A web-based lifestyle intervention to decrease postpartum weight retention in women with recent gestational diabetes mellitus: The Balance after Baby pilot RCT

Jacinda M. Nicklas1,2, Chloe A. Zera3, Bernard A. Rosner4,5, Sue E. Levkoff6,7, Ellen W. Seely2; 1. Division of General Medicine, University of Colorado School of Medicine, Aurora, CO, United States. 2. Division of Endocrinology, Diabetes and Hypertension, Brigham and Women's Hospital, Boston, MA, United States. 3. Division of Maternal-Fetal Medicine: Obstetrics and Gynecology, Brigham and Women's Hospital, Boston, MA, United States. 4. Channing Division of Network Medicine, Harvard Medical School, Boston, MA, United States. 5. Department of Biostatistics, Harvard School of Public Health, Boston, MA, United States. 6. Division of Women's Health, Brigham and Women's Hospital, Boston, MA, United States. 7. College of Social Work, University of South Carolina, Columbia, SC, United States.

Background: Women with a history of gestational diabetes mellitus (GDM) have a 7-fold increased risk for developing type 2 diabetes (T2DM). A post-hoc analysis of women with self-reported history of GDM in the Diabetes Prevention Program (DPP) demonstrated that an intensive face-to-face lifestyle intervention focused on weight loss significantly decreased the incidence of T2DM by 53% over 3 years. However, face-to-face weight loss interventions in postpartum women in general have demonstrated poor adherence and efficacy. We sought to develop and test a postpartum lifestyle intervention based on the DPP and modified for women with recent GDM.

Methods: After conducting focus groups and informant interviews with women with prior GDM, we developed a web-based program named Balance after Baby. Key modifications from the DPP included web-delivery to allow 24-hour access, lifestyle coaching by phone/email, and content tailored for the postpartum period. Women with GDM in their most recent pregnancy were recruited during pregnancy or early postpartum and randomized into the Balance after Baby program or enhanced control arm (glucose tolerance tests) 4-12 weeks postpartum. Pre-pregnancy weight was self-reported at recruitment; gestational weight gain and insulin use were extracted from medical records. We administered demographic questionnaires and measured height, weight, and response to a 2 hour 75 gram oral glucose tolerance test, at 6 weeks, 6 months, and 12 months postpartum. We compared mean weight changes using an intent-to-treat model by t-tests and by estimating a mixed-effects regression model using a random intercept and an unstructured covariance matrix. We conducted structured exit interviews with women completing the program.

Results: 75 women with recent GDM were randomized (mean age 33.4 ±5.4 years; BMI 31.4 (±5.6) kg/m2; 57% White, 29% African-American, 15% Asian, with 20% Hispanic; 34% low-income). There were no significant differences between groups at baseline for age, race, education, income, weight, BMI, pre-pregnancy weight, gestational weight gain, insulin use in pregnancy, breastfeeding, or glucose tolerance. Clinically determined weights were collected 12 months postpartum for 95% of eligible participants. Women assigned to the Balance after Baby arm lost a mean 5.0 (±13.5) lbs compared to women in the control arm who gained 1.3 lbs (±9.8) (p=.0223) between 6 weeks and 12 months postpartum. Women in the Balance after Baby arm were at their pre-pregnancy weight (mean 0.2 ±15.4 lbs) at 12 months postpartum vs. the control arm (+7.9 ±15.3 lbs) (p=0.025). In a longitudinal mixed model controlling for pre-pregnancy weight, assignment to the Balance after Baby arm resulted in greater loss at 6 (mean 8.5 lbs, SE 2.7, p=0.002) and 12 months (mean 7.0 lbs, SE 2.9, p=0.0175) compared to women in the control arm. While there were no significant group differences in glucose tolerance at 12 months, 3 women in the control group developed T2DM compared to none in the intervention group. Women randomized to the Balance after Baby program expressed a high degree of satisfaction with the program.

Conclusions: The web-based Balance after Baby program is feasible, acceptable, and resulted in greater postpartum weight loss in women with recent GDM. If confirmed and found cost-effective in a longer study, the Balance after Baby program could be used at the population level to increase postpartum weight loss and potentially delay or prevent development of T2DM in women with recent GDM.
Changes in Mortality after Massachusetts’ Health Care Reform

Benjamin D. Sommers¹,², Sharon K. Long³, Katherine Baicker¹; 1. Harvard School of Public Health, Brookline, MA, United States. 2. Brigham & Women's Hospital, Boston, MA, United States. 3. Urban Institute, Washington, DC, United States.

Background: Massachusetts’ health reform of 2006 has been called the model for national health reform under the Affordable Care Act. The law attained near-universal insurance coverage in the state, as well as well-documented gains in access to care. The policy’s impact on population health is less clear, as prior work has relied on self-reported health measures. Our objective was to determine whether Massachusetts’ health reform was associated with any change in all-cause mortality and in mortality amenable to health care.

Methods: We used a quasi-experimental differences-in-differences design, comparing the change in mortality rates for Massachusetts from 2001-2005 (pre-reform) to 2007-2009 (post-reform) versus a propensity-score matched group of U.S. counties similar to Massachusetts in the pre-reform period. Analyses used multivariate regression to further control for population demographics, local economic factors, and county/state of residence. The primary outcome was annual all-cause mortality, obtained at the state- and county-level, in sex-age-race specific cells (n=32,121 for state-level analyses, n=323,538 for county-level analyses). Secondary analysis examined deaths from causes more likely amenable to health care, using a definition adapted from previous research. The primary study sample contained non-elderly adults (ages 20-64) in Massachusetts and in the control group. Subgroup analyses examined outcomes based on age, race/ethnicity, and local area pre-reform insurance coverage rates and median income. Data were from the CDC’s Compressed Mortality File.

Results: Massachusetts’ health reform was associated with declines in all-cause mortality of 13.0 per 100,000 (relative decline 4.6%; p=0.003) and deaths amenable to health care of 10.2 per 100,000 (relative decline 5.5%; p<0.001), compared to matched controls in states without expansions. The greatest changes occurred for adults in areas with lower incomes and lower insurance coverage rates pre-reform, and among those ages 35-64. We found mixed evidence on whether the reform narrowed racial disparities in mortality. Our results imply that for every 600 adults who gained insurance under the state’s health reform law, one death was prevented per year.

Conclusions: Massachusetts’ 2006 health care reform was associated with significant declines in all-cause mortality compared with matched controls in states without a reform. Those declines were concentrated in causes of death amenable to timely health care and in populations most likely to benefit from expanded access, including residents of areas with lower pre-reform insurance coverage and demographic groups with higher baseline mortality. Our results offer encouraging evidence that the Affordable Care Act – modeled after the Massachusetts law and slated to extend health insurance to over 30 million Americans beginning in 2014 – may not only affect coverage and access, but also objective health measures such as mortality.
The Association Between Hospital Performance for Pharmacologic Venous Thromboembolism Prophylaxis and Rates of Venous Thromboembolism

Scott Flanders¹, M. Todd Greene¹, Paul Grant¹, Scott Kaatz², David Paje³, Bobby Lee⁴, James Barron⁵, Steven J. Bernstein¹,⁶; ¹. Internal Medicine, University of Michigan, Ann Arbor, MI, United States. ². Hurley Medical Center, Flint, MI, United States. ³. Henry Ford Health System, Detroit, MI, United States. ⁴. Oakwood Healthcare System, Dearborn, MI, United States. ⁵. Spectrum Health, Grand Rapids, MI, United States. ⁶. VA Ann Arbor Healthcare System, Ann Arbor, MI, United States.

Background: Hospital-associated venous thromboembolism (VTE) affects up to 15% of hospitalized medical patients and is felt to be one of the most common preventable causes of death in the hospital. Pharmacologic prophylaxis has been shown to reduce rates of hospital-associated VTE, yet is underutilized in U.S. hospitals. Although improving VTE prophylaxis rates in hospitals has been the focus of recent quality improvement efforts, the effect of improving prophylaxis rates on VTE outcomes in hospitalized patients admitted to the general medical ward has not previously been described.

Methods: The Michigan Hospital Medicine Safety Consortium is a quality collaborative of 35 hospitals with a goal of preventing adverse events in hospitalized medical patients. Using web-based data entry, an abstractor at each hospital collects detailed demographic and clinical data, including all known risk factors for VTE and use of pharmacologic prophylaxis for 800 patients per year. For this analysis, patients < 18 years of age, obstetric or surgical patients, patients with contraindications to prophylaxis, and patients admitted directly to the ICU were excluded. VTE outcomes during hospitalization and at 90 days after discharge were determined by medical record review and follow-up phone calls. High risk was defined as a Caprini score ≥ 2. Performance categories based on pharmacologic prophylaxis rates were defined as follows: high ≥ 80%; moderate < 80% - ≥ 65%; low <65%.

Results: Among 20,796 high-risk patients, the mean age was 66 years, mean Caprini score was 5.6 and mean length of stay was 4.4 days. Hospital rates of pharmacologic prophylaxis varied between 27% and 90% with an overall average of 70%. A total of 11 hospitals were classified as high performers on prophylaxis. There were 12 hospitals in each of the moderate and low performance categories. Average rates of prophylaxis differed significantly by performance level (figure). The rate of VTE at 90 days in the high, moderate, and low performing hospitals was 1.09%, 1.30%, and 0.99% respectively, and did not differ significantly. Relative to high performing hospitals, moderate and low performing hospitals did not have significantly higher rates of risk-adjusted VTE. Caprini score was associated with in-hospital (OR=1.21, 95%CI 1.09-1.35) and 90-day (OR=1.13, 95% CI 1.08-1.18) rates of VTE.

Conclusions: Hospital level of performance for pharmacologic VTE prophylaxis does not appear to be associated with in-hospital or 90 day rates of VTE. The impact of increasing rates of pharmacologic prophylaxis to prevent hospital associated VTE in general medical patients may be minimal.
Proactive Tobacco Treatment and Population-Level Cessation: a Pragmatic Randomized Controlled Trial

Steven Fu1,2, Michelle van Ryn5, Scott Sherman3,4, Diana Burgess1,2, Siamak Noorbaloochi1,2, Barbara Clothier1, Brent C. Taylor1, Anne Joseph2; 1. Center for Chronic Disease Outcomes Research, Minneapolis VA Health Care System, Minneapolis, MN, United States. 2. Medicine, University of Minnesota Medical School, Minneapolis, MN, United States. 3. New York Harbor VA Health Care System, New York City, NY, United States. 4. Medicine, New York University School of Medicine, New York City, NY, United States. 5. Family Medicine and Community Health, University of Minnesota Medical School, Minneapolis, MN, United States.

Background: Current tobacco use treatment approaches are reactive and require smokers to initiate treatment or depend on the provider to initiate smoking cessation care. As a result, most smokers do not receive evidence-based treatments for tobacco use that include intensive behavioral counseling and pharmacotherapy. Proactive tobacco treatment integrates population-based and individual-level treatment strategies to address both patient and provider barriers to tobacco cessation care. The primary objectives of this study was to assess the effect of a proactive care intervention on population-level smoking abstinence rates (i.e., abstinence among all smokers including those who use and do not use treatment) and on use of evidence-based tobacco treatments compared to reactive/usual care among a diverse population of current smokers.

Methods: We identified a population-based registry of current smokers from four Veterans Health Administration (VHA) facilities using the VHA electronic medical record health, who were randomized to proactive care or usual care. The proactive care intervention combines: (1) proactive outreach and (2) offer of choice of smoking cessation services (telephone or face-to-face). Proactive outreach included a mailed invitations followed by telephone outreach (up to 6 call attempts) to motivate smokers to seek treatment with choice of services. Because this study was testing proactive outreach, smokers were randomized prior to contact and a baseline survey was administered after randomization using a multiple-wave mailed questionnaire protocol. Outcomes from both groups were collected 12 months post-randomization from participant surveys and from VHA administrative databases. The primary outcome was population-level cessation at one year using a self-reported, 6-month prolonged smoking abstinence measure.

Results: Current smokers (N=6400, 1600 per site) as identified by the electronic medical record were randomly assigned to proactive care or usual care with an allocation ratio of 1:1 within each site and mailed a baseline survey. The sample was diverse; 28% African American, 62% Caucasian, 4% other race, and 4% unknown race. Seven percent were of Hispanic ethnicity.

In the proactive care intervention group, 2519 were mailed outreach invitation materials. During telephone outreach, 1556 (62%) were successfully contacted. Of the participants mailed an outreach invitation packet, 392 (16%) elected VA telephone coaching and 77 (3%) elected in-person smoking cessation services at their VA Medical Center.

The follow-up survey response rate was 67%. We observed a significant increase in the population-level cessation rate of 2.6%. The population-level cessation rate at one year was 13.4% for proactive care compared to 10.8% for usual care (p=0.025). In generalized linear mixed model analysis, proactive care resulted in increased odds of population-level cessation, OR=1.274 (1.033, 1.571). In additional analyses incorporating multiple imputation to estimate missing outcome measures and adjusting for baseline group differences in age of smoking initiation, and length of prior quit attempts, the effect of proactive care on population-level cessation persisted, OR=1.220 (1.002, 1.484).

Conclusions: Population-based proactive tobacco treatment using proactive outreach to connect smokers to evidence-based telephone or in-person smoking cessation services is effective for increasing long-term population-level cessation rates.