Signal and noise: applying an automated trigger tool to screen for adverse drug events in the setting of outpatient chronic disease care

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BACKGROUND: The extent of outpatient adverse drug events (ADEs) remains unclear. Information about ADEs is limited by our ability to detect and monitor these events. Trigger tools are used as a screening method to identify care episodes that may be adverse drug events, but their value in a population with a high chronic-illness burden remains unclear. We sought to determine if a six-item trigger tool would successfully identify ADEs in a chronically ill patient population.

METHODS: We used 6 abnormal laboratory values (international normalized ratio (INR)>5, serum creatinine (Scr)>2.5, blood urea nitrogen(BUN)>60, alanine aminotransferase (ALT)>84, aspartate aminotransferase (AST)>80, thyroid-stimulating hormone (TSH) undetectable while on levo-thyroxine) because they have been shown to have a high positive predictive value for detecting ADEs among older adults in outpatient care, but have not been tested in a safety net population with high burden of chronic illness. Eligible patients were included if they were >18, sought primary or urgent care within the study period (November 2008-November 2009) and were prescribed at least one medication. We then used the clinical/administrative database to identify patients with these triggers. Two physicians conducted in-depth chart review of any medical records with identified triggers. The physicians determined 1) whether an adverse drug event did occur 2) the stage of the medication process where the event occurred 3) the severity of the effect on the patient. Physician reached an inter-rate agreement of 94%.

RESULTS: We reviewed 782 triggers representing 583 patients. The mean patient age was 55 (14), 64% were male, 70% were English-speaking. The trigger tool identified 109 (14%) adverse drug events. We identified 18 ADEs that took place in the inpatient setting that were omitted from further analysis. Of the 91 ADEs included in our analysis, 49 (54%) occurred during medication monitoring, 41 (45%) during patient-self administration, and the other could not be determined. 90% posed minimal or mild harm to the patient, 8% posed moderate harm or severe harm and 1 (1%) could not be determined. 96% of abnormal INR triggers were adverse drug events, followed by 12% of abnormal BUN triggers, 9% of abnormal ALT triggers, 8% of abnormal Scr triggers, and 3% of AST triggers.

CONCLUSION: When we employed an ADE screening trigger tool in a safety-net primary care clinic with a high prevalence of chronic illness, the yield was less than in the healthier population originally studied. Moreover, utility varied significantly among the 6 triggers. While the INR>5 successfully identified ADEs, concomitant chronic disease lowered the yield for other abnormal-laboratory-value triggers. Our findings imply that other tools, such as text triggers, or more complex automated screening rules which combine data hierarchically, are needed to effectively screen for ADEs in chronically ill adults seen in primary care.
Targeting Scarce Clinical Resources in Real-Time: An EMR-based Intervention to Reduce Heart Failure Readmissions

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BACKGROUND: 30-day readmission for heart failure (HF) has gained widespread attention as a federal pay-for-performance measure. Current approaches to improve readmission performance recommend intensive clinical and case management interventions for all patients admitted with HF, an organizational posture difficult to sustain for many institutions, particularly safety net hospitals. In this study, we test a novel, multi-disciplinary approach to reduce HF readmissions that tailors the intensity of the intervention to the risk of the patient using a real-time electronic predictive model.

METHODS: We conducted a prospective cohort study to assess the impact of the intervention on rates of readmission for adult inpatients admitted with HF between December 1, 2008 and December 1, 2010 at Parkland Memorial Hospital, a 800-bed safety net hospital in Dallas, TX. During the intervention period (December 1, 2009 to December 1, 2010), a software platform we developed stratified all admitted HF patients on a daily basis according to their risk for 30-day readmission using a previously published electronic predictive model. The electronic platform calculated the risk of readmission using clinical, social, behavioral, and utilization data that it self-extracted from the hospital electronic medical record (EMR) within 24 hours of admission. HF patients in the 2 highest quintiles of risk were immediately assigned to an intensive set of evidence-based interventions designed to reduce readmission including: a) detailed clinical assessments, patient coaching and discharge planning by a HF nurse practitioner, pharmacist, nutritionist, and case manager; b) a follow-up nurse phone call within 48 hours of discharge (D/C); c) outpatient case management for 30 days including home visits; d) a cardiology appointment with a HF specialist within 7 days of D/C; e) and a primary care appointment within 30 days of D/C. HF patients in the lower 3 quintiles of risk received less intensive discharge planning, and no involvement of the HF clinicians, case managers, or home visit nurses. Readmission for any cause and to any hospital within 30 days of discharge was collected for all patients. We calculated both crude and adjusted readmission rates before and after the intervention. Adjusted analyses controlled for: 1) patient clinical and SES factors, and 2) the change in readmission rates among patients hospitalized for 2 concurrent control conditions (acute myocardial infarction [AMI] and pneumonia [PNA]), allowing for adjustment of secular readmission trends at the institutional level.

RESULTS: There were 779 HF admissions (1435 for AMI or PNA) in the pre-intervention period and 753 HF admissions (1446 for AMI and PNA) in the post-intervention period. The pre- and post-populations were similar across clinical and socio-demographic variables. Although the clinical and case management interventions were restricted to patients in the top 2 quintiles of calculated risk, the overall unadjusted readmission rate for HF declined from 20.2% in the pre-intervention period to 16.0% in the post-intervention period (p=.04). In contrast, the readmission rate for PNA and AMI did not change (12.0% vs. 13.9%, p=0.34). In the final adjusted analysis, the readmission rate for patients with HF was significantly lower in the intervention period (15.7% vs. 21.5%; adjusted incidence rate ratio, 0.72 [95% CI, 0.55 to 0.95]; p=.02). A subgroup analysis revealed that the intervention was especially effective among Medicare recipients, with a decline in overall adjusted readmission rates from 24.5% (similar to the mean incidence nationally) to 13.5% (within the top decile nationally; aIRR=0.57,CI, 0.55-0.99; p=.05). There was no corresponding change in readmissions among Medicare patients with AMI and PNA (12.0% vs 13.0%; p=.80).

CONCLUSION: A novel, electronic strategy that carefully directs scarce clinical resources to highest risk patients significantly reduced 30 day readmission rates among patients with HF at a large, safety net hospital. Real-time electronic predictive models may allow institutions to concentrate resources more effectively, enabling more powerful interventions in an era of constrained resources.
Prospective Comparison of Scores and Clinical Judgment to Predict Major Bleeding in Patients Receiving Oral Anticoagulants

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BACKGROUND: The benefit of oral anticoagulant therapy in preventing thromboembolism must be weighed against the risk of bleeding. Clinicians often use subjective clinical judgment to estimate a patient's bleeding risk. As a decision aid, several objective clinical scores that predict the risk of bleeding in patients treated with oral anticoagulants have been developed. These include the Outpatient Bleeding Risk Index (OBRI) for unselected patients and the Shireman, HEMORR2HAGES, and HAS-BLED scores for patients with atrial fibrillation, the most common indication for oral anticoagulation. We sought to compare the performance of these 4 clinical scores and clinical judgment in predicting the risk of major bleeding in a cohort of patients receiving oral anticoagulants.

METHODS: We prospectively enrolled consecutive patients receiving oral anticoagulants at the department of medicine and ambulatory and community care of a Swiss university hospital (January 2008 to March 2009). The outcome was the first major bleeding event within 12 months of enrolment. We classified patients into three classes of bleeding risk (low, intermediate, and high) according to each score and the treating physician's clinical judgment with regard to bleeding risk. The treating physicians had an average clinical experience of 4 years (SD 3.4). We assessed the discriminatory power to predict major bleeding by calculating the area under the receiver operating characteristic (ROC) curve of each score and clinical judgment.

RESULTS: We enrolled a total of 515 anticoagulated patients (mean age=71.2 years; female gender=36.1 %). The incidence of major bleeding was 6.8% (35/515) at 12 months. The major bleeding rates varied from 3.0% to 6.2% among patients at low-risk of bleeding and from 4.5% to 16.7% among patients at high-risk of bleeding using the various scoring systems and clinical judgment. The discriminative power of the 4 clinical scores and clinical judgment to predict major bleeding did not differ significantly and was generally poor, with areas under the ROC curve ranging from 0.54 to 0.58 (P=0.89; Table). In the subgroup of 314 patients with atrial fibrillation, the 12-month incidence of major bleeding was 6.4% (20/314). The discriminative power of the 4 scores and clinical judgment was similarly poor, with areas under the ROC curve from 0.51 to 0.59 (P=0.82; Table).

CONCLUSION: Our results indicate that neither clinical judgment nor clinical scores have sufficient power to discriminate between anticoagulated patients who are at high-risk of major bleeding and those who are not. New, accurate risk stratification methods with sufficient discriminative power to predict the risk of bleeding in patients under oral anticoagulants are needed.
BACKGROUND: Optimal strategies for widespread primary care transformation are unknown. One challenge to scale up is how to design programs to address variation in the organizational or contextual factors that may be associated with successful quality improvement (QI) efforts. The Improving Performance in Practice (IPIP) initiative is a program of the primary care specialty societies and boards that aims to improve the pace and success of primary care transformation efforts and establish ongoing improvement networks. The IPIP program assists states in developing regional ambulatory care quality initiatives that support practices in undertaking routine performance measurement and data sharing, education in QI methods and clinical content, and the creation of networks of practices to share the ideas and work of improving care. State programs also provide on-site practice coaching to facilitate the improvement process. IPIP enrolled its first practices in 2006, and is currently active in seven states, with more than 350 participating practices. The objective of this study is to investigate whether practices that have participated in the IPIP program have improved the quality of care for patients with diabetes, and to determine if practice characteristics influenced the pace of improvement.

METHODS: Practices participating in the IPIP program submit monthly performance reports on standardized measures. We studied practices reporting the following diabetes measures: percent of diabetic patients in the practice with: A1c>9%, systolic blood pressure (SBP) <130mmHg, LDL<100mg/dL, an eye exam, smoking cessation counseling, a foot exam, and testing or treatment for nephropathy. We included all practices that had participated in the IPIP program for at least six months prior to November 2009, and excluded practices that did not focus on diabetes, and practices that used a convenience consecutive sampling method for data reporting. We used linear regression to determine the mean rate of change over time for each measure, and estimated the projected improvement over 12 months based on the mean rate of change per month for each measure. We then compared the rate of improvement by practice characteristics including: practice size (number of provider FTEs), presence of an electronic health record (EHR), prior experience with quality improvement, initial performance, and number of months participating in the IPIP program.

RESULTS: 165 practices participating in the IPIP program were included. 33% of practices were in Pennsylvania, 32% in Colorado, 23% in North Carolina, and 12% in Michigan. 64% of practices had less than or equal to 3 FTEs. 49% had an EHR in place, and 22% reported prior experience with quality improvement. 46% had participated in IPIP for more than 12 months. Practices participating in the IPIP program improved significantly in all of the measures except for the blood pressure and cholesterol goals (SBP<130mmHG and LDL<100mg/dL).(Figure 1) Practices with worse initial performance improved faster than those with better initial performance (p<0.01 for all of the diabetes measures). Presence of an electronic health record, prior experience with QI, and practice size did not impact the rate of improvement (p>0.05 for all of the diabetes measures).

CONCLUSION: Practices participating in the IPIP program improved the quality of care for their patients with diabetes. Improvement was faster in practices with worse initial performance. Creating networks of practices can be an effective model to disseminate quality improvement to community primary care practices. Consistent, frequent measure reporting across a large number of practices, combined with information on practice context and facilitation, can help to understand factors that expedite translation of evidence into practice. Such an improvement infrastructure can also lead to more rapid adaptation of the practice support strategies.
Gender Disparities In Lipid-Lowering Therapy Among Veterans With Diabetes Varsha G. Vimalananda 1; Donald R. Miller 2; Madhuri Palnati 2; Cindy L. Christiansen 3; B. Graeme Fincke4. 1Boston University Medical Center, Boston, Massachusetts; 2VA Center for Health Quality, Outcomes, and Economic Research, Bedford, Massachusetts; 3Boston University School of Public Health, Boston, Massachusetts. (Proposal ID # 10956)

BACKGROUND: Women with diabetes are more likely than men to have a low-density lipoprotein cholesterol (LDL) above recommended levels. This is an important quality issue because 1) hyperlipidemia is a risk factor for cardiovascular disease, 2) hyperlipidemia may have a higher impact on cardiovascular outcomes in women compared to men with diabetes, and 3) treatment of hyperlipidemia with statins in diabetes is associated with a more than a 20% reduction in cardiovascular disease risk. The reasons for worse lipid control among women with diabetes are unclear, but may be due in part to differences in treatment patterns. We undertook this study to assess differences in lipid-lowering therapy between female and male veterans with diabetes and elevated LDL.

METHODS: We conducted a cross-sectional study of veterans serviced by the Veterans Health Administration (VA) in 2006 who had both diabetes and hyperlipidemia and compared all females (N = 22,475) to age- and facility-matched males (N =89,431). We compared proportions of patients with any VA prescription for lipid-lowering therapy in the year and, among those with elevated LDL (>100 mg/dl) and no prior treatment, we compared initiation of lipid-lowering therapy. Likelihood of treatment was estimated using multiple logistic regression with adjustment for race, VA eligibility, health care utilization, cardiovascular diseases, mental health conditions, and a comprehensive list of other co-morbidities. We also performed the analysis stratified by age.

RESULTS: Women had higher LDL levels than men (110±38 vs. 101±36 mg/dL) and fewer of them were receiving lipid-lowering therapy (80% vs. 84%). Women were less likely to receive therapy (adjusted odds ratio [95% confidence interval]: 0.79 [0.76-0.82]) or to be initiated on such therapy (37% vs. 42%, 0.84 [0.77-0.90]). Differences were greatest in the youngest women (<45 years old) for both any lipid-lowering therapy (61% vs. 75%, 0.53 [0.48-0.59]) and initiation of therapy (27% vs. 39%, 0.56 [0.47-0.67]). Adjustment for potential confounders did not change the risk estimates.

CONCLUSION: Women veterans with diabetes and hyperlipidemia receive less aggressive lipid-lowering therapy than men, especially in younger age groups. This disparity is of concern, because early intervention to control hyperlipidemia can reduce the later burden of cardiovascular disease among diabetic women.
Community Health Centers Outperform Private Physician Offices on Ambulatory Care Performance Measures

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BACKGROUND: Community health centers (CHC) serve as a safety-net for many low-income and minority patients. Many are designated as Federally Qualified Health Centers, Federally Qualified Health Center "look-alikes," and Indian Health Centers that receive cost-based reimbursement to provide comprehensive services to patients with higher burdens of chronic disease. Under health care reform, continued safety-net support will be predicated on demonstrated quality and efficiency. Currently, there is little data directly comparing the quality of safety-net care to that in private offices and none account for patient social and medical complexity.

METHODS: We examined the performance of CHC to private practice physicians on 18 previously established outpatient quality indicators using the 2006-2008 National Ambulatory Medical Care Survey, a national sample of office-based and community health center-based physician visits. CHC surveyed included Federally Qualified Health Centers, Federally Qualified Health Center "look-alikes," and Indian Health Centers. Quality indicator performance was defined as the percentage of applicable visits receiving appropriate care. We compared unadjusted performance, as well as adjusted for patient age, sex, type of insurance, number of chronic diseases, depression, median zip code percent poverty and bachelor's degree to account for visit complexity.

RESULTS: Across all U.S. providers, performance on the 18 indicators was variable. Adherence ranged from 14% to 100%. Compared to private office care, however, CHCs performed better on 6 indicators (p <0.05) and no differently on 11 indicators. Adjusting for visit complexity, CHCs performed better on 8 indicators and no differently on the remaining indicators.

CONCLUSION: CHC provide as good or higher quality care on select well established ambulatory care measures for patients in the setting of a greater chronic disease burden and socioeconomically complex patients. Future work should monitor performance on ambulatory care quality indicators with implementation of reimbursement modifications and performance incentives.