C-B4-03:

EMR-based Clinical Decision Support System Improved Glucose and Blood Pressure Control in Adults With Diabetes

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Context: Medical groups have invested billions of dollars in outpatient Electronic Medical Records (EMR), but few studies demonstrate a positive impact of EMR-based clinical decision support on clinically important patient outcomes. **Objectives:** To assess the impact of an EMR-based diabetes clinical decision support system on control of glycated hemoglobin (A1c), blood pressure (BP) and LDL Cholesterol (LDL) in adults with diabetes. **Design, Setting, and Participants:** The study was conducted from October 2006 to May 2007 in Minnesota. Eleven clinics with 41 consenting primary care physicians (PCP) and these physicians' 2556 diabetes patients were randomized either to receive or not to receive an EMR-based clinical decision support system designed to improve A1c, BP, and LDL in diabetes patients not at recommended clinical goals at the time of an office visit. **Main Outcome Measures:** Post-intervention levels of A1c, BP, and LDL controlling for pre-intervention levels. **Results:** Intervention group PCPs used the EMR-based decision support system at over 62.6% of all diabetes patient visits, and intensified drug therapy at 61.9%, 43.6% and 18.8% of visits with uncontrolled A1c, BP, and lipids, respectively. Intervention group diabetes patients had significantly better A1c ($P=.014$) and SBP ($P=.035$) but not LDL ($P=.63$) relative to patients of PCPs randomized to the control arm of the study based on general linear mixed models with a repeated time measurement to control for clustering. Additional analytic models that adjusted for patient age, gender, and co-morbidity showed similar results. Ninety-four percent of PCPs expressed satisfaction with the intervention, and moderate rates of use persisted for over a year after withdrawal of feedback and incentives to encourage use. **Conclusions:** An EMR-based diabetes clinical decision support significantly improved glucose control and BP control in adults with type 2 diabetes who were not at recommended clinical goals.

C-B4-04:

Personalized Physician Learning Intervention Improved Glucose Control in Adults With Diabetes

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Context: Personalization of learning interventions using opinion leaders improves care but is expensive. Automated methods to deliver personalized learning interventions to physicians have not been widely studied or rigorously evaluated. **Objectives:** To assess the impact of a computer-based personalized learning intervention for primary care physicians designed to improve control of glycated hemoglobin (A1c), blood pressure (BP) and LDL Cholesterol (LDL) in adults with type 2 diabetes. **Design, Setting, and Participants:** The randomized trial was conducted from October 2006 to May 2007 in Minnesota. Eleven clinics with 40 consenting primary care physicians (PCP) were randomized either to receive or not to receive a simulated personalized learning intervention designed to improve A1c, BP, and LDL in actual diabetes patients not at recommended clinical goals. **Main Outcome Measures:** Post-intervention levels of A1c, BP, and LDL controlling for pre-intervention levels and nesting of data. **Results:** Patients of intervention group PCPs had significantly better A1c ($P=.044$), SBP ($P=.018$), and DBP ($P=.001$), but not LDL relative to patients of PCPs randomized to the control arm of the study based on general linear mixed models with a repeated time measurement to control for clustering. Additional analytic models that adjusted for patient age, gender, and

co-morbidity showed similar results. Nearly all PCPs were very satisfied with the intervention, which most completed in fewer than three hours in split sessions over one to two days. **Conclusions:** An inexpensive simulated personalized physician learning intervention for primary care physicians significantly improved glucose and BP control in adults with type 2 diabetes who were not at recommended clinical goals.

PS2-19:

Validation of Self-Reported Diabetes From the Women's Health Initiative (WHI) Clinical Trials

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Background: The Women's Health Initiative (WHI) clinical trials offer a wealth of data on patient outcomes including cancer, coronary heart disease, and hip fracture, which were confirmed via medical record review. Diabetes was self-reported, but was not validated by independent review. The literature shows wide variations on the validity of self-reported diabetes in diverse populations. **Aims:** To compare the rates of positive and negative predictive values of self-reports of incident and prevalent diabetes during the WHI trials. **Methods:** At four WHI field centers (Minneapolis MN, Winston-Salem NC, Birmingham AL, Portland OR), all WHI trial participants with a self-report of diabetes at baseline or follow-up were identified. A random sample of participants who did not self-report diabetes was also identified. Women were surveyed regarding details of their diagnosis and treatment of diabetes. Medical records were obtained and reviewed for consenting subjects using a standardized protocol based on documented treatment with anti-diabetic medications, or physician diagnosis of diabetes supported by laboratory measurements of glucose. **Results:** A total of 1280 eligible subjects were available across the four sites. To date, subject information from the Minneapolis field center has been collected and analyzed. Of the 295 eligible subjects contacted at the Minneapolis site, 227 (77%) consented to participate and provided survey data. Medical records were obtained for 224 (57 prevalent, 81 incident, and 86 no self-reported diabetes). Medical records confirmed 84% (95% CI 74%–94%) of self-reported prevalent diabetes and 85% (95% CI 74%–94%) of self-reported incident diabetes. Among those who never self-reported diabetes there was no medical record evidence for diabetes in 99% (95% CI 92% to 100%). Results from all four sites will be presented. **Conclusions:** Preliminary data suggest a high positive predictive value of both prevalent (84%) and incident self-report of diabetes (85%) from WHI and a low false negative rate of about 1%. These results indicate that self-reports of diabetes may be sufficiently accurate for use in epidemiologic studies.

PS2-20:

Racial Disparities in A1c Change and Medication Intensification

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Introduction: While it is well documented that disparities exist across racial groups of diabetes patients relative to glucose control, the underlying causative factors are not well understood. The purpose of this study was to examine differences in physician orders for adjustments of glucose control medications in diabetes patients between African Americans and Caucasians. **Methods:** A cohort of 434 African American and 1,471 Caucasian diabetes patients was followed for a period of 18 months from 6/1/2006 through 11/30/2007. All patients were being treated in one of 6 primary care clinics within a large mid-western medical group. First and last A1c values were collected during the study period and an A1c change score was calculated. Patients were also classified as to whether English was their primary

language and whether they were on medical assistance at any time during the study period. The presence of a medication adjustment was tracked for metformin, thiazolidinediones, sulfonylureas (initiation or titration) and insulins (initiation only). Medication adjustment data was from the prescribing data in the medical record and thus represents physician actions. **Results:** There was a significant difference between African Americans and Caucasians on their initial A1c values (8.2% vs 7.3%; $P<0.0001$). Adjusted for the initial A1c, mean number of visits was similar between the two groups (16.9 vs. 15.8, $P=.50$). When change in A1c was calculated while controlling for initial A1c African Americans had less than half the decline found in Caucasians (.20% vs .45%; $P=0.0009$). English as a primary language ($P=.81$) and medical assistance ($P=.81$) status were not related to the disparity in change value. Examination of medication adjustment for African Americans relative to Caucasians found that they were less likely to have adjustments of metformin (OR .69; $P=.0021$) and TZDs (OR .65; $P=.0122$) but no differences were found for Sulfonylureas ($P=.49$) or insulins ($P=.30$). **Conclusions:** This study suggests that part of the racial disparity in glucose control is related to physician orders for medication intensification. This indicates a need for better understanding of the reasons for medication adjustment disparities and effective interventions to reduce them.

PS2-22:

Disease Management Strategies to Optimize Cardiovascular Risk in Type 2 Diabetes Mellitus

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Abstract: A number of disease management strategies have been developed in the last decade to reduce cardiovascular (CV) risk in adults with type 2 diabetes. On average such programs improve glycated hemoglobin (A1c) only 0.5%, and often have little or no effect on blood pressure (BP) control or low-density lipoprotein (LDL) control, which are critically important CV risk factors. In a large randomized Medicare demonstration program, diabetes disease management programs were unable to recover fees through cost savings to the Centers for Medicare and Medicaid Service (CMS). Available data suggest several strategies to improve the effectiveness and reduce the cost of diabetes disease management: (a) integrate disease management operationally and fiscally with primary care, (b) focus on treatment intensification, (c) focus on BP, LDL, aspirin use, and smoking cessation, as well as glucose control, and (d) individualize patient goals based on potential CV risk reduction potential and patient preference to maximize clinical benefit and return on investment for each patient.

PS2-30:

Study Recruitment Challenges for a Clinical Trial of Diabetes Education Interventions

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Background: While a scientifically sound study design is the basis for all clinical trials, activities such as patient recruitment present ongoing challenges. The availability of electronic data greatly enhances recruitment efforts, but also may bring new problems. The Journey for Control of Diabetes: the IDEA Study, a randomized clinical study conducted in two distant healthcare settings, utilizes an advanced electronic data system to identify and recruit eligible participants. We believe that communication of difficulties encountered could help researchers who face similar recruitment challenges. **Methods:** The inclusion criteria included: Type 2 diabetes (DM), an A1C > 7 within 6 months of enrollment, and diabetes education-naïve within the last year. Preliminary estimates of patient availability were calculated with the following assumptions: 1) two ICD-9 codes for Type 2 DM (10,000 patients); 2) 52% with A1C > 7 (5,200); 3) 60% with no DM education in the last 12 years (3,120); 4) 15% excluded with Type 1 or gestational DM (2,652); and 5) 15% willing to participate (397). Recruitment of 311 subjects was estimated to take five months. **Results:** Recruitment has been much slower than predicted (50% of subjects recruited at seven months). Recruitment

results to date are: 1) 3,706 individuals identified as eligible using electronic data; 2) 156 enrolled; 3) 1,921 (50.4%) individuals not interested, 4) recent DM education (8.3%), and 5) Type 1 DM (2.1%). The electronic data on the pool of potential subjects is often out of date by the time the subject is screened and randomized. Refreshing the electronic data creates a moving target of potential candidates. A1C data and date of last diabetes education change at a rate faster than the recruitment mailing, screening and randomization process. Therefore, more time, programming, and staffing resources have been needed than originally anticipated to recruit study participants. **Conclusions:** This analysis of recruitment data demonstrates that initial recruitment capability estimates did not account for the inefficiencies created by outdated data and refreshed electronic encounter data. Daily tracking of all criteria for database accuracy has been a difficult and time-intensive task.

Genetics

C-B3-01:

Variation in Seven Obesity-Related Genes and Risk of Postmenopausal Breast Cancer

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Background/Aims: Obesity has been consistently associated with postmenopausal breast cancer risk. Proteins secreted by adipose tissue or involved in regulating obesity may play a role in breast tumor development. We conducted a nested case-control study among white, postmenopausal women from the American Cancer Society Cancer Prevention Study II (CPS-II) Nutrition Cohort to determine whether genes associated with obesity increase risk of breast cancer. **Methods:** Tagging single nucleotide polymorphisms (tagSNPs) were selected to capture common variation across seven candidate genes that encode adipose-related proteins: ADRB2, ADRB3, GHRL, HSD11B1, IRS1, IRS2, SHC1. Thirty-nine SNPs were genotyped in 648 cases and 659 controls. Logistic regression models and haplotype analysis were used to examine the association between each tagSNP and risk of breast cancer while adjusting for matching factors and potential confounders. We also examined whether these SNPs were associated with measures of adult adiposity. **Results:** Two of five tagSNPs in HSD11B1 were associated with breast cancer (rs11807619, $P=0.006$; rs932335, $P=0.0002$). The rs932335 C allele was associated with a nearly two-fold increased risk of breast cancer (OR=1.83; 95% CI: 1.01–3.33 for C/C versus G/G). The rs11807619 and rs932335 were highly correlated ($r^2=0.74$), and when modeled as a haplotype, only haplotypes containing the rs932335 C allele were associated with breast cancer. Three of the eleven SNPs for IRS2 were associated with breast cancer (rs4773082, $P=0.007$; rs2289046, $P=0.016$; rs754204, $P=0.03$). When these 3 SNPs were examined as a haplotype, only the haplotype that included the G allele of rs2289046 was associated with breast cancer (OR=0.74, 95% CI: 0.62–0.90 for TGC compared to CAT). IRS2 rs2289046 and rs754204 were also associated with adult weight gain. None of the other SNPs in any gene investigated were associated with breast cancer or adiposity. **Conclusions:** Our results suggest that these tagSNPs in HSD11B1 and IRS2 mark regions of the genome that may harbor risk alleles for breast cancer, and these associations are likely independent of adiposity.