Study: Integrating Community Health Workers to Improve Diabetes Prevention
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Research Protocol

Purpose of the Study and Background

Purpose of the Study

Type 2 Diabetes Mellitus (DM) is a preventable chronic disease that affects 9.3% of US adults and children. It is estimated that 86 million American adults are prediabetic (37%), and thus at risk of DM and cardiovascular disease. DM is a leading cause of death, one of the major causes of heart disease and stroke, and severely threatens quality of life. DM more than doubles the health care costs compared to the general population. Safety-net institutions like Bellevue Hospital Center (BH) and the VA NY Harbor Healthcare System (VA) care for populations with a disproportionate burden of DM and DM risk. Nearly 25% of the 8.7 million US veterans have DM and the rate among Bellevue's 30,000 primary care adult patients is more than 15%.

Despite the potential for reduced morbidity and cost-savings, primary care systems must overcome several barriers to systematically deliver these proven, preventive strategies to patients at highest risk of DM. Employing community health worker (CHW) coaches to conduct behavioral counseling, follow-up referral to programs, and education is a promising approach that could extend the capacity of health systems to better prevent and manage chronic conditions. Despite the potential for peer-led intervention to enhance DM prevention efforts within the patient-centered medical home (PCMH) model, there is need for high quality, randomized trials to asses specific models for CHW support; to aid with implementation of such model, including identification of effective strategies for recruitment, training, monitoring and retention of lay personnel; and to successfully integrate these personnel within the PCMH.

The goal of this proposal study is to develop and test a model of CHW health coaching, designed to prevent the onset of Type 2 DM in a large population of underserved patients at risk. CHWs will be recruited from the target populations and trained in core competencies to serve as peer health coaches. Our central premise is that CHWs are uniquely suited to engage fellow patients by encouraging lifestyle change through shared experiences and social support to extend the reach of primary care (PC) beyond the clinic visit. This study will test a scalable model of peer health coaching to address the millions of patients at risk for DM, using low cost, culturally congruent personnel to promote prevention of DM in PCMH practice.

Background

Type 2 DM is a preventable chronic disease that affects 11% of US adults. An additional 35% (79 million) have pre-DM and thus at risk of developing DM and cardiovascular disease. DM is a leading cause of death in the US and a major cause of heart disease and stroke. It is essential that the US leverage prevention strategies to mitigate the health and economic impact of DM in the population. Up to 20% of adult PC patients at BH and 25% of veterans at NY Harbor have DM, 2x and 3x the rate in the general population, respectively, and this rate has been steadily increasing. There is also a substantial population with undiagnosed pre-DM, half of who are expected to develop DM in the next decade. Our preliminary analysis of VA NY Harbor data from 2010-2012 showed that 9,610 (62%) of 15,500 veterans <75 years old, without DM, had a glycosylated hemoglobin (HbA1c) test, and 1,730 (18%) of them had pre-DM.

Study Design

We will conduct a cluster-randomized trial to test the impact of peer health coaches on prediabetic patients cared for by PCMH teams at BHC and VA to:
1. Reduce the incidence of type 2 DM in pre-diabetic, PCMH patients;
2. Promote weight loss among pre-diabetic patients;
3. Increase patient activation levels, a measureable construct of engagement, efficacy, skills, and confidence in managing one's health, among pre-DM patients, resulting in:
a. Improved secondary clinical outcomes: better glycemic and blood pressure control, and lower Framingham risk scores;

b. Increased utilization of preventive services (e.g. MOVE!, TeleMOVE!, Healthy Lifestyles, etc.);
c. Improved health behaviors (e.g. making dietary and exercise changes); and
4. Develop, implement and assess strategies to recruit, train, and integrate peer CHW health coaches within the PCMH model.

The 36-month intervention will be conducted using a staggered entry design across four, overlapping, 12-month waves to account for CHW caseload limits. This study will test a scalable model of peer health coaching to address the millions of patients at risk for DM, using low cost, culturally congruent personnel to promote prevention of DM in PCMH practice. If successful, our study team will work with VA's Central Office and NY City's Health and Hospital Corporation to translate the model for larger scale implementation.

Characteristics of the Research Population

Number of Subjects
All 12 PC teams at VA NY Harbor and all 4 PCMH teams at BH will be eligible to participate. In our VA PROVE study, 51/52 PCPs participated in the intervention, and we expect similar rates in this project. Eligible patients will be identified through the study's pre-DM registry, which will be based on the EMR and Corporate Data Warehouse (CDW) at each site. This methodology builds on our ongoing national, retrospective cohort study of predictors of DM among veterans with pre-DM back to 2008. Based on preliminary analysis of VA NYHHS data from 2010-2012, 62% of veterans enrolled in PC without DM, have had an HbA1c test in the previous two years.

In the intervention group, we anticipate contacting 2,100 randomly selected patients (1,050 at the VA* and 1,050 at BH) to ultimately enroll about 1,100 patients (550 at the VA and 550 at BH). This outreach sample reflects our assumption that 20% of patients will be unreachable and that 60% of those reached will enroll in the study. Another 1,100 patients attributed to control group providers will be randomly selected as the control group, in accordance with the waiver of HIPAA authorization. As detailed below, the control group will not participate in the CHW intervention. The total sample, including the intervention and control groups, will be about 2,200 patients. This amounts to approximately 265 patients (across intervention and control groups) per wave and per clinical site.

> *We will work closely with the staff of another research study being conducted at the VA that has similar eligibility criteria, resulting in dual-eligible patients. In order to avoid patients being enrolled in both studies, which could result in patient burden, both studies will work with a statistician to identify these dual-eligible patients and randomly assign them to one study only prior to patient outreach and recruitment. 75% of these dual-eligible patients will be allocated to our study and 25% will be allocated to the other study in accordance with both programs' statistical power needs. Since both studies are similar in scope (e.g., weight loss, increasing exercise), we do not anticipate patients enrolled in one study will receive greater health benefits than patients enrolled in the other study.

Gender of Subjects
Subjects of both genders are included in the study.

Age of Subjects
The minimum age of the subjects is 18 and the maximum age is 75.

Racial and Ethnic Origin
There are no enrollment restrictions based upon race or ethnic origin.

Inclusion Criteria
Inclusion criterion: Having at least one HbA1c result in the prediabetic range (5.7-6.5%) in the 2 years prior to the start date of the study wave. In order to communicate with CHWs, patients must also speak either English or Spanish.

Exclusion Criteria
A diagnosis of DM, based on ICD-9 and ICD-10 codes applied during ambulatory encounters in the 2 years prior to the study wave; treatment with DM medication other than metformin (e.g. insulin or oral agents); age greater than 75 years; or exclusion by patient's PCP due to contraindication for lifestyle intervention or CHW outreach.

Vulnerable Subjects
The protocol includes collecting data from BH and VA clinical providers whose participation is vital to the success of the study. There is no coercion to enroll these clinic staff subjects. All such subjects can opt out by notifying the study staff that they would no longer like to participate in the study. Alternatively, subjects can decide not to complete surveys.

As we will be surveying a large random sample of pre-diabetic patients, it is possible that some of the survey respondents will be pregnant, mentally disabled, economically or educationally disadvantaged. Their exclusion from possible participation would prevent us from accurately sampling the population at random.

Such vulnerable patient populations may be excluded from CHW outreach as instructed by primary care physicians. (i.e. patient will not receive a letter about services or CHW coaching intervention).

Methods & Procedures

Control Group
The control group will not have access to CHWs. They will experience usual care in their primary care clinics. PCPs in the control group will receive reminders from the study team to order A1C tests for their patients in their study, as this pragmatically collected data is necessary to evaluate the study's main outcome.

Intervention Group: (CHW Health Coaching Integrated into Team)
CHWs will provide the diabetes prevention intervention, described below, to a randomly selected subset of eligible patients per wave in the intervention teams at each hospital. CHWs and the researchers will provide regular updates to the primary care providers in the intervention group on these activities. As with PCPs in the control group, intervention group providers will receive reminders to order follow-up A1C tests for their patients enrolled in the study.

Choice of intervention strategies for each patient: We will have patients across the entire spectrum of motivation. Since we target the full population at risk, it will include highly motivated patients, highly resistant patients and a large group in between with varying degrees of motivation and activation. Our toolkit driven approach, which includes a wide range of strategies aligned with patient activation levels, will be based on the same framework used when Dr. Sherman helped revise the VA-DOD smoking cessation guidelines from a referral-based approach to a population-based one. In the revised guidelines, the underlying principle guiding all treatment decisions – which applies equally well in this proposed study – was *all patients should be offered treatment in the most intensive setting they are willing to attend*. Similarly, all patients with pre-DM will be encouraged to use the most intensive DM prevention intervention that they are willing to attend.
CHW Reach: We anticipate that up to 40% of pre-DM subjects will participate in hospital-based programs (MOVE! at VA and Healthy Lifestyles at BH) and another 10-20% will participate in the community based Diabetes Prevention Program (e.g. at local YMCAs).

Community Health Worker (CHW) Coaches - Recruitment and Training
CHW Recruitment: We will hire and train 6 CHWs (3@VA, 3@BH), from local patient support organizations (Veteran Service Organizations and BH volunteer office, as we have done in prior CHW studies) to implement the toolkit strategies. CHW employment opportunities announcements will be created. Requirements will include: 1) evidence of a leadership role in the patient community through social support or advocacy organizations; 2) strong communication and interpersonal skills; and 3) a high school education or GED. CHW candidates will not be required to have a background in health. Personal experience with DM will not be required.

CHW Training: We will train the CHWs in key DM concepts, motivational interviewing, brief action planning, and stages of behavior change. CHWs will participate in a 105-hour core competency training developed collaboratively developed by Dr. Islam and her team and the Community Health Worker Network of New York. CHWs will conduct mock telephone counseling calls with trained standardized patients to enhance skills, gain feedback, and develop confidence in these techniques. In addition to these training experiences, CHWs will have letter templates, motivational interviewing scripts, and protocols available for patient outreach to standardize and guide patient outreach

CHW Intervention

At each wave's outset, ~ 250 patients at each study site will be randomly selected for outreach and paired with one of five CHWs (2 at BH, 2 at VA, 1 at both clinics). Researchers will provide each intervention group PC provider their selected list of prediabetic patients. PCPs will be asked to review the list to identify anyone they think should be excluded from the intervention. Patients are matched to a CHW according to the patient's language and neighborhood of residence, as the study aims to cluster CHWs' patients to facilitate CHW travel and expertise in local resources. We mail selected patients a letter on behalf of their PCP alerting them of their DM risk status, available prevention resources, and introducing them to their assigned CHW. CHWs will then call patients to describe the program and seek verbal informed consent to enroll in the study. Patients who decline participation will be asked if they are willing to be invited again in subsequent waves of the study. CHWs will continue outreach until they have met their caseload for the wave.

We developed a toolkit of strategies for pre-DM coaching outreach to standardize the intervention across CHWs and to focus on evidence-based strategies for preventing DM. The toolkit was adapted from the version we developed and used in the PROVE study aiming to improve outcomes in HTN and smoking. The toolkit interventions reflect standards of care and can be selected and tailored for the broad population of pre-DM patients. We will enhance uptake and effectiveness of services by employing CHWs to regularly contact, counsel, remind, and follow-up with patients. Outreach strategies will be tailored to patients' health care needs and their stage of activation. CHWs will deliver outreach based on patient preferences and activation level, as there is evidence that the fit between an intervention and a patient's motivations, beliefs and perceptions encourages activation, goal setting and ultimately behavior change. During their first contact with patients, CHWs will use a standardized, 6-item questionnaire (PAM-6) to quickly assess patients' activation level. Thus, CHWs will offer toolkit strategies that best fit the patients' level of activation, matching patients with the most intensive intervention they are ready to accept. Standardized protocols will also be used to ensure that CHWs dedicate sufficient time to engaging patients with lower levels of activation.

Within the 3-year intervention period, each patient's 12-month CHW intervention will consist of a 6-month intensive phase followed by a 6-month maintenance phase, as described below.

- *Phone Call*: CHWs will call eligible pre-DM patients and ask to obtain informed consent (in accordance with our waiver of documentation of consent) to participate in the study, fully describing the study and reviewing all elements of consent. If the patient consents, CHWs will conduct the intake process, which includes a survey, the PAM, and a conversation about health goals. CHWs encourage the patient to engage in the most intensive strategy that is matched to their activation level and health goals (Health Action Plan).

- *Telephone-Based Coaching*: CHWs will offer a minimum of 6 monthly, 30-minute phone counseling sessions to all patients using motivational interviewing (MINT) and brief action planning (BAP). However, patients will be offered more frequent coaching, up to once per week. BAP is a counseling approach emphasizing goal setting and MINT principles that can be completed in short telephone counseling sessions.

Telephone coaching will be timed to occur just before or after PC visits to optimize the value of the visit for DM prevention. For patients with lower activation scores (Stages 1 and 2), who are less engaged in their own care, CHWs will prepare patients for PC visits, empowering them to ask questions, seek information and participate in decision-making. This approach can increase PAM scores and help patients to have more effective

encounters with their health care teams and to improve health outcomes such as HbA1c among patients with chronic illnesses.
    - CHWs will re-call patients, who are not yet ready to engage in behavior change during the initial phone call, every 6 months unless they ask to be taken off the re-call list.
- *Referral to VA's MOVE! Program or BH's Healthy Lifestyles Program*: These programs offer a series of weekly workshops (BH 8 weeks, VA 12 weeks) focused on healthy eating and exercise. Patients "graduate" after 6 months but then continue with maintenance activities and ongoing peer support. CHWs will also encourage VA patients to participate in Tele-MOVE!, which provides daily interaction with in-home messaging technologies, and clinician contact as needed.
- *Referral to the DM Prevention Program (DPP)*: The DPP is a 16-session, weekly lifestyle intervention with certified DPP coaches, which is effective in preventing DM onset in pre-diabetics. The intensive program is then followed by monthly maintenance phone workshops with the DPP coach. This program will be provided by the study to all patients who wish to participate. These programs are offered by the NYC YMCA and by other community-based organizations.
- *Metformin*: Although not commonly used for DM prevention, metformin has been shown to prevent DM among patients with pre-DM, particularly those struggling with making lifestyle changes or with a BMI>30. CHWs will suggest that such patients with normal renal function (GFR>50%) discuss this option with their PCP and will provide a list of these patients to the team.
- *Maintenance*: After 6 months of intensive coaching, CHWs will transition to making monthly phone check-ins with patients for another 6 months to reinforce the knowledge and behaviors taught earlier.

Data Collection

Patient Data

As a pragmatic, population-based trial, we aim to understand the impact of our interventions on panels of patients in a real clinic environment and therefore will not collect any clinical data directly from patients. Instead we will rely on measurements taken during regular clinic visits and recorded in the EMR. We will access this clinical and administrative data for VA patients through the VA Informatics and Computing Infrastructure (VINCI), a secure, high performance interface with VA's Corporate Data Warehouse (CDW), and for BH patients from the NYC Health and Hospitals CDW. Relying on routinely collected clinical data does have its challenges. Patients in our cohort at baseline may not return to the clinic at appropriate intervals, and there may be incorrect information within the EMR limiting our ability to assess the impact of the interventions on all patients. Learning from our previous work, we will mitigate these challenges by updating the study registry regularly, and validating our data during Phase I of the study as we construct the pre-DM registries.

We will have the CHWs administer a survey (in person or by phone) of all intervention patients to assess patient activation and self-reported behaviors (diet and exercise habits). We will survey each wave's cohort of intervention patients twice: at baseline and at the end of their 1-year intervention phase. Surveys will include an MTA MetroCard worth $11 to incentivize response. Non-responders will be mailed up to two reminders. A statement will be included with the survey outlining the number of times the survey will be conducted (two), the timeframe for the surveys (now, and one year from now).

Implementation Research

Survey of providers: We will conduct a survey of primary care providers to assess the impact of the intervention on staff with measures described below to understand implementation issues. The survey will be conducted at baseline and following the 3-year intervention, using a mixed approach, including hard copies, in person or in office mailboxes, and email. In our previous study, we had a 65% response rate from providers and nurses, and we anticipate a similar response rate in the proposed study. A statement will be included with the survey outlining the number of times the survey will be conducted (2) and the timeframe for the surveys.

Semi-structured interviews: To further understand the clinic staff's lived experience of the CHW intervention, we will conduct brief, semi-structured interviews of the providers at baseline and semi-annually, for a total of 6 times (baseline, and after years 1, 1.5, 2, 2.5, and 3) with a subset of participating PCPs identified as key informants based on their experience and institutional knowledge. To understand any changes in how teams collectively integrate CHWs into their practices, we will also conduct brief, semi-structured interviews with primary care team members other than providers at the same intervals. Through these surveys and interviews, we will assess key aspects of the implementation of the CHW intervention as experienced and perceived by clinic staff. To additionally understand factors that impede or facilitate the implementation of the intervention, we will conduct semi-structured interviews annually (after years 1, 2, and 3) with practice administrators at each health care organization; key informants knowledgeable about population health and health policy at city level as relevant to DM prevention; and staff at the nutrition and exercise programs, whose involvement in the program can enable implementation success. Interviews will continue until emerging themes are saturated, anticipating up to 25 subjects at each site (approximately 20 involved in primary care delivery, 2 in managerial or administrative roles, and up to 3 staff at nutrition and exercise programs) and up to 5 informants outside the two sites who can speak to macro-level factors. These interviews will be audio-recorded and transcribed for analysis.

Process indicators: In this pragmatic trial, we will systematically track and examine the process of implementation and the contextual factors that influence implementation of the CHW intervention. To do so, we will draw on available study data in REDCap, the secure program used to record CHW-patient encounters for the study. At the end of the study we expect to have data on approximately 1,000 enrolled intervention patients, with each patient followed for one year, with CHW-patient contacts limited to the intensity that patients are willing to attend. From REDCap, we will collect data semi-annually on four indicators of implementation fidelity, namely (1) the content of CHW activities. (2) the coverage (number of patients reached), (3) duration (how long each patient is followed up), and (4) frequency (how often patients are contacted) of CHW-patient contacts. Content of CHW activities will be assessed through assessing CHW case notes on a random selection of 15 enrolled patients and interviews with CHWs. Case notes will be assessed to examine how CHWs handle patients' behavioral barriers and social needs, including the referrals they make to various services (e.g., mental health, social work, exercise programs). To understand barriers that CHWs confront in the course of implementation, we will conduct semi-structured interviews with the CHWs and identify major themes (questions, concerns) related to behavioral counseling and referrals that may be discussed during the study team's meetings and case conferences. Similar to the semi-structured interviews with providers and other primary care team members, interviews will be conducted at end of year 1, 1.5, 2, 2.5, and 3. Findings resulting from analysis of patient case notes and other CHW materials will be reported anonymously.

Influence of neighborhood factors: To examine the influence of contextual factors on implementation and intervention effectiveness, we will conduct population-level analysis of variation in implementation and health outcomes across NYC neighborhoods. We will conduct this analysis with patient data available at the start of the study and data on enrolled patients post-intervention. To obtain information on neighborhood-level factors, we will use publically available data on social and environmental aspects of NYC neighborhoods in the FACETS database (data accessible at https://github.com/mcantor2/FACETS). We will map patient addresses to census tracts, aggregate census tracts to neighborhoods, and statistically examine the association of neighborhood-level contextual factors on prediabetes prevalence across NYC. Patients' location information will be used at an aggregate neighborhood level, and it will not be possible to identify their precise location in the city. Individual patients and their PHI will not be identifiable.

Data Analysis and Data Monitoring

The analytic methods described below are designed to test the primary hypotheses that prediabetic patients cared for by PCMH teams randomly allocated to the CHW Coaching group, will have lower annual hazard rate of incident cases of DM overtime more weight loss, and higher PAM scores by the end of the intervention

period than similar patients cared for by PCMH teams allocated to the Control group, adjusting for baseline rates. The unit of analysis is patients, aggregated to the provider level.

Analysis: Patient Clinical Outcomes and Health Behaviors

Descriptive analysis techniques (measures of central tendency and variability, frequencies and proportions) will be used to present baseline characteristics of participants (patients and their PC staff) in the control and intervention arms. Chi-square tests and t-tests will be used to check if these baseline characteristics are balanced between the two study groups. For continuous outcomes, normal assumptions will be checked, and non-parametric alternatives and transformations will be considered as needed.

To assess the overall effectiveness of the CHW intervention we will compare cumulative DM incidence rates and time to DM incidence (in addition to other outcomes: weight loss, obesity rate, and health care utilization) between the two study groups, using intention-to-treat and per protocol analyses. Time to DM incidence at 12-month follow-up of the intervention and control arms, aggregated across the 4 study waves, will be compared using Cox proportional hazard regression models. Chi-square analyses will be conducted to compare outcomes between the two groups for categorical variables (e.g. obesity rate, PAM stage) and t-tests will be conducted for continuous outcomes (e.g. weight change, PAM score). We will then conduct (generalized) linear mixed-effects modeling, which will (1) take into account the intra-cluster correlation coefficient (ICC) of patients within providers and teams, (2) analyze repeated measures at several time-points (baseline, midpoint, and post-intervention) simultaneously, (3) include team or patient level baseline covariates easily, if they are found to be unbalanced between two arms, and (4) deal with attrition problems and other missing data automatically. For categorical outcomes, such analyses will be implemented using SAS Proc GLIMMIX, while using SAS Proc MIXED for continuous outcomes.

We will use multilevel survival analysis to determine the effect of the intervention on time to DM, as patients are enrolled in waves and the time to DM incidence may be censored by the end of study. Specifically, we will fit Cox proportional hazard regression models with mixed effects to examine the hazard ratio between two groups, adjusting for important covariates and taking into account the correlation among patients within teams.

We will use a similar generalized linear mixed-effects modeling for the secondary outcomes, to explore the relationship of the intervention's effectiveness to specific patient and provider or team characteristics. We will investigate interactions between the intervention and the patients' level of activation, co-morbidities (HTN, depression, and smoking), and health care utilization. We will also test the correlation (Pearson's *r*) of provider self-efficacy and team collective-efficacy on patient outcomes. We will conduct secondary analyses to better understand the impacts of the individual components of this complex set of interventions. While designed to test the effectiveness of an overall strategy, we will seek to determine which of the intervention elements and dose of intervention (e.g. number of phone contacts, number of mailings, successful referral to *MOVE!*, Healthy Lifestyles, DPP or other programs) were most strongly associated with any improved outcomes. We will also conduct subgroup analyses to see which subgroups may benefit more from the intervention than the others. Such group analyses are data dredging; they should be considered as exploratory analyses and any resulting findings should be confirmed by independent studies.

Because control patients are not surveyed, follow-up survey data for a given wave will serve will serve as the control group for the following wave's baseline survey data. For example, wave 1 follow-up data will be compared against wave 2 baseline data. The data collected in the survey are secondary outcomes.

Attrition/missing data: Although the retention of patients with specific provider panels is relatively stable at the VA and BH, there are a number of reasons for changes including moving, entering a nursing home or rehab facility, not being seen in PC for >2 years, or requiring specialty-based PC. Patients seldom switch among teams or providers within teams, limiting the potential for contamination between study groups. In our VA study of panel management (PROVE), only 7% of 9,841 hypertensive patients switched teams over 12 months of follow-up. In the event that a provider changes teams and moves from one study arm to the other, patients of theirs already enrolled in the study will remain in the study arm in which they were enrolled. In waves after a

provider has switched teams, newly enrolled patients attributed to this provider will enter the study in their provider's current study arm. For the intervention group, CHWs will contact patients when they are due for PC visits to ensure that they complete regular screenings as one of the toolkit strategies. Loss to follow-up of patients assigned to control teams is a concern, however we will address it through data reports provided to the control teams, which will include patients due for an HbA1c screening.

To limit bias due to contamination and missing values, we will assess the baseline characteristics of patients who switch teams or are removed from the panel or have incomplete repeated outcomes, and compare them with that of the other participants. The (generalized) linear mixed-effect models discussed earlier can deal with attribution problem and other missing data automatically, under the missing-at-random assumption. This model assumes that the missing information only depends on the observed information, which allows us to utilize all the observed information. To better understand the nature of our missing data and its mechanism; we will summarize the outcome variables by discontinuation status/reason in each arm. If the trajectories of the primary outcome variables from those with incomplete data are similar to those with complete information, the data may be missing at random; otherwise, it may be missing not at random. We will then conduct sensitivity analysis to assess the impact of missing not at random data on our analysis. The sensitivity analysis will test whether our primary statistical analysis remains credible if we investigate cases where those patients with incomplete data have outcomes that are unfavorable to the intervention arm of the study (e.g. those with incomplete outcome data in the control arm are less likely to develop DM, lose weight or have improved glycemic control or that those with incomplete outcome data in the intervention group are less likely to have lost weight or improved glycemic control but more likely to have developed DM). The sensitivity analysis will be conducted via multiple imputation using sequential modeling, applying a SAS macro.

Analysis: Intervention Implementation

Staff survey data will be used to assess the self-efficacy and collective-efficacy as a team in preventing DM and in working with a CHW coach. We will compare baseline and post-intervention scores on each of the measures. To test the hypothesis that staff assigned to the intervention teams who work closely with a CHW will improve their self and collective efficacy of DM prevention and CHW coaching, we will compare post-intervention scores for these measures across the study arms using linear regression and controlling for baseline scores and adjusting for staff roles, length of time in their role and site. Survey data will also be used to assess PCPs' readiness to work with CHWs for DM prevention. Baseline and post-intervention scores will be compared using Wilcoxon signed-rank tests.

All interviews transcripts (from PCMH and other staff, practice administrators, CHWs, and key informants) and observations of study team meetings and case conferences will be analyzed for common themes by two independent researchers for qualitative analysis. First, two researchers will read the transcripts to identify key domains. Second, the researchers will independently code two of each set of transcripts. They will then meet to develop initial codebooks with code names and meanings. Third, each coder will apply the codebook to the remaining transcripts. Fourth, coders will meet to compare codes and identify patterns and common themes throughout the transcripts. Baseline interviews will be used to guide toolkit refinement and to explore anticipated facilitators and barriers to incorporating CHWs into the PCMH workflow. Mid- and post-intervention interview data will help us to determine key barriers, facilitators and lessons learned from staff, CHWs, and key informants regarding the implementation of CHWs in PC practice.

To assess implementation fidelity, baseline and 6-monthly scores on the coverage, duration, and frequency of CHW-patient contact for BH and VA patients will be compared using ANCOVA. Content of delivery will also be assessed qualitatively based on a sample of CHW-patient contacts. Implementation fidelity will be compared across BH and the VA to examine if differences in organizational setting shape the implementation process.

Data from the FACETS neighborhood database of social determinants will be conjoined with study data to describe whether contextual factors pertaining to NYC neighborhoods are associated with prediabetes prevalence across neighborhoods. We will use a multilevel statistical model, with patients nested within neighborhoods, to conduct this analysis.

Process Evaluation: To ensure that the intervention was delivered completely and standardized across the sites, CHWs and clinical teams, there will be continuous monitoring of process outcomes and fidelity to the protocol during the CHW intervention. We will maintain standardized protocols for each toolkit strategy and documentation of peer coaching. The CHW Coordinator will conduct quarterly assessments of the interventions, proportion of patients reached and engaged by site and CHW, fidelity to counseling protocols, and the preferred toolkit and contact strategies.

Statistical Power and Sample Size
The primary study outcome for power calculations is the annual hazard rate of incident DM.

To determine sample size, we begin with the total accessible population of about 46,000 primary care patients served at the two sites (BH and VA). Of these we exclude patients with diagnosed DM (25% at VA and 15% at BH) and those over 75 years of age (who are ineligible for this intervention). Of these eligible subjects, we estimated that about 70% will have had the HbA1c test in the last 2 years and that about 40% of these will have had a test result in the prediabetes range.

While the above inclusion and exclusion criteria return about 9,300 eligible patients, 8,200 at BH and 1,100 at the VA, CHW caseload limitations preclude us from reaching all these eligible patients during the 3-year intervention. Assuming a caseload of 72 patients per fulltime CHW per wave (with 3.5 fulltime equivalent CHWs across both sites and 4 waves), the intervention is projected to enroll a minimum of 1,008 subjects into the intervention group. An equivalent number of subjects will be randomly selected from the Control teams for a total of at least 2,016 study subjects overall. The intervention and control subjects will be split across the two study sites. After assuming that we will not be able to reach about 20% (due to missing or incorrect contact information) unreachable rate, and that about 60% will consent to enroll in the intervention, we will randomly select about double the 1,008 subjects (about 2,100) for potential enrollment into the intervention in order to enroll the minimum of 1008 intervention subjects needed to have adequate statistical power.

Power: In the pre-DM population we estimate the 3-year DM incidence to be 15% (based on preliminary analysis of a similar VA cohort from 2010-2012). Based on our analyses, with 1,008 patients allocated to each of the intervention and control groups, we anticipate having 80% power (alpha = 0.05) to detect a difference in time-to-event (DM incidence) between the intervention and control group.

To assess measures of implementation fidelity, specifically coverage, duration, and frequency of CHW-patient contact, we will base calculations on all patients enrolled. Since we will use all available study data from the electronic medical records, power and sample size considerations do not apply. We will assess content of CHW-patient contact using qualitative methods, hence power and sample size considerations do not apply.

To examine the variation in prediabetes prevalence across NYC neighborhoods, we will use available data from BH at the start of the study, in approximately 19,000 patients. These patients meet the study's previously stated eligibility criteria, with two modifications: patients must have (1) any HbA1c result in the past 5 years and (2) an address available in the EHR. Data on all enrolled BH patients at the end of the study, an estimated 1,000 patients, will also be used. Since we will use all available study data, power and sample size considerations do not apply.

Data Storage and Confidentiality

Many steps will be taken to ensure the security and integrity of all study data. Information obtained for this study will be stored on password-protected research drives. Data obtained from surveys, the BH and VA CDW, and the local EMR will be coded and stored separately from their code key files on a secured, password-protected, HIPAA compliant network drive. Only the Research Director, Project Manager and Evaluator will have access to the subjects' codes. Once coded, the de-identified data will be securely transferred to a password-protected, shared research drive for analysis. Hard copies of surveys returned from patients will be locked in a secure cabinet or drawer located in the team's research space. A waiver of authorization for both recruitment/identification purposes and for study procedures has been sought.

Audio recordings of the in-person interviews with an anticipated 60 subjects will be taped using approved recording devices, which will be stored in a locked cabinet or drawer. Interview recordings will be transcribed without identifiers. We will present informed consent forms and audio/visual consent forms (VA form 3203 "Consent for Use of Picture and/or Audio" and NYU Research Subject Audio/Video/Photo Use Consent Form) to all staff participants involved in qualitative research interviews who verbally consent to participate in the protocol.

Risk/Benefit Assessment

Risk
The main risk to patients, primary care and other staff, practice administrators, CHWs, and key informants, though unlikely, is a loss of confidentiality.

Protection Against Risks
Provider /staff participants will be asked to participate in the different parts of the study (CHW intervention, surveys) but not required to do so. Patient survey respondents will be offered a modest incentive ($11 MetroCard) to compensate them for their time. Questionnaires and interviews will be delivered by a neutral party not in the employee's supervisory chain. Participation is completely voluntary and participants may drop out of the study at any time.

For the neighborhood effects analysis, patients' location information will be maintained at the level of the neighborhood, which is an aggregate of census tracts. NYC has over 2,100 census tracts. The NYC Department of City Planning constructs approximately 210 Neighborhood Tabulation Areas (NTA) out of the 2,100+ census tracts by aggregating whole census tracts. Although individual patient data is initially mapped to census tract level, it is used and analyzed only at the NTA level. Each NTA includes an average of about 50,000 residents. Patients' precise geographic location therefore will not be identifiable. Seeking consent from patients for their data to be used for this study would increase the likelihood of loss of confidentiality.

Potential Benefits to the Subjects
Staff subjects may improve their clinical practice if they are randomized to the intervention, which provides a CHW to the PC provider that assists in accessing and interpreting the large VA and Bellevue electronic datasets in attempt to enhance patient care. Patients may receive improved care as a result of their providers receiving the information in an organized, usable fashion and having support to encourage patients to enroll in and complete programs that reduce the risk of developing type 2 DM. Potential risks are minimal and primarily include loss of confidentiality, while the potential benefit to individual and scientific knowledge is sizeable. CHWs will not be making any management decisions for patients' care but rather will be acting under the direction of each patient's primary care physician. CHWs who participate in interviews will gain opportunities to reflect upon the challenges and successes of their work and subsequently incorporate this understanding into their work, thus providing improved counseling and support to patients.

Investigator's Qualifications & Experience

See attached biosketches for qualifications and experience.

Subject Identification, Recruitment and Consent/Assent

Method of Subject Identification and Recruitment, and Consent
All primary care staff will be given information about the proposed research during regular staff meetings, email announcements and a study flyer and then asked to participate. Staff providing verbal consent to participate will be randomized (as part of their PACT team) to either work with a CHW or serve as controls. Staff who opt-out will not be randomized, although might still work on a team that is included in the study. For example, if one primary care provider in a team declines participation, the other providers and team members consent, the team will be randomized to a study arm. If that team is randomized to an intervention arm, the

CHW would only work with the patients of the consenting providers. We anticipate that we will be able to obtain sufficient numbers of staff consenting to participate, as in our previous panel management study only one PCP out of fifty-one declined, and a majority of staff reported that the interventions and CHW support were helpful. Lastly, as CHWs will be extending services and interventions that are a part of regular, evidence-based practice on behalf of patients' primary care physician, patients will not individually consent to receiving phone calls, mailings, or any other contact with the CHW. For surveys, which are research procedures specific to this study, consenting elements will be presented at the top of the survey. Primary care teams will pre-approve all lists of patients receiving interventions as well as approving the content of the CHW's intervention. Patients will have the right to opt out of receiving outreach at any time. All mail materials will include instructions on how to stop receiving mail from the CHW.

A waiver of authorization for both recruitment/identification purposes and for study procedures has been sought. We use the electronic medical record to generate a list of eligible participants, in order to approach them to screen for eligibility. Without the requested Waiver, screening could not be practically carried out and would adversely affect the scientific rigor of the study.

A waiver of consent has been requested. Informed consent is given when a provider chooses to participate in the intervention. He or she can opt out of the study at any point. With regard to surveys, completion of the survey will serve as implied consent. The survey cover sheet includes all elements of consent. Informed consent is implied by patients completing and returning a mail-based survey. Similar to the staff survey, all patient surveys will state that the survey is voluntary, all data will be reported in the aggregate, and completion of the survey serves as consent for participation. The survey will also specify that completion of the survey will not impact their health care in any way and that their individual responses will not be shared with members of their health care team.

Further, patients will be considered to have given informed consent by choosing to continue to interact with CHWs. Patients can request to not be contacted by a team's CHW at any point. This will be clearly stated on all materials given to staff and patients. Interventions will consist of educating patients of existing services at the institution or outside of the institution that they can access to improve their health, ensuring coordination and follow-up on referrals already made by their health care team. Patients interested in attending a institution-provided service (such as MOVE, smoking cessation classes, or Telehealth) will be referred as a part of usual care from their team. Programs such as YMCA DPP are available to anyone that meets pre-diabetes criteria, not just our subjects. Anyone is able to join these programs without the referral of a physician. The study team will only offer existing evidence-based services already available to pre-diabetics. Patients interested in attending the community based DPP will be provided contact information or a warm transfer by telephone, but will need to register themselves and consent to the outside program. PHI will not be sent to either organization by the study team. Patients will be making an informed decision to join such groups and will be explicitly explained this via phone or letter. This same implied consent applies to patients who register for VA's Telehealth or MOVE services and BH's Healthy Lifestyle services.

CHWs will be interviewed in groups and/or individually, as they prefer. Their participation in interviews is voluntary. Identifying information on CHWs or on our study team members will not be collected or recorded in these interviews and observations.

Costs to the Subject

Subjects or their health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if they were not in the study, or if your insurance agrees in advance to pay.

Payment for Participation

Patient survey respondents will be offered a modest incentive ($11 MetroCard) to compensate them for their time.

Documentation of Consent

We will present informed consent forms and audio/visual consent forms (VA form 3203 "Consent for Use of Picture and/or Audio" and NYU Research Subject Audio/Video/Photo Use Consent Form) to all staff participants involved in qualitative research interviews who verbally consent to participate in the protocol. We will not be obtaining informed consent from those who will not be audiotaped. The consent will be obtained immediately prior to starting the interview.