in the number of participating plans. We compare utilization of services, overall and for specific procedures, between Medicare beneficiaries enrolled in Medicare Advantage plans and matched samples enrolled in traditional Medicare.

METHODS: The Centers for Medicare and Medicaid Services collects annual standardized utilization data from all HMO plans participating in MA. These data include rates of selected procedures (e.g., cardiovascular and orthopedic procedures) as well as overall outpatient and inpatient visit data, and are available at the level of individual enrollees. For the time period 2003-2008, coinciding with the implementation of the Medicare Modernization Act, we compare HEDIS utilization measures collected for each health plan and similar utilization data constructed using the HEDIS specifications from a random 20% sample of the TM population. Using robust statistical weighting, we compared MA and TM enrollees of similar age, sex, and race/ethnicity in the same markets.

RESULTS: MA enrollees were substantially less likely than comparable TM enrollees to receive most of the specific procedures we examined, including elective orthopedic procedures such as knee or hip replacement (absolute ∆: 10-15%) as well as general surgical procedures such as cholecystectomy and prostatectomy (absolute ∆: 5-10%). MA enrollees, however, were slightly more likely to receive CABG surgery and colectomy (absolute ∆: > 10%). Overall outpatient visits were approximately 11% lower for MA enrollees. Inpatient visits and days were slightly higher for TM enrollees (absolute ∆: 2-5%). Medical hospitalization rates were higher for MA enrollees whereas surgical hospitalization was higher for TM enrollees. Ongoing analyses will assess differences in utilization rates over time and for enrollees of health plans participating in MA for the duration of the study versus those that began enrolling patients in later years. Sensitivity analyses suggest that differences in health status do not explain our findings.

CONCLUSION: Utilization rates for MA enrollees are substantially lower than for matched samples of TM enrollees, despite the fact that MA plans generally receive higher reimbursement overall. Alternative payment arrangements are needed for MA plans in order to harness the potential cost savings that might be realized from enrolling more Medicare beneficiaries in the MA program.