Official Title:	Diabetes Management Intervention For South Asians
NCT Number:	NCT03333044
Study Number:	17-01479
Document Type:	Protocol and Statistical Analysis Plan
Date of the Document:	• July 8, 2021

Study Title: Integrated Community-Clinical Linkage Model to Manage Diabetes among South Asians Principal Investigator (NYU Site): Nadia Islam, PhD

I. PURPOSE OF THE STUDY AND BACKGROUND

A. Purpose of the Study

The proposed study "Integrated Community-Clinical Linkage Model to Manage Diabetes among South Asians" aims to test the effectiveness of a multi-level diabetes management intervention compared to usual care. The primary outcome is reduction in hemoglobin A1c (HbA1c) for patients with baseline HbA1c of >7%. The secondary outcomes include enhanced use of community and social services and increased self-efficacy.

The integrated intervention involves:

1. An electronic health record (EHR) intervention for primary care providers (PCPs) utilizing embedded alerts to identify South Asian patients with uncontrolled diabetes.
2. Registry-driven community health worker (CHW)-led health coaching for patients. Using a stepped-wedge design, we will implement the study in-20 NYC PCP clinics enrolling 886 South Asian patients at- risk for Type 2 Diabetes Mellitus (T2DM).
3. Linkage to culturally relevant community-level resources
4. CHW-integration into primary care teams. The project will leverage Health Information Technology (HIT) tools to support integration of CHWs in healthcare teams, feedback between healthcare providers and CHWs, and establish a referral mechanism between CHWs, patients, and community resources

In addition, using a mixed-methods approach and the RE-AIM evaluation framework[26], we aim to systematically assess the implementation process and delineate factors that influence adoption, sustainability, and scalability of the integrated EHR-CHW intervention within applied practice settings.

This will be achieved through the completion of:

5. Provider Surveys (n=80) to capture data on satisfaction with workflow before and after intervention, information sources for EHR-CHW initiatives before and after intervention, acceptability of and satisfaction with the integrated EHR-CHW intervention, and barriers and facilitators of point-of-care use of the tools.
6. Key Informant Interviews (n=100) with physician champions at each clinic and/or administrator of each clinic, Healthfirst representatives, community advisory board members, research staff, and CHWs. At baseline, the interviews will be incorporated into the workflow analysis to assess current satisfaction and usage of EHR and health coaching. At follow-up, the interviews will assess barriers and facilitators to the implementation and adoption process of the integrated EHR-CHW intervention, fidelity to the interventions, and to solicit recommendations for the replication and scalability of the intervention to other clinics and insurer organizations.

Impact: This multi-level study will inform efforts to manage diabetes in a high-risk population and generate a reproducible and sustainable model for use in healthcare and community settings that engage vulnerable populations with a high burden of chronic disease.
The contributions of this study to generalizable knowledge are further described in the "Background".

B. Background

B1. South Asians are a rapidly growing population in the US and NYC. Asian Americans currently compose 5% of the US population and approximately 32% of the immigrants entering the country. [66] The US Census Bureau projects that by 2060 the number of Asian Americans nationally will grow to over 39 million, approximately 9.3% of the US population.[11, 19]In this proposal, we focus on the South Asian community (persons with ancestry from India, Bangladesh, Pakistan, or other parts of the South Asian continent). This community is among the largest and fastest growing Asian subgroups in the nation. In NYC, the South Asian community grew by 49% from 2000 to 2010 (216,179 to 323,675, respectively). Across South Asian groups, a significant portion of the community live in poverty (ranging from 17% of Asian Indians to 32% of Bangladeshis), have limited English proficiency (LEP) impacting access to care (ranging from 25% of Asian Indians to 53% of Bangladeshis), and have poor access to culturally appropriate community resources. [8-10, 67] For the purposes of our study, South Asians will be defined as individuals who self-identify as South Asian, including those from India, Bangladesh, Pakistan, Sri Lanka, Nepal, and Bhutan, Guyana, Trinidad.

B2. South Asians in the US experience diabetes disparities. Diabetes prevalence in the US South Asian community are high, with national data revealing the highest prevalence of diagnosed diabetes among Asian Indians compared to other Asian groups and compared to non-Hispanic whites. [38, 72,36, 46, 61] In NYC, population-based studies reveal strikingly high diabetes rates among South Asians. [33, 61] South Asians in NYC have significantly higher prevalence of clinically measured diabetes (35.4% vs 10.8%) and nearly five times the odds of having diabetes compared to whites (Adjusted Odds Ratio: 4.88, 95% CI [1.52, 15.66]).[57] Additionally, the prevalence of self-reported diabetes diagnosis among South Asians of normal weight (using adjusted-BMI guidelines for Asians) in NYC is more than triple the rates of diabetes among non-Hispanic whites of normal weight (10.2% vs 2.9%, respectively).[28] Thus, scalable and translatable interventions that promote diabetes management in this population may have significant potential for public health impact.

B3. Asian Americans have lower rates of diabetes screening and poorer provider- and self-management of diabetes than other communities. Nationally representative data indicates that Asian Americans are the least likely racial and ethnic group to receive recommended diabetes screening, with a 34% lower adjusted odds compared to non-Hispanic whites.[65] In a population-based study in NYC, we have found that Asian Indians have lower average rates of diabetes management practices. [22] Providers were significantly less likely to perform recommended guidelines for diabetes management, including feet checks or eye examinations.[32] Interventions targeting health systems, primary care physicians, and patients are salient for improving diabetes management and outcomes in this community.

B4. Team-based care and intensive diabetes self-management programs in clinical settings are effective in improving Hemoglobin A1c (HbA1c). The US Preventive Services Taskforce has found sufficient evidence for three key strategies to improve diabetes management among patients including 1) Multi-disciplinary team-based care[21] 2) Intensive lifestyle (diet or physical activity) interventions coupled with counseling;[22] and 3) Identification and tracking of diabetic patients at risk through electronic health record (EHR)-based platforms according to risk and use

guidelines. Despite the evidence for these interventions, questions still remain as to the most effective members of the healthcare team to deliver lifestyle interventions, mechanisms for the coordination of care within healthcare settings, and the effectiveness of these strategies in LEP communities. Further, studies have found that social determinants of health, including low self-efficacy, low social support, food insecurity, and poor built environment [15, 70]are associated with higher levels of HbA1c (a key clinical marker for diabetes management), suggesting that clinically-oriented interventions should be coupled with interventions that address patients' social context.

B5. Incorporating Community health workers (CHWs) into healthcare teams can improve diabetes related outcomes. A substantial body of evidence demonstrates that CHWs are viewed as trusted sources of information and can be a natural bridge and effective strategy to disseminate efficacious interventions between underserved communities and the health care system. With the advent of the patient-centered medical home model, primary care practices (PCPs) increasingly aim to work in an integrated coordinated care manner for patients.[31] A growing evidence base suggests that the addition of CHWs to the primary care team is a low-cost and cost-effective approach to improve care and adherence for patients with chronic disease. [4, 35, 42, 73] A recent review of the impact of CHWs on diabetes management found that on average, CHW interventions produce 0.2% reduction in HbA1c with the greatest reduction (>0.5%) among individuals at the most elevated levels.[51] A 0.2% reduction in HbA1c is associated with 10% reduction in mortality, and 0.5% reductions in HbA1c considered clinically significant.[49, 60] In African American and Latino communities, studies that have integrated CHWs into clinical teams have demonstrated higher reductions in HbA1c. [25] Our own work has demonstrated that a culturally adapted CHW-led intervention in community-based settings is acceptable and efficacious in improving HbA1c control, weight loss, self-efficacy and social support, and health behaviors for South Asian
patients with diabetes.[34] The integration of CHWs in clinical settings to support team-based diabetes management for patients, and reimbursement options for this workforce, offers a unique opportunity for sustainable, scalable models for diabetes management and linkage to community-based resources.

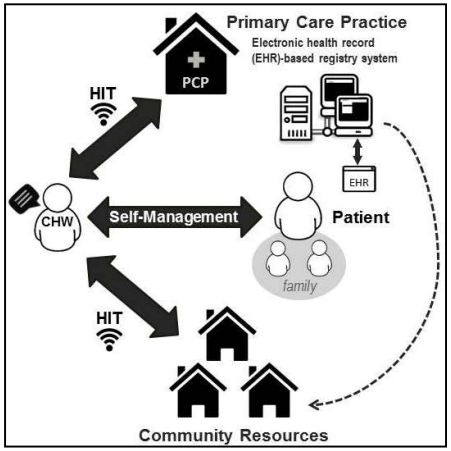
B6. Health information technology (HIT) strategies and EHR data can be leveraged to improve diabetes management and link patients to community resources. EHR data can identify candidates for recommended follow-up[14] and targeted risk-reducing interventions[27, 53, 54]and facilitate physician referral of patients to counseling and other services. [24, 27, 37, 53, 54] The use of clinical decision support systems (CDSS) or alerts can increase provider adherence to screening and monitoring guidelines for diabetes management and prevention, such as foot and retinal exams, as well as cholesterol & hemoglobin A1c testing. [45, 47, 50] EHR-based goal-setting modules, intention exercises, and tailored reminders to encourage behavior change during clinical encounters has enhanced provider capacity to counsel patients.[40] Recent efforts to use EHR systems and HIT strategies to identify, refer and link patients to community resources, including social services, have found it to be feasible, acceptable and effective. For example, an EHR-based e-prescribing model that linked patients to community resources according to patient needs generated 253,479 personalized prescriptions for more than 113,000 participants. Nearly 83% of the recipients found the referral very useful, and 19% of them adhered to the referral.[41] To date, such models have not been widely implemented in small primary care settings that serve high-risk immigrant communities. Furthermore, referral systems may be limited in their ability to appropriately connect to culturally appropriate services for linguistically isolated, LEP, and minority populations.

B7. The effect of integrated, multi-level interventions to improve diabetes management has not been well-tested. Recent studies have demonstrated that EHR access and communication between the PCP and the CHW can facilitate the acceptance and effectiveness of emerging care

management models and lead to improved patient outcomes, yet no one has conducted studies in small primary care settings.[5, 31, 71] Several studies[13, 64] have noted that the integration of health systems and provider, patients, and community level components may enhance the impact of diabetes management interventions. However, few studies have examined the impact of integrating multi-component interventions and how best to engage both physician and non-physician members of the healthcare team, including CHWs, in these efforts. Scalable and sustainable models that assess the implementation process of integrating multi-level intervention in clinical practice settings are needed, particularly for immigrant and LEP populations like the South Asian community. Our study will meet this need and aligns with the proposed Center of Excellence (COE) thematic focus on addressing scientific knowledge gaps of the health interventions that work across Asian American subgroups in community and clinical contexts.

Contributions

Figure 1: Multi-Level Diabetes Management



The goal of this study is to evaluate the effectiveness and implementation process of a multi-level, integrated intervention to decrease HbA1c among South Asians with uncontrolled diabetes, including four components: 1) an EHR-based registry function to increase identification of South Asian patients with uncontrolled diabetes; 2) CHW-led health coaching of registered patients to promote health behavior change; 3) HIT-enabled and CHW-facilitated identification and referral to culturally relevant community resources for patients; and 4) HIT- enabled care coordination between the CHW and other members of the healthcare team (**See Figure 1**).

This study is innovative in four main areas. First, though a limited number of studies have integrated EHR-CHW approaches, our study would represent the first to examine integration of a multi-level approach that combines EHR-based tools to identify high risk patients, culturally adapted CHW-led coaching, HIT-enabled community referrals, and CHW-physician feedback to improve diabetes management in a high risk community served by small primary care practice settings. Small provider practices, including primary care, are often the provider of care for minority, immigrant, and other underserved populations.[55] Our study uniquely assesses both effectiveness outcomes and implementation processes. Thus, it *informs the replication of integrated models in other primary care settings and for other communities*, *aligning with the proposed COE's thematic focus*. Second, our culturally adapted CHW-led diabetes management intervention has demonstrated efficacy, feasibility, and acceptability among South Asians in innovative in four main areas. Our study uniquely assesses both effectiveness outcomes and implementation processes. Thus, it *informs the replication of integrated models in other primary care settings and for other communities*, *aligning with the proposed COE's thematic focus*.

Second, our culturally adapted CHW-led diabetes management intervention has demonstrated efficacy, feasibility, and acceptability among South Asians in community settings, and *the proposed study can be reproduced for integration into clinical settings*.

Third, our study offers a *replicable model for linking patients within clinical systems to culturally relevant community settings and resources that can impact social support and other material conditions which have a demonstrable effect on diabetes outcomes*. CHWs will play a linkage role

that is facilitated by health IT tools, thus expanding their reach, efficiency, and effectiveness. Finally, through a multi-sector partnership that represent community, healthcare, payers, and health information technology, *the study will disseminate tools, products, and processes to inform scalable community-clinical linkage models*.

C. Study Design

C1. Overall Design/Clinic Selection/Clinic Enrollment

We will use a randomized controlled trial design with staggered-entry and a waitlisted control group to compare the effectiveness of an alert and registry-driven CHW-led coaching compared with usual care among patients with HbA1c at > 7%. Randomization will be at the individual-level and stratified by PCP, meaning eligible treatment and control participants will be randomized for each PCP. PCPS will be clustered into waves, aligning with the original stepped-wedge design. Entry into the study will be staggered in three waves, with each wave consisting of six to seven PCPs (See Figure 1). All 20 PCPs will be recruited and enrolled by month 6 of Year 1 (study period 6, Figure 1), and we will assign 6-7 practices into each of the 3 waves upon enrollment. For each PCP, there will be a total of two rounds of consecutive six-month CHW intervention periods for the treatment group: 1 month for recruitment and enrollment of treatment participants and five months of community health worker-led group education sessions (approximately one session per month). Data related to the study outcomes will be extracted from EHR systems a total four times (baseline, 6 month, 12 month, and 18 month) for each PCP; we will be comparing EHR data from 443 treatment participants with 443 control participants. Prior to allocation into treatment group, each treatment participant will be matched to a control participant based on age, gender, and BMI. Treatment participants will be split into two groups and assigned to either first or second round. All control participants will be waitlisted during the first round and will be offered the full CHW group education sessions during the second round as a point of service (i.e., not for research purposes).

Randomization at each PCP will occur during the first round. PCPs will be placed into waves based on geographic location and CHW caseload considerations. PCPs will be eligible for participation if they have a) an overall patient volume of N≥1000 ; b) at least 70% of the patient population is South Asian; and c) the practice has used EHR for at least 12 months. All PCPs will sign a Memorandum of Understanding (MOU) between the PCP and NYU outlining study commitments.

There are four primary research groups for this study: 1) 446 treatment participants who will receive the CHW intervention; 2) 446 waitlisted control participants who may receive the CHW intervention as a point of service at a later point (de-identified EHR data collection only); 3) 40 subjects who will participate in provider surveys; and 4) 35 subjects who will participate in qualitative key informant interviews.

Figure 1. Recruitment, Enrollment, and CHW Intervention Timeline

Participant Accrual Projections	Year 1		Year 2				Year 3				Year 4				Year 5				Enrollment by wave	Cumulative enrollment for entire study
	Apr - June 2018	July - Sept 2018	Oct - Dec 2018	Jan - Mar 2019	Apr -June 2019	July -Sept 2019	Oct - Dec 2019	Jan - Mar 2020	Apr - June 2020	July - Sept 2020	Oct - Dec 2020	Jan - Mar 2021	Apr - June 2021	July - Sept 2021	Oct - Dec 2021	Jan - Mar 2022	Apr-June 2022	July-Sept 2022		
Wave 1	PCP Recruitment			**Round 1**		**Round 2**													308 out of 886 target participants = **35%**	35%
PCP1			Recruit/ Enroll N=44	CHW intervention		CHW intervention														
PCP2			Recruit/ Enroll N=44	CHW intervention		CHW intervention														
PCP3			Recruit/ Enroll N=44	CHW intervention		CHW intervention														
PCP4			Recruit/ Enroll N=44	CHW intervention		CHW intervention														
PCP5			Recruit/ Enroll N=44	CHW intervention		CHW intervention														
PCP6			Recruit/ Enroll N=44	CHW intervention		CHW intervention														
PCP7			Recruit/ Enroll N=44	CHW intervention		CHW intervention														
Wave 2								**Round 1**		**Round 2**									264 out of 886 target participants = **30%**	65%
PCP8							Recruit/ Enroll N=44	CHW intervention		CHW intervention										
PCP9							Recruit/ Enroll N=44	CHW intervention		CHW intervention										
PCP10							Recruit/ Enroll N=44	CHW intervention		CHW intervention										
PCP11							Recruit/ Enroll N=44	CHW intervention		CHW intervention										
PCP12							Recruit/ Enroll N=44	CHW intervention		CHW intervention										
PCP13							Recruit/ Enroll N=44	CHW intervention		CHW intervention										
Wave 3												**Round 1**		**Round 2**					308 out of 886 target participants = **35%**	100%
PCP14											Recruit/ Enroll N=44	CHW intervention		CHW intervention	Analysis & Dissemination					
PCP15											Recruit/ Enroll N=44	CHW intervention		CHW intervention						
PCP16											Recruit/ Enroll N=44	CHW intervention		CHW intervention						
PCP17											Recruit/ Enroll N=44	CHW intervention		CHW intervention						
PCP18											Recruit/ Enroll N=44	CHW intervention		CHW intervention						
PCP19											Recruit/ Enroll N=44	CHW intervention		CHW intervention						
PCP20											Recruit/ Enroll N=44	CHW intervention		CHW intervention						

C2. EHR-CHW Intervention
The implementation and content of EHR and CHW components of the intervention at each clinic align with the Chronic Care Model.

EHR Components: This component of the intervention will leverage clinical information systems and impact delivery system design by enhancing practice capacity and workflow to implement and use EHR-based alerts to identify patients with uncontrolled diabetes. The EHR component of the integrated EHR-CHW intervention will include: 1) An alert to identify South Asian patients with uncontrolled diabetes Hb1AC >7 and 2) Generation of registry lists of individuals with A1C >7). Building upon existing protocols the study team will coordinate the implementation of the proposed EHR modifications at clinics. The implementation process will be characterized by: 1) Workflow analysis; 2) Procedures for identifying system requirements; and 3) Adequate training and support for users upon and following go-live.

Workflow analysis. Using a rapid assessment process,[6, 7, 20, 43, 44, 68] baseline workflow analysis will be conducted at each clinic. The workflow analysis consists of an iterative process including ethnographic observation and key informant interviews (see below) to provide contextual data on organizational workflow, culture, and practice. Results from the analysis will be used to improve alert and registry functions and to align with the workflow of each clinic.

Implementation of System Requirements for the Intervention. System requirement definition and implementation ensures that various EHR systems across PCP clinics are configured to provide the functionality called for by the study design. The research team will work with a PCP clinics to develop a framework for creating the proposed EHR enhancements. This process includes specifying and confirming the system's functional requirements based on the users' needs as well as the study design. The EHR modifications will be made at each study clinic, and providers and staff will be trained. Functional and technical specifications (and any updates) will be maintained and documented for training, workflow development, troubleshooting and dissemination purposes.

Training. The training will be designed to enable clinicians to use the decision-supports and/or alerts independently, proficiently, and effectively. At the start of the intervention period, clinicians will receive an estimated 8 hours of didactic and interactive training. Individualized training will also be available during the initial implementation period for all users. Clinic staff will also be provided with user documentation.

CHW Component:
CHW Protocol. Patients that meet the eligibility criteria will be drawn from registry lists and randomized to treatment or waitlisted control.

1. *Data collection and consenting with treatment participants*

Patients assigned to the treatment group will be sent an invitation letter to participate in the CHW intervention (See *Recruitment Letter for CHW Intervention*). Invitation letters will be followed up with phone calls by CHWs (See *Script for Telephone Screening for CHW Intervention*). In addition, a screening form (See *Telephone Screening Form for CHW Intervention*) will be completed to verify eligibility. CHWs will call patients a maximum of 10 times over a two-week period at varying times of day to screen and invite them to enroll into the study.

The CHW intervention includes a protocol that consists of 5 monthly 90-minute group health education sessions, providing the tools and strategies to manage diabetes. All sessions employ adult learning techniques and group-based learning and activities. All session materials have been culturally and

linguistically adapted into Bengali, Urdu, Hindi, Punjabi, and Nepali. Sessions will be held remotely via audio phone calls via telephone, MCIT approved Zoom or Webex platforms, remote sessions will be conducted for the community health worker intervention as a result of the current COVID-19 pandemic. Remote sessions are preferred due to limited abilty to properly socially distance in the small offices of the participating PCP clinics and community organizations. When clinic restrictions and limitations due to COVID-19 have been lifted, a modification to the protocol will be submitted and in person health educations session will resume as initially underlined in the protocol. In that cirucumstance sessions will be implemented in PCP clinics and ., community spaces identified by partner agencies or at private residences with approval from tenants.

Patients will also receive 2 one-on-one phone calls from CHWs to discuss individualized challenges, strategies, and action plans for diabetes management and referral to community resources. The tested curriculum also incorporates a family-centered approach; for example, family members are invited to attend sessions and participate in one-on-one calls.

In addition to group sessions, patients will receive up to 9 follow-up phone calls from CHWs, during which individualized challenges, strategies, and action plans for improving diet and physical activity will be discussed (See *Progress Note Form for CHW Intervention*). CHWs will also contact patients via text messages to communicate study activities via a secure NYULMC phone.. CHWs will also work with partner agencies to conduct community-level activities, such as culturally tailored physical fitness classes and healthy cooking demonstrations, that patients will be invited to attend. The CHWs will make necessary referrals to other services available in the community (i.e. exercise classes, social services, mental health, tobacco cessation, etc.). Participants will also complete the *Mobile Phone Use Questionnaire* to assess the type of phone they use, use of messaging and data capabilities on the phone after the first session. This questionnaire will be used to allow the CHWs to communicate with the participant according to their preferences and to tailor future interventions. CHWs will complete an *Encounter Report* to document unscheduled encounters with study participants (ie. such as when a participant calls the CHW to request referrals to services or to report an illness or diabetes related event or new diagnosis.) In order to understand the COVID-related impact and needs of study participants in managing their health and to improve CHW referrals during the COVID19 pandemic, CHWs will complete a Rapid COVID Assessment via phone up to once per month or as needed (see study forms for: *Rapid COVID Assessment*, *Rapid COVID Assessment – Repeating Form*).

Multiple sessions will be hosted at varying times/days of the week to accommodate schedules of both working individuals and at-home caretakers. Small incentives will be provided throughtout the intervention to encourage ongoing attendance, and incentives will be distributed at program completion for individuals who attended all 5 sessions.

Verbal consent (See application for *Waiver of Authorization and Documentation of Consent*) will be obtained via telephone. A verbal consent is preferable due to the 1) remote nature of the intervention 2) the South Asian immigrants have limited technological literacy and are unable to complete an electronic consent via REDCap as this will also require them to have email accounts which are used sparingly in this population.

Upon completion of the verbal consent, CHW will offer to provide a key information page (see *Key Information (*Patients), this form contains all the elements of consent and can be provided via text upon participant agreement. Clinical measures related to diabetes (e.g., HbA1c, BMI) will be obtained from regularly generated diabetes registry lists that practices generate as part of quality improvement initiatives and these measures will be tracked over time. In addition, baseline surveys will also be conducted by NYU study staff within two weeks after consent. (See *Patient Baseline Survey for CHW Intervention*). (See *CHW Participant Baseline Survey in English and Bengali*). An Urdu baseline survey will be

submitted for approval in a subsequent modification as translation is in progress. A follow-up survey will be completed with treatment participants approximately six months after the start of intervention in order to evaluate the effectiveness of the CHW intervention. Survey questions include health access, socioeconomic status, personal and family history of Type II diabetes and its risk factors. Measures will be drawn from nationally validated surveys such as the BRFSS survey.[56] Translated Bengali and Urdu follow-up surveys will be submitted in a subsequent modification.

•Self-efficacy: whether participants feel that they can successfully or competently complete the task of seeking screening or prevention services for diabetes and engage in self-management of diabetes. Measures will be drawn from the Personal Mastery Scale[52], the Rosenberg Self-Esteem Scale (1965), and the Bandura Self-Efficacy Scale.

•Social Support: number of friends and family members in participants' social network, type of support received (e.g., enabling, tangible, emotional support), the density and degree of homogeneity of their social network, the use of faith-based organizations or religious counselors for support. Measures will be drawn from the Arizona Social Support Interview Schedule (Barrera 1980, 1981) and the UCLA Social Support Interview [23]

•Spousal Support: the degree and nature to which participants receive support and encouragement from spouses or partners to initiate and/or maintain screening and prevention services. Measures will be drawn from Multi-dimensional Scale of Perceived Support. [74]

•Knowledge and Health Behaviors:
•Perceived severity – i.e., diabetes can lead to heart attacks and strokes
•Perceived susceptibility – i.e., untreated diabetes can lead to renal complications
•Perceived benefits – i.e., engaging in self-monitoring will reduce the risks of diabetes
•Perceived barriers – i.e., negative side effects are worth enduring (i.e., barriers do not outweigh benefits)
•Diabetes risk factors: We will include questions on the importance of self-monitoring, nutrition and diet, smoking habits, and exercise patterns.

•COVID-19 Pandemic: Participants enrolled during the COVID-19 pandemic will be asked questions on vaccine hesitancy and COVID19 vaccination; as well as questions on mental health and mobile/technology use in order to understand how participants' chronic health and mental was affected in during the pandemic and to understand how best to tailor remote intervention strategies to encourage vaccination among patients with diabetes who are at higher risk for complications from COVID-19.

Surveys will take approximately 30 minutes to complete.

2. *Data collection and consenting with waitlisted control participants*

The NYU study team will only be collecting de-identified EHR data with control participants (n=443). EHR data will include clinical measures related to diabetes (e.g., HbA1c, BMI) and will be obtained from regularly generated diabetes registry lists that practices generate as part of quality improvement initiatives and these measures will be tracked over time. The PCPs will be conducting the de-identification and the link to the unique identifier will remain with the PCP staff. NYU study team members will not have access to these links. Beyond EHR data collection, no other data collection will occur with control participants (e.g., no survey data collection) and the control group will not have any interaction with study personnel for the purposes of research. PCPs will invite control participants to CHW education sessions at a later time (post round 1 of CHW intervention with treatment participants) as a point of service (i.e., not for research

purposes). The PCPs themselves are not involved in the research aside from providing NYU with de-identified EHR data.

C3. Care Coordination Component

The intervention will support team-based care by creating structured mechanisms for feedback between PCPs and CHWs and increasing care coordination that includes three components, adapted from best practices noted in other studies. [31],[16, 18, 63]First, templates will be created that CHWs can complete - Providers will be given access to these templates which will include: 1) CHW action planning documents and individualized counseling conducted during phone calls; and 2) Patient progress in reaching goals related to diabetes management. Second, health coaching and referral materials are available to providers through the EHR, including 1) Culturally adapted CHW curriculum materials; and 2) Systems to link patient to community resources and activities.[5, 48, 71]Healthify's tools, as described above, will be used to facilitate these feedback mechanisms. Third, CHW communication with the healthcare team will be facilitated by participation and report-backs from CHWs.Frequency of participation will be clinic-specific and guided by input from the provider and workflow analysis findings to avoid provider burnout.

C4. Provider Survey

At baseline and follow-up, brief surveys will be administered to all participating physicians (n=80) by the NYU Study team to capture data on: satisfaction with workflow before and after intervention, information sources for EHR-CHW initiatives before and after intervention, acceptability of and satisfaction with the integrated EHR-CHW intervention, and barriers and facilitators of point-of-care use of the tools. The follow up provider survey will also include variables of organizational climate and priority and effects of the COVID-19 pandemic at the individual practices (eg. including questions to assess impact of COVID-19 on the practice and if providers are providing and/or tracking COVID-19 vaccination among patients in order to inform tailoring of remote intervention to support vaccination efforts and assist follow-up by CHWs to encourage vaccination among patients with diabetes who are at higher risk for complications from COVID-19)

The follow up survey will also include questions on cognitive impairment focused on use and knowledge of community resources for patients with cognitive impairment, as well as interest in information about referrals to resources and opportunities to provide feedback. These (See*Provider Survey*). Survey items with response scales will be designed to capture data on each of the research questions. For instance, participants may be asked to respond on a five-point scale from strongly agree to strongly disagree to the following statements: "Diabetes management recommendations are useful to me in my practice", or "The HbA1c testing alerts in the EHR are helpful to me", or to indicate how frequently they use each in a set of common information sources for clinical decision support. Provider Surveys will be administered via the online survey software, RedCap, or a paper copy if requested. Providers will be given the option of completing provider surveys electronically through a secure Redcap survey link. This data will be stored on New York University databases and will only be accessible through a unique secure link sent to an individual provider through RedCap's secure database by a NYU staff. Surveys will take approximately 15 minutes to complete.

C5. Key Informant Interviews

Qualitative key informant interviews will be conducted with physician champions at each clinic and/or administrator of each clinic, Healthfirst representatives, community advisory board members, research staff,and CHWs (n=100) (See *Key Informant Interview Guide*). At baseline, the interviews will be incorporated into the workflow analysis to assess current satisfaction and usage of EHR and health coaching. At follow-up, the interviews will assess barriers and facilitators to the implementation and adoption process of the integrated EHR-CHW intervention, fidelity to the interventions, and to solicit recommendations for the replication and scalability of the intervention to other sites and insurer organizations. Follow-up surveys completed during the pandemic will assess impact of COVID-19 on the practice, attitudes towards the remote CHW intervention adapted for their patients during the pandemic, and if providers are providing and/or tracking COVID-19 vaccination among patients. These questions

are intended to assess satisfaction with the remote intervention and inform strategies to support vaccination efforts and assist follow-up by CHWs to encourage vaccination among patients with diabetes who are at higher risk for complications from COVID-19 (See Key Informant *Interview Guide - provider – remote intervention*). The NYU Study team will conduct the interviews. Questions will be adapted from existing validated measures on acceptability, feasibility, adoption, organizational culture, and scalability.[1-3, 39, 59, 69] What organizational barriers and facilitators appear to influence implementation and how? Did members of the practice understand and respect the respective roles of physicians, CHWs, and other members of the team? How did this organization customize the intervention to better serve its own local needs? How were users involved in design and implementation? What are recommendations for replicating this model for other clinical settings and communities? Do project findings motivate payer organizations to reimburse CHW services? Key Informant Interviews will take approximately 30 minutes to complete.

II. CHARACTERISTICS OF THE RESEARCH POPULATION

The overall number of subjects expected to participate in this study is 1066
This includes a total enrollment of 886 participants in the EHR-CHW Intervention (443 treatment participants and 443 wait-list control participants), 80 subjects who participate in the provider surveys and 100 participants in the key informant interviews.

CHW Intervention
Inclusion Criteria: Participants will be eligible for study participation if they meet the following criteria: a) are of South Asian ethnicity; b) are at least 21 years of age and younger than age 75, c) had an appointment with a physician or mid-level clinician for routine non-emergent primary care in the last 12 months; d) a diagnosis of diabetes and e) an HbA1c reading of >7 in the last 12 months.

Exclusion Criteria: Patients under the age of 21 and older than 75 will be excluded. Pregnant women and all visits with an obstetrician gynecologist are excluded. Patients will be excluded if they were enrolled in a CHW led hypertension or diabetes education intervention in the past five years.

No children or vulnerable subjects will be enrolled in this study.

Provider Assessment Surveys
Inclusion criteria for the surveys are as follows: adult (18 years and over); clinicians employed by independent primary care practice that are members of HealthFirst's network and have enrolled into the study.

Exclusion criteria include the following: clinicians who are unable to complete the survey in the English language.

Key Informant Interviews
Inclusion criteria for the interviews are as follows: Adult (18 years and over); must be a provider, clinic manager, Healthfirst staff, community advisory board member, research staff, or community health worker.

Exclusion criteria include the following: participants who are unable to participate in the interview conducted in the English language.

III. METHODS and PROCEDURES

A. Methods and Procedures

A1. Integrated EHR-CHW Intervention

Clinic Enrollment
Practices that express interest in participating in the CHW intervention will sign a Memorandum of Understanding (MOU) that outlines the nature of the evaluation and the uses of any data collected, including:

i. Training requirements
ii. CHW intervention components to be implemented
iii. Individual-level participant data to be extracted routinely from EHR and provided to study team
iv. Confidentiality and data storage procedures

All relevant parties will then sign the MOU.

Intervention Components
A minimum set of proposed intervention components will be implemented at all participating practices, including:

- An alert to identify South Asian patients with uncontrolled diabetes with HbA1c of >7
- 5 group-based health education sessions on diabetes management
- Provision of culturally and linguistically tailored health information and resources
- Two one-on-one in-person meetings and upto 9 follow-up calls/meetings to engage in goal-setting activities regarding changes to health behaviors, medication adherence, or other issues related to diabetes prevention as identified jointly by patient and CHW.
- Participants will develop with the CHW and receive a copy of their long-term and short-term Participant Action Plan.
- Referrals to other services available in the community (i.e. exercise classes, social services, mental health, tobacco cessation, etc.
- EHR-CHW integration supporting team-based care and feedback between PCPs and CHWs within the clinic, including:
    - First, providers will be sent Enrollment Update Letters during the recruitment phase of the intervention regarding the status of enrollment at their site (see Provider Enrollment Update Letter). This document will be sent as a password protected file with the password sent in a separate file from the enrollment status.
    - Second, templates will be created that CHWs can complete and upload into the EHR. Providers will be able to access these templates which will include the following: 1) CHW action planning documents and individualized counseling conducted during protocolized phone calls; and 2) Patient progress in reaching goals related to weight loss and behavior change.
    - Third, health coaching and referral materials will be made available to providers through the EHR, including 1) Culturally adapted CHW curriculum materials; and 2) Systems to link patient to community resources and activities.[5, 48, 71]
    - Fourth, CHW communication with the healthcare team will be facilitated by participation and report-backs from CHWs during regular team "huddles" or staff meetings at least once per month. Further frequency of participation will be clinic-specific and guided by input from the provider and workflow analysis findings in order to avoid provider burn-out. CHWs will note any diabetes related events (high or low blood sugar events if encountered and communicated to the CHW), these will be noted in Encounter Reports.

CHW Curriculum
Participants enrolled in the CHW intervention will receive group-based health education sessions:

Curriculum Session Title & Content	**Tailored cultural components**
Session 1: Diabetes Overview • Diabetes information	· Concept of prevention tied to South Asian core values (in religion/culture)

• Myths and Facts about diabetes • Signs of Symptoms of Diabetes • Goal-setting • Blood Glucose Levels • Basics on Eating Healthy • Staying motivated and goal-setting	· Discussion of diabetes prevalence and increased risk of diabetes in Asians · Discussion of diabetes among South Asians · Explanation of BMI and at-risk BMI in Asian communities · Dispelling common cultural misconceptions regarding diabetes (eg. getting diabetes is a natural part of aging) · Incorporation of culturally appropriate images and language Discussion of diabetes complications, heart disease, stroke · Discussion of prevention and inter-connectedness of chronic diseases · Discussion of cholesterol and fats in diet, blood pressure and salt in diet · Review of popular Punjabi foods high in salt and fat and limiting these foods · Incorporation of culturally appropriate images/language
Session 2: Healthy Eating • Nutrition and Food • Eating a balanced diet: The Plate Method • Overcoming barriers to eating out/social situations • Reading a Nutrition Label • Goal-setting for healthy eating	· Photos of typical South Asian foods · Healthy elements in traditional South Asian cooking (eg. whole grain options for rotis, incorporating fruits and vegetables) · Identifying and limiting deep-fried snacks high in salt and sweets high in fat and sugar; substituting sweets with fruits · Healthy vegetarian options · Healthy versions of popular South Asian recipes · Following the Plate Method with traditional South Asian foods · Managing expectations for eating out, langar at gurdwara (for Sikhs), etc. · Reading food labels · Working with women participants to improve nutrition in the entire household · Incorporation of culturally appropriate images and language
Session 3: Physical Activity • Caloric intake and energy balance • Benefits and types of exercise • Injury prevention • Incorporating routines • Overcoming barriers • Practice activity and goal-setting	· Discussion of physical activity as essential to physical and mental fitness (eg. encouragement to practice similar discipline in physical activity as in prayer) · Home-based exercise/activities · Practice Activity · Incorporation of culturally appropriate images and language
Session 4: Diabetes Management • Diabetes complications • Heart disease and stroke • Communicating with the doctor • Preparing for a doctor's visit • Heart disease and stroke • Staying motivated and goal-setting • Discussion of diabetes complications, heart disease, stroke • Discussion of prevention and inter-connectedness of chronic disease • Discussion of cholesterol and fats in diet, blood pressure and salt in diet	• Incorporation of culturally appropriates images

Session 5: Stress and family support • Effects of stress on health • Stress and anger management • Strategies to manage depression Family support and goal-setting	· Discussion of meditation practice · Progressive muscle relaxation for stress relief · Strategies to manage depression; discussion around stigma associated with mental health (eg. depression) · Incorporation of culturally appropriate images and language

A2. Data Collection

EHR Data

Data will be extracted from the PCP clinics' EHR systems every 6 months. De-identified EHR data will be collected from both treatment and control participants.

The process for collecting de-identified patient data is described here: This will entail PCP staff exporting de-identified patient information via a secure sftp site to a central repository managed by NYU. In order to de-identify patient information, PCP staff will generate a set of unique study identifiers to assign to treatment and control patients by associating a specific study number with a specific medical record number in the EHR system. The table of study identifiers and corresponding medical record numbers for the duration of the study in a secure and locked location in their respective clinics. All other potentially identifying data will also be stripped from the dataset prior to extraction. Only the PCPs will retain the table necessary to link patient identifiers and the study ID. Using this method, we will ensure that patient confidentiality is maintained, but that patients who are observed more than once will have the same study ID in each extraction, which is necessary for the planned analyses. Using the described approach, a pre-defined set of patient data will be exported every 6 months from the clinics' EHR systems into a de-identified Excel spreadsheet or delimited text file. Data elements will be based on functionalities of EHR platforms and will include patient demographic information such as year of birth, gender, race/ethnicity, diagnoses, medications, and laboratory results.

Follow-up height, weight and HbA1c measures will be obtained during routine office visit at six months. Scheduled office visits will be tracked via quarterly data pulls from the PCPs. If no visit is scheduled during the follow-up period, project CHWs will conduct follow-up calls to schedule patients for a height and weight recording at the clinic. Patient travel incentives will be provided to facilitate follow-up data collection.

De-identifed EHR data will include the following:

- Clinic ID, patient study ID, and demographics - gender, age, race/ethnicity (if available), Language (if available)
  - Any diagnoses for: hypertension, diabetes, pre-diabetes, and high cholesterol during the study period , including month and year of diagnosis
  - Height and weight data during the data collection period, Month and year of measurement
  - All lab results for: HbA1c, lipid profile during the study period, Month and year of measurement

All data collection measures and procedures will be the same for treatment participants as control patients with the exception that data will no longer be de-identified. PHI and other data will be collected from treatment participants and with their full consent only. Treament participants will also have the option to authorize staff to take photographs, video and audio for the purpose of disseminating health promotion and CHW led health intervention work in the audio/video consent form.

B. Data Analysis and Data Monitoring

B1. Aim 1 Analysis

AIM 1: Specific Aim I: Test the effectiveness of a multi-level diabetes management intervention compared to usual care. The primary outcome is reduction in HbA1c for patients with baseline HbA1c of >7%. The secondary outcomes include enhanced use of community and social services and increased self-efficacy.

Hypothesis: Individuals receiving the multi-level diabetes management intervention will be more likely to achieve >0.5% reduction in HbA1c 6 months following the index office visit than invididuals receiving care as usual.

The analysis of the effect of intervention on the outcome measure will proceed using a Generalized Linear Mixed Model (GLMM). In particular, we will use a random effects model that assumes a binomial distribution with a logit link function. The comparison will make no linear assumption about the time trend for each outcome over the course of the trial. The model will be as follows:

(1) $$logit(Y_{ijt}) = \mu + \alpha_j + \theta_t + \tau C_i,$$

where $Y_{ijt} = 1$ if the i^{th} subject attached to the j^{th} clinic at time quarter t achieves an HbA1c reduction of 0.5% or more within six months following the index visit, $Y_{ijt} = 0$ otherwise. α_j is a random effect for clinic j with mean 0 and variance σ^2_b. θ_t is a time-specific effect of quarter t,$t \in$(1,2,…,12). C_i is an indicator variable, and Ci =1 if individual i receives care under the EHR/CHW intervention, C_i =0 if individual i . τ represents the treatment effect of the intervention. The model will be fit using the LME4 package using R software. The hypothesis will be tested using two-sided level of significance $\alpha\alpha$=.05. Because outcome data will be derived from administrative data, we do not anticipate missing data. However, in the event that there is missing data, we will use multiple imputation under the assumption of data missing at random (MAR). This is consistent with following an intent-to-treat protocol. Sex as a biological variable will be addressed by exploring gender as a potential moderator of intervention effects.

Power Calculation:

We conservatively estimate a 10% difference in effect size (i.e., ≥0.5% reduction in HbA1c) comparing treatment and control group participants. Accrual of 886 participants, evenly randomized to treatment or control groups, provide greater than 80% power to detect this difference, using a 2-sided, 0.05-level test (i.e., 44 participants (22 treatment and 22 control participants per PCP). These calculations assume 15% loss to follow-up and enrollment of 20 PCPs.

Sampling. Preliminary data from our practice needs assessment indicates that approximately 375 unique patients for every six months will have an office visit. Based on our past research, we estimate 40% of those individuals will have a Type II Diabetes diagnosis (n=150), and conservatively estimate that only 40% will meet our eligibility criteria for the study (n=60). In our previous diabetes management CHW intervention among South Asians, screening to enrollment rate is 41%. [58] For this study, we apply a similar estimate that 40% of patients will be interested in the study and will be contacted by a CHW (n=24). Based on retention rates from our CHW studies,[9,10,60,68,69,71,89] we estimate that approximately 90% of individuals in control and treatment quarters will be followed up at six months (n=22). Thus, for each clinics, we will enroll approximately 22 patients every six months over a period of one year, resulting in total recruitment of approximately 886 participants across 20 clinics. Thus, approximate CHW caseload over a six-month period is 22 participants (about 4 patients per month for a part-time CHW), consistent with caseloads from our previous studies.

B2. Aim 2 Analysis.

Analysis to address this aim will be guided by the following questions:

1. Utilization Patterns: How frequently do clinicians utilize the integrated EHR-CHW system? What is the percentage of adoption? Does the utilization pattern change over time? Does the intervention increase the utilization and quality of quality measurement reports?

The system utilization files from HF's data warehouse will be used to analyze utilization patterns of the enhanced physician alert and registry functions, as well as the integrated EHR-CHW options. These data will yield descriptive trends for frequency of utilization across the participating PCP clinics as well as an estimate of the percentage of adoption in terms of patient visits for HbA1c testing. The frequency of quality measurement reports will be described and compared 12 months pre- and post- intervention.

2. Physicians' Attitudes Regarding the Integrated Intervention: What are physicians' attitudes regarding ADA recommendation for diabetes management? How satisfied are the physician's with the integrated EHR-CHW tools? What are the barriers and facilitators of point-of-care use of the tools? How does the intervention affect clinicians' satisfaction with workflow around T2DM management and HbA1C reduction?

This set of research questions will be primarily addressed with data from brief surveys collected from the participating clinicians. Survey items with response scales will be designed to capture data on each of the research questions above. For instance, participants may be asked to respond on a five-point scale from strongly agree to strongly disagree to the following statements: "Pre-diabetes testing recommendations are useful to me in my practice", or "The HbA1c testing alerts in the EHR are helpful to me", or to indicate how frequently they use each in a set of common information sources for clinical decision support. The survey data come from a small sample (n=approximately 40) and are only intended to quantify descriptive information and will not be used in extensive statistical analyses. The data will be tabulated and summarized descriptively to address each research question listed above and to assess change in attitudes from baseline to 12 months.

3. Barriers and Facilitators to Implementation Adoption and Implications for Scalability: What organizational barriers and facilitators appear to influence implementation and how? Did members of the practice understand and respect the respective roles of physicians, CHWs, and other members of the team? How did this organization customize the intervention to better serve its own local needs? How were users involved in design and implementation? What are recommendations for replicating this model for other clinical settings and communities? Do project findings motivate payer organizations to reimburse CHW services?

Interview data will be transcribed and analysis transcribed data will follow "constant comparison" analytic approach.[17] The "constant comparison" approach is a method of explanation building in which the findings of an initial case are compared to a provisional category, property or proposition, revised as necessary and then other details or new cases are then compared against the revision and revised again as needed. This process is continued until an area of interest is fully explicated, reaching theoretical saturation.[17] Using "thematic" coding, we will develop an initial set of codes, which will be reviewed by the community-clinical coalition to ensure they are relevant and complete. For each core code, we will ultimately develop one or more "secondary codes" that represent either more specific or restricted aspects of the phenomenon, to contextualize it, or to suggest underlying meanings. The secondary codes will vary in specificity or subtlety depending on the judged substantive value of additional refinements. Transcripts will be coded by at least four coders. Discrepancies in coding will be discussed and resolved, then the process is repeated with a new set of transcripts until an acceptable level of inter-coder reliability between them has been by the achieved, estimated using an appropriate chance-corrected statistic (e.g., kappa for nominal data and T-index for ordinal data).[62] The coded transcripts will be analyzed with *Atlas.ti*, a software package for qualitative data analysis.[12] Analysis will be conducted to inform best practices for scalability that can be replicated by payer organizations and health care systems.

C. Data Storage and Confidentiality

Confidentiality will be maintained for participants according to mandatory Institutional Review Board regulations, under the supervision of Dr. Nadia Islam.

EHR-CHW Intervention

As described above, all patient data will be de-identified prior to transfer to a NYU MCIT managed network databases via a secure sftp site. All computer systems are protected from possible external access. No internet access is possible with the research systems.

Treatment Participants and Provider Survey Data

To safeguard confidentiality and anonymity, unique identifiers will be assigned to all participants for all portions of the study and all data collection instruments will identify participants only by these unique identifiers. A log of consented treatment participants will be stored on REDCap.On the baseline and follow-up surveys, the first page of the survey will ask treatment participants for updated contact information so that CHWs can maintain contact throughout the intervention period. Data will be entered into REDCAP, a HIPPA-compliant a research database platform, by a study staff member and all data will be housed on a secure MCIT managed network drives. Pages containing participants name and contacts information and logs linking subjects' identifying information to study numbers will be kept in a subject file per IRB regulation in a locked in a file cabinet in a secure location. Baseline and followup survey data will be kept in individual subject files per IRB regulation. Contact information from consented participants will be kept on file for the duration of the trial and will be destroyed (both electronic and hard copy) upon the dissemination of trial results (approximately 5 years).

Key Informant Interview

Unique study IDs will be assigned to each key informant in Excel, and these unique study IDs will track interview logistics (including interview date/time/location), interview audio file names, and interview transcripts. The, audio-recordinsg and interview transcrips will be housed on secure MCIT managed network drives. Only study staff will have access to these audio-recordings and study data. To safeguard confidentiality and anonymity, audio files are deidentified, and subject names will not be collected or included in interview transcripts.

D. Data Sharing Policy

The Prinicipal Investigator, scientific advisors and research team staff will be responsible for developing publication procedures and establishing authorship policies. This study will comply with the NIH Public Access Policy, the public will have acess to the published results of this intervention. Manuscripts will be submitted to peer-reviewed journals and accepted manuscripts will be submitted to PubMed Central upon acceptance of publication. The study will be submitted to clinicaltrials.gov and updated as necessary in accordance with study development. The clinicaltrials.gov record id is NCT03333044.

IV. RISK/BENEFIT ASSESSMENT

Risks and protection against risks

The proposed study poses minimal risk to participants. Loss of confidentiality is the greatest potential risk to study subjects. We will not obtain written consent from providers who participate in surveys and interviews; and, no identifying information is included on the transcripts of clinician interviews or surveys. The interviews will be taped using a digital recorder. No identifying information will be included in the key informant audiotapes. All interviews will bestored on password protected documents housed within MCIT managed network drives. Once transcribed and entered onto a password protected Atlas TI© database, the recordings will be deleted from the study files. All provider survey data entered into the research database will be protected by confidential entry codes. Names will be replaced with identification numbers. Providers will have the right to refuse to participate without any compromise of

their employment status. Also, if a participant is uncomfortable during an interview situation, they may stop the interview at any time without penalty.

All patient data will be de-identified by NYU staff prior to transfer to NYU managed network drives. Locked file cabinets will be used to store materials with identifying information. All computer systems are protected from possible external access. No internet access is possible with the research systems. The data collected for this study will be used strictly for the purposes stated in this application and will only be available to NYU research staff.

Potential Benefits to the Subjects
CHW Intervention: By participating in the proposed research, participants may gain the benefit of augmented services related to their diabetes and CVD-related risk factors. Some patients may individually experience no benefit. This study will yield knowledge regarding methods for increasing adherence to evidence-based guidelines for treating diabetes among providers and health staff serving South Asian populations. Overall, the benefits of understanding effective methods for helping patients reduce their risk of diabetes far outweigh the remote possibility of a breach of confidentiality.

Provider Surveys/Staff Key Informant Interviews: Participating providers and staff may benefit from the interventions which are meant to assist them with improving the quality of care they provide for South Asian patients at-risk of diabetes. The study may also have relevance to the US health care system by testing a practice facilitation model to enhance implementation of team-based care integrated with EHR systems for managing diabetes.

V. INVESTIGATOR'S QUALIFICATIONS AND EXPERIENCE

NYU Personnel

Nadia Islam, PhD will serve as PI of the proposed study. Dr. Islam is an *Early Stage Investigator* and Assistant Professor in the Department of Population Health at NYU School of Medicine with substantial experience in leading R01-level research projects examining the efficacy of CHW efforts in the prevention and management of CVD and diabetes in Asian American communities. Dr. Islam is the Project PI of the DREAM Project, a clinic-based CHW intervention to improve T2DM management in the Bangladeshi population, the core research for the NYU Center for the Study of Asian American Health. She also is the research director of the NYU-CUNY Health Promotion and Prevention Research Center, where she serves as PI of the core research study, Project IMPACT, an integrated EHR-CHW intervention designed to increase hypertension control for South Asian patients conducted in partnership with HealthFirst. She was also the PI of the core research for the NYU PRC, Project RICE, a culturally tailored CHW-led adaptation of DPP for Korean and South Asian individuals at risk of T2DM. Previously, she was co-investigator on Project AsPIRE, an NIMHD-funded CHW-led hypertension intervention in the Filipino community. Most recently, Dr. Islam is the PI of a CDC-funded implementation and dissemination program project to increase access to healthy foods and beverages and increase hypertension management among Asian American communities in NY and NJ through policy, systems, and environmental level changes.

Lorna Thorpe, PhD will serve as a scientific advisor to the study. She has extensive leadership and research experience in the field of epidemiology, particularly chronic disease epidemiology, as well as with population-based surveillance, interdisciplinary research collaboration, and translation of research into policy. Dr. Thorpe will assist with her expertise in intervention design, survey rsearch, and analysis of EHR data.

Andrea Troxel, Sc.D. will serve as the biostatistician for the study. She is the Director of Biostatistics at the NYU School of Medicine. She has extensive experience in the design, conduct and analysis of all phases of clinical studies. She is also an expert on randomized trials of behavioral economic interventions and on adaptive trial designs.

Sahnah Lim, PhD, MPH, MIA will serve as the Program Manger for the study. Dr. Lim began her career providing social services to immigrant communities in New York City at various community-based organizations. She then transitioned to doing research with marginalized communities (sexual minorities, sex workers, street youth) both domestically and internationally and in both governmental and non-governmental settings. Her research focuses on various health inequities, including those that relate to gender, race/ethnicity, and class. She is experienced in mixed methods approaches and specializes in survey research and psychosocial statistical methods. Dr. Lim's work has been featured in various peer-reviewed journals such as Journal of Acquired Immune Deficiency Syndromes, Journal of Urban Health, and Culture, Health, and Sexuality. She received her dual masters degree from Columbia University and her PhD from the Johns Hopkins Bloomberg School of Public Health.

Jennifer Zanowiak, MA is the Senior Project Coordinator for the study. Ms. Zanowiak has seven years experience coordinating CHW interventions to improve cardiovascular health in NYC South Asian and Korean communities. She will supervise the community healthworkers and oversee the implementation of the CHW Intervention. Ms. Zanowiak graduated with a MA in International Affairs and has extensive experience with program development and interventions involving CBPR approaches among immigrant populations.

Shinu Mammen, MPH is Program Coordintor for the study. Ms. Mammen has three years of experience coordinating the first multi center longitudinal cohort study to research the risk factors for heart disease and diabetes among South Asians living in the United States based at Northwestern University. Ms. Mammen has experience collaborating with South Asian immigrant community based organizations, hospital health systems, and public health departments in order to successfully implement community based interventions. Ms. Mammen graduated from Benedictine University with her Masters in Public Health.

Laura Wyatt, **MPH** is the Research Data Manager for the NYU Center for the Study of Asian American Health. She manages and oversees the data sources across CSAAH, which includes the NYU-CUNY PRC, and performs analyses and assists with the dissemination of study findings. In addition, she provides epidemiological and biostatistical support for grant development activities within the center. Ms. Wyatt received her MPH in Epidemiology from Columbia University, Mailman School of Public Health and also studied public health at the University of North Carolina at Chapel Hill.

Mursheda Ahmed is a Community Health Worker (CHW) for this study. She is fluent in Bengali and is well connected to the Bengali community in New York City. She is also a certified IPA/Navigator by the New York State of Health Benefit Exchange. She provides research support for the project and is involved with practice outreach and engagement, as well as with group and one-on-one health education and coaching for participants of the CHW intervention.

Gulnahar Alam is a Community Health Worker (CHW) for this study. She is fluent in Bengali and is well connected to the Bengali community in New York City. She provides research support for the project and is involved with practice outreach and engagement, as well as with group and one-on-one health education and coaching for participants of the CHW intervention.

Mamnunul Haq is a Community Health Worker (CHW) for this study. He is fluent in Bengali and is well connected to the Bengali community in New York City. He provides research support for the project

and is involved with practice outreach and engagement, as well as with group and one-on-one health education and coaching for participants of the CHW intervention.

Md. Jalal Uddin is a Community Health Worker (CHW) for this study. He is fluent in Bengali and is well connected to the Bengali community in New York City. He is currently studying to receive his Masters degree in Statistics and Applied Mathematics from Hunter College. He provides research support for the project and is involved with practice outreach and engagement, as well as with group and one-on-one health education and coaching for participants of the CHW intervention.

Sidra Zafar is a Community Health Worker (CHW) for this study. She is fluent in Punjabi and Urdu, and is well connected to the Pakistani community in New York City. She provides research support for the project and is involved with practice outreach and engagement, as well as with group and one-on-one health education and coaching for participants of the CHW intervention.

Haroon Zafar is a Community Health Worker (CHW) for this study. He speaks Punjabi and Urdu fluently and is connected with Pakistani organizations within the bourgouh of New York City. He provides research support for the project and is involved with practice outreach and engagement, as well as with group and one-on-one health education and coaching for participants of the CHW intervention.

Sabiha Sultana is a Community Health Worker (CHW) for this study. She has her Bachelor of Sciene degree in Social Work from York Colleg in New York. She is fluent in Bengali and is well connected to the Bengali community in New York City. She provides research support for the project and is involved with practice outreach and engagement, as well as with group and one-on-one health education and coaching for participants of the CHW intervention.

External collaboraters

Stacy Lindau, MD will serve as a scienfic advisor on the study Steering Committee. . Her translational research lab in the biological sciences division at the University of Chicago focuses on the health and health care of marginalized populations, using an asset-based community engaged approach. She brings expertise in a wide range of quantitative and qualitative data collection and analytic methodologies and has used the tools of healthcare delivery science to develop and replicate healthcare-based interventions. Specialized areas of leadership and expertise include community-engaged, population-based and clinical survey research; national and international population- and and the integration of clinical trials with agent- based modeling to evaluate a community-wide, multi-site population health intervention. Dr. Lindau will contribute her expertise to evaluate the facilitators and barriers to community-based self-care referrals, including factors influencing referral behaviors and experiences of providers, community health workers, and patients, to reduce diabetes disparities among South Asian communities.

Healthify is a leading software provider to health plans, hospitals, and provider networks working in low-income communities, and has worked with NYU Lutheran, New York Presbyterian Health Systems, and Westchester Medical Center to support care management with HIT tools. Healthify has developed multiple platforms used by care teams to make quick and accurate referrals to social services for patients which will be utilized by the study for the community referral component of the intervention. They will also provide reporting and analytics to understand use and adoption of tools and referral success.

HealthFirst Personnel

Rashi Kumar, MUP is the Healthfirst Program Manager for this study. She has extensive experience in health workforce development and training. At Healthfirst, she is Senior Program Manager, Clinical Partnerships, and is responsible for overseeing innovative grant-based programs that aim to reduce disparities in health outcomes and test diverse models of value based payment. She manages HealthFirst's

involvement as a payer partner in the development and implementation of the research. She will help with PCP clinic recruitment and dissemination of educational material.

VI. SUBJECT IDENTIFICATION, RECRUITMENT, AND CONSENT/ASSENT

A. Method of Subject Identification and Recruitment

Treatment participants for CHW intervention
Patients that meet eligibility criteria will be drawn from registry lists and randomized to treatment or waitlisted control. Patients assigned to the treatment group will be sent an invitation letter (See *Recruitment Letter for CHW Intervention*) to participate in the CHW intervention. Invitation letters will be followed up with phone calls by CHWs (See *Script for Telephone Screening for CHW Intervention*), during which CHWs will explain the study and elements of informed consent. Participant names, telephone numbers, and email addresses will be needed in order for CHWs to contact participants regarding participation in the intervention (Please see *Application for Waiver of Authorization for Telephone Screening Form*). In addition, a screening form (See *Telephone Screening Form for CHW Intervention*) will be completed to verify eligibility. CHWs will call patients a maximum of 10 times over a two-week period at varying times of day to invite them to enroll into the study.

Provider Surveys
Providers at participating practices will be invited to complete the Provider Assessment via email link. Paper surveys will also be available for those who prefer to fill out the survey in hard copy. No undue pressure will be given to subjects for participation as the participation is entirely voluntary, and will be described via email or verbally to the invited participants (see *Invitation and Elements of Informed Consent for Provider Survey*).

Key Informant Interviews
Participating providers, Healthfirst staff, community advisory board members, research staff, and community health workers will receive an invitation to participate in the interview (See *Invitation and Elements of Informed Consent for Key Informant Interview*). No undue pressure will be given to subjects for participation as the participation is entirely voluntary (See *Verbal Consent Script for Key Informant Interview*).

B. Process of Consent
All study personnel will have completed the mandatory CITI human subjects research training before commencing any study-related activities.

The informed consent form for this study have been created by the NYU Grossman School of Medicine Office of Science and Research in accordance with Federal guidelines, including the Health Insurance Portability and Accountability Act (HIPAA). A verbal consent will be obtained via telephone from participants (see *Waiver of Authorization and Documentation of Consent* and *Telephone Consent Form*). A verbal consent is preferable due to the 1) remote nature of the intervention 2) the South Asian immigrants have limited technological literacy and are unable to complete an electronic consent via REDCap as this will also require them to have email accounts which are used sparingly in this population. The CHW will review all the elements of informed consent over this call and (see *Telephone Consent Form*) will offer to provide a key information page subsequently, (see *Key Information (Patients)*) via text message(See *Text Message Script*). Texts will be sent from a secure NYULMC phone A log of consented treatment participants will be stored on REDCap.

CHW Treatment Participants

All potential treatment participants will receive a copy of the study consent form by the CHW. The format of the consent form consists of a 1-page consent signature form with an accompanying brochure fully detailing all components of the full informed consent (See *Consent Brochure* and *Consent Signature Page for CHW Intervention*). This layout is more appropriate for clinic-based and community-based recruitment. First, based on our experience in previous community-based studies, community members were discouraged by a multiple-page consent form, and we expect the same in a clinic setting. Even though this format provides the same exact information as the standard consent form, we expect that it will be less intimidating for participants who are learning about the study in a community-based recruitment atmosphere.

When COVID 19 limitations and restrictions at the clinics are lifted, the study will return to the in person intervention, at that time point a modification will be submitted to revise the protocol to an in person intervention. If screening is conducted in person, consent processes will take place at PCP offices in a manner that maximizes confidentiality and privacy and allows questions to be asked. All study staff will follow COVID-19 workplace safety and personal protective equipment policies at each PCP office and as required by NYUGSOM. Participants will be screened in advance for symptoms as per the PCP office guidelines and asked in advance to wear a mask/face covering. All study staff and participants will follow efforts for social distancing whenever possible. Eligible participants demonstrating interest in participating in the project will meet with a study team member who will explain the intervention and answer any questions. Verbal consent (see *Telephone Consent*) will be obtained in a location allowing privacy and appropriate social distancing, on a one-on-one basis.

Participants are free to withdraw from participating in the study at any time without repercussions. Participants will be advised during the consent process that they have the right to withdraw entirely and that their refusal will not jeopardize their relationship with their CHW or primary care physician. Treatment participants will have the option to authorize staff to take photographs, video and audio for the purpose of disseminating health promotion and CHW led health intervention work via the verbal consent. Videos will be used for the purpose of obtaining testimonials regarding the impact of the program. Video and photos will be kept for a period of 5 years after the study closes on MCIT secured drives, only NYU study staff will have access to these materials. Participants will have the right to retract permission of the use of video, audio, and photos. The retraction of permission will not affect participant involvement in the study. Upon retraction of permission, video, audio and or photos will be deleted from MCIT secured drives and will no longer be used in any form.

Provider Assessment Surveys

A Waiver of Documentation of Consent is being requested for participants of the Provider Survey for this study (see *Application for Waiver of Documentation of Consent for Provider Survey and Key Informant Interview*). This request is being made because the consent form, if collected, would require names to be collected and in doing so would be the only record linking the subjects name to the research. The study will invite participation by email to complete the online survey, who will give implied consent if they click on the hyperlink to complete the survey, or if particpants wish to complete a paper-based survey, the study team will obtain verbal consent (see *Invitation and Elements of Informed Consent for Provider Survey*). The consent email will be sent out by study staff. The study offers a hyperlink for participants if they agree to participate in the study. It will state clearly that participation is completely voluntary, and there is no penalty in declining to participate in the study. Participants will be informed they are free to withdraw from participating in the study at any time without repercussions.

Key Informant Interviews

A Waiver of Documentation of Consent is being requested for participants of the Key Informant Interview for this study (see *Application for Waiver of Documentation of Consent for Provider Survey and Key Informant Interview*). This request is being made because the consent form, if collected, would require names to be collected and in doing so would be the only record linking the subjects name to the research. Verbal consent will be obtained prior to start of the interview, but we will not collect any personal information or identifiers. No names of individuals will be recorded or appear in interview notes. Participants will be free to withdraw from the interview at any time without repercussions. Participants will be provided with an invitation including the elements of the written consent as well as contact information for the study PI. Verbal consent will be obtained from the key informants prior to beginning the interview (See *Verbal Consent Script for Key Informant Interview*).

C. Subject Capacity
We anticipate that all subjects will have the capacity to give informed consent. Language barriers will be minimized by having data collectors who speak Bengali, Urdu, and Punjabi and translated consent forms for the CHW Intervention (to be translated upon approval of the English version and submitted to IRB for review and approval via a modification).

E. Debriefing Procedures.
Information will not be withheld from the subjects related to their participation in the study.

F. Consent Forms. Eligible patients will provide verbal consent and enrolled to participate in the study.. Please refer to consent forms: *Telephone Consent, Key Information (Patients)* and *Invitation and Elements of Consent* and *Verbal Consent Script* documents for the Provider Survey and Key Informant Interviews.

G. Documentation of Consent
CHW Treatment Participants
Study staff will obtain consent by reading the verbal informed consent script to the subject and the subject or will be given adequate opportunity to read it and clarify questions before verbally consenting. The subject will receive a copy of the key information sheet by text message with prior approval from the participant(See *Text Message Script*). Texts will be sent from a secure NYULMC phone. A translated verbal informed consent and key information sheet will be used for non-English speaking subjects, depending on their preferred language(upon approval of the *Waiver of Authorization and Documentation of Consent* Telephone Consent for CHW Intervention in English, Bengali and Urdu; Key Information (Patients) in English, Bengali and Urdu)).

Study staff who have obtained the verbal consent will document the consent and the date of consent on a secure REDCap database. The REDCap database tracking form is the only record linking a participant's name and Subject ID.

Signed informed consent forms from participants consented in earlier versions of the protocol will be stored in a separate folder in a locked cabinet accessible only to study staff.

Baseline surveys will also be conducted by NYU study staff with intervention participants within two weeks after consent. A follow-up survey will be completed with intervention participants approximately six months after the start of intervention in order to evaluate the effectiveness of the CHW intervention, the CHW Intervention 6 month survey will be completed at the last education session.

EHR data will be used to generate a registry of eligible participants for recruitment. EHR data will also be used to compare clinical outcomes (e.g., height and weight). EHR data will be collected at baseline, 6-months and 12 months. The informed consent for treatment participants will outline elements of the EHR data collection, CHW group education, one-on-one counseling, survey data collection, and Healthfirst claims data collection.

Control Participants

The NYU study team will only be collecting de-identified EHR data with control participants. The PCPs will be conducting the de-identification and the link to the unique identifier will remain with the PCP staff. NYU study team members will not have access to these links. Beyond EHR data collection, no other data collection will occur with control participants (e.g., no survey data collection) and the control group will not have any interaction with study personnel for the purposes of research. PCPs will invite control participants to CHW education sessions as a point of service (i.e., not for research purposes). For these reasons, we will not be obtaining consent with control participants.

Provider Assessment Surveys

A Waiver of Documentation of Consent is being requested for participants of the Provider Survey for this study (see *Application for Waiver of Documentation of Consent for Provider Survey and Key Informant Interview*). This request is being made because the consent form, if collected, would require names to be collected and in doing so would be the only record linking the subjects name to the research. The study will invite participation by email to complete the online survey, who will give implied consent if they click on the hyperlink to complete the survey, or if particpants wish to complete a paper-based survey, the study team will obtain verbal consent (see *Invitation and Elements of Informed Consent for Provider Survey*).

The consent email will be sent out by study staff. The study offers a hyperlink for participants if they agree to participate in the study. It will state clearly that participation is completely voluntary, and there is no penalty in declining to participate in the study. Participants will be informed they are free to withdraw from participating in the study at any time without repercussions.

Key Informant Interviews

A Waiver of Documentation of Consent is being requested for participants of the Key Informant Interview for this study (see *Application for Waiver of Documentation of Consent for Provider Survey and Key Informant Interview*). This request is being made because the consent form, if collected, would require names to be collected and in doing so would be the only record linking the subjects name to the research.

Verbal consent will be obtained prior to start of the interview, but we will not collect any personal information or identifiers. No names of individuals will be recorded or appear in interview notes. Participants will be free to withdraw from the interview at any time without repercussions. Participants will be provided with an invitation including the elements of the written consent as well as contact information for the study PI. Verbal consent will be obtained from the key informants prior to beginning the interview (See *Verbal Consent Script for Key Informant Interview*).

H. Costs to the Subject

There are no costs to participate in this study. Any doctor visits and laboratory tests, including the HbA1c test, are part of standard of care.

I. Payment for Participation

Participants will a giftcard for their participation in the study. Participants may receive metro cards for travel associated with the project. In addition, small prizes such as pedometers may be raffled at educational sessions.

VII. APPENDIX

A. Recruitment Letter for CHW Intervention
B. Script for Telephone Screening for CHW Intervention
C. Bengali Script for Telephone Screening for CHW Intervention
D. Urdu Script for Telephone Screening for CHW Intervention
E. Telephone Screening Form for CHW Intervention
F. Action Plan
G. Progress Notes Form for CHW Intervention
H. One v. One Form
I. Patient Baseline Survey (English)
J. Patient Baseline Survey(Bengali)
K. 6 Month Followup Survey
L. Provider Survey(baseline and followup)
M. Key Informant Interview Guide(baseline and followup)
N. Telephone Consent for CHW Intervention
O. Telephone Consent for CHW Intervention Bengali
P. Telephone Consent for CHW Intervention Urdu
Q. Invitation and Elements of Informed Consent for Provider Survey
R. Invitation and Elements of Informed Consent Text for Key Informant Interview
S. Audio/Video Consent Form
T. Verbal Consent Script for Key Informant Interview
U. Application for Waiver of Authorization for Telephone Screening Form
V. Application for Waiver of Documentation of Consent for Provider Survey and Key Informant Interviews
W. Application for Waiver of Authorization Documentation of Consent
X. Encounter Report
Y. Key Information (Patients)
Z. Key Information Form (Patients) Bengali
AA. Key Information (Patients) Urdu
BB. Rapid COVID Assessment
CC. Rapid COVID Assessment – Repeating Form
DD. Mobile Phone Use
EE. Text Message Script
FF. Key Informant Interview Guide – CAB
GG. Key Informant Interview Guide – CHW
HH. Key Informant Interview Guide – Staff
II. Key Informant Interview Guide – Provider – Remote Intervention

References

1. *Program Sustainability Assessment Tool Project*, Center for Public Health Systems Science, Editor. 2013, Washington University in St. Louis: St. Louis.
2. Aarons, G.A., *Mental health provider attitudes toward adoption of evidence-based practice: the Evidence-Based Practice Attitude Scale (EBPAS).* Ment Health Serv Res, 2004. **6**(2): p. 61-74.
3. Aarons, G.A., et al., *Confirmatory factor analysis of the Evidence-Based Practice Attitude Scale in a geographically diverse sample of community mental health providers.* Adm Policy Ment Health, 2007. **34**(5): p. 465-9.
4. Adair, R., et al., *Improving chronic disease care by adding laypersons to the primary care team: a parallel randomized trial.* Ann Intern Med, 2013. **159**(3): p. 176-84.
5. Allen, C.G., et al., *Strategies to Improve the Integration of Community Health Workers Into Health Care Teams: "A Little Fish in a Big Pond".* Prev Chronic Dis, 2015. **12**: p. E154.
6. Ash, J.S., et al., *A Rapid Assessment Process for Clinical Informatics Interventions.* AMIA Annual Symposium Proceedings, 2008. **2008**: p. 26-30.
7. Ash, J.S., et al., *Clinical decision support in small community practice settings: a case study.* Journal of the American Medical Informatics Association : JAMIA, 2011. **18**(6): p. 879-882.
8. Asian American Federation, *Profile of New York City's Bangladeshi Americans: 2013 Edition*, in *Ethnic Profiles*. 2013.
9. Asian American Federation, *Profile of New York City's Indian Americans: 2013 Edition*. 2013.

10. Asian American Federation, *Profile of New York City's Pakistani Americans: 2013 Edition*. 2013.
11. Asian/Pacific American Heritage Month: May 2011. Profile American: Facts for Features. 2011. 2011; Available from: http://www.census.gov/newsroom/releases/archives/facts_for_features_special_editions/cb11-ff06.html.
12. ATLAS.ti. 2013, Scientific Sofware Development: Berlin.
13. Baptista, D.R., et al., *The chronic care model for type 2 diabetes: a systematic review.* Diabetology & metabolic syndrome, 2016. **8**(1): p. 7.
14. Baus, A., et al., *Registry-based Diabetes Risk Detection Schema for the Systematic Identification of Patients at Risk for Diabetes in West Virginia Primary Care Centers.* Perspectives in Health Information Management, 2013. **10**(Fall): p. 1f.
15. Becerra, M.B., N.L. Allen, and B.J. Becerra, *Food insecurity and low self-efficacy are associated with increased healthcare utilization among adults with type II diabetes mellitus.* Journal of Diabetes and its Complications, 2016. **30**(8): p. 1488-1493.
16. Blewett, L.A. and R.A. Owen, *Accountable Care for the Poor and Underserved: Minnesota's Hennepin Health Model.* American Journal of Public Health, 2015. **105**(4): p. 622-624.
17. Blumer, H., *Symbolic interactionism: Perspective and method*. 1986: Univ of California Press.
18. California Health Workforce Alliance, *Taking Innovation to Scale: Community Health Workers, Promotores, and the Triple Aim*. 2013.
19. Colby, S.L. and J.M. Ortman, *Projections of the Size and Composition of the U.S. Population: 2014 to 2060*, in *Current Population Reports*, U.S.C. Bureau, Editor. 2015: Washington D.C.
20. Collins, S.A., et al., *Clinical Workflow Observations to Identify Opportunities for Nurse, Physicians and Patients to Share a Patient-centered Plan of Care.* AMIA Annual Symposium Proceedings, 2014. **2014**: p. 414-423.
21. Community Prevention Services Task Force, *Diabetes Management: Team-Based Care for Patients with Type 2 Diabetes*. 2016, The Community Guide.
22. Community Prevention Services Task Force, *Diabetes Prevention and Control: Intensive Lifestyle Interventions for Patients with Type 2 Diabetes*. 2016, The Community Guide.
23. Dunkel-Schetter, C., S. Folkman, and R.S. Lazarus, *Correlates of social support receipt.* J Pers Soc Psychol, 1987. **53**(1): p. 71-80.
24. Fellows, J.L., et al., *Health and economic effects from linking bedside and outpatient tobacco cessation services for hospitalized smokers in two large hospitals: study protocol for a randomized controlled trial.* Trials, 2012. **13**: p. 129.
25. Gary, T.L., et al., *The effects of a nurse case manager and a community health worker team on diabetic control, emergency department visits, and hospitalizations among urban African Americans with type 2 diabetes mellitus: a randomized controlled trial.* Archives of internal medicine, 2009. **169**(19): p. 1788-1794.
26. Glasgow, R.E., T.M. Vogt, and S.M. Boles, *Evaluating the public health impact of health promotion interventions: the RE-AIM framework.* Am J Public Health, 1999. **89**(9): p. 1322-7.
27. Guide to Community Preventive Services, *Cardiovascular Disease Prevention and Control: Clinical Decision-Support Systems (CDSS)*. 2013.
28. Gupta, L.S., et al., *Prevalence of diabetes in New York City, 2002-2008: comparing foreign-born South Asians and other Asians with U.S.-born whites, blacks, and Hispanics.* Diabetes Care, 2011. **34**(8): p. 1791-3.

29. Handley, M.A., D. Schillinger, and S. Shiboski, *Quasi-experimental designs in practice-based research settings: design and implementation considerations.* J Am Board Fam Med, 2011. **24**(5): p. 589-96.
30. Hemming, K., et al., *The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting.* Bmj, 2015. **350**: p. h391.
31. Islam, N., et al. *Integration of Community Health Workers into Primary Care Health Systems: The Time for New York is Now!* . 2016.
32. Islam, N.S., et al., *Disparities in diabetes management in Asian Americans in New York City compared with other racial/ethnic minority groups.* American journal of public health, 2015. **105**(S3): p. S443-S446.
33. Islam, N.S., et al., *Diabetes and Associated Risk Factors Among Asian American Subgroups in New York City.* Diabetes Care, 2013. **36**(1): p. e5-e5.
34. Islam, N.S., et al., *Evaluation of a community health worker pilot intervention to improve diabetes management in Bangladeshi immigrants with type 2 diabetes in New York City.* Diabetes Educ, 2013. **39**(4): p. 478-93.
35. Kangovi, S., et al., *Patient-centered community health worker intervention to improve posthospital outcomes: a randomized clinical trial.* JAMA Intern Med, 2014. **174**(4): p. 535-43.
36. King, G.L., et al., *Understanding and addressing unique needs of diabetes in Asian Americans, native Hawaiians, and Pacific Islanders.* Diabetes Care, 2012. **35**(5): p. 1181-8.
37. Kruse, G.R., et al., *Implementation of an electronic health record-based care management system to improve tobacco treatment.* J Gen Intern Med, 2012. **27**(12): p. 1690-6.
38. Lee, J.W., F.L. Brancati, and H.C. Yeh, *Trends in the prevalence of type 2 diabetes in Asians versus whites: results from the United States National Health Interview Survey, 1997-2008.* Diabetes Care, 2011. **34**(2): p. 353-7.
39. Li, R., et al., *Organizational factors affecting the adoption of diabetes care management processes in physician organizations.* Diabetes Care, 2004. **27**(10): p. 2312-6.
40. Lin, J.J. and D.M. Mann, *Application of persuasion and health behavior theories for behavior change counseling: Design of the ADAPT (Avoiding Diabetes Thru Action Plan Targeting) program.* Patient education and counseling, 2012. **88**(3): p. 460-466.
41. Lindau, S.T., et al., *CommunityRx: A Population Health Improvement Innovation That Connects Clinics To Communities.* Health Affairs, 2016. **35**(11): p. 2020-2029.
42. Matiz, L.A., et al., *The impact of integrating community health workers into the patient-centered medical home.* J Prim Care Community Health, 2014. **5**(4): p. 271-4.
43. McMullen, C.K., et al., *Rapid Assessment of Clinical Information Systems in the Healthcare Setting: An Efficient Method for Time-Pressed Evaluation.* Methods of information in medicine, 2011. **50**(4): p. 299-307.
44. McNall, M. and P.G. Foster-Fishman, *Methods of Rapid Evaluation, Assessment, and Appraisal.* American Journal of Evaluation, 2007. **28**(2): p. 151-168.
45. Meigs, J.B., et al., *A controlled trial of web-based diabetes disease management: the MGH diabetes primary care improvement project.* Diabetes Care, 2003. **26**(3): p. 750-7.
46. Menke, A., et al., *Prevalence of and trends in diabetes among adults in the united states, 1988-2012.* JAMA, 2015. **314**(10): p. 1021-1029.
47. Montori, V.M., et al., *The impact of planned care and a diabetes electronic management system on community-based diabetes care: the Mayo Health System Diabetes Translation Project.* Diabetes Care, 2002. **25**(11): p. 1952-7.
48. National Community Voices Initiative at the Center for Primary Care at Morehouse School of Medicine and The Northern Manhattan Community Voices at the Columbia

University Center for Community Health Partnerships, *Financing Community Health Workers: Why and How* 2007.
49. NGSP Clinical Advisory Committee, *ADA 71st Scientific Sessions Meeting Minutes*. 2011.
50. O'Connor, P.J., et al., *Impact of electronic health record clinical decision support on diabetes care: a randomized trial.* Ann Fam Med, 2011. **9**(1): p. 12-21.
51. Palmas, W., et al., *Community health worker interventions to improve glycemic control in people with diabetes: a systematic review and meta-analysis.* Journal of General Internal Medicine, 2015. **30**(7): p. 1004-1012.
52. Pearlin, L.I., et al., *The stress process.* J Health Soc Behav, 1981. **22**(4): p. 337-56.
53. Persell, S.D., et al., *Electronic health record-based cardiac risk assessment and identification of unmet preventive needs.* Med Care, 2009. **47**(4): p. 418-24.
54. Persell, S.D., et al., *Electronic health record-based patient identification and individualized mailed outreach for primary cardiovascular disease prevention: a cluster randomized trial.* J Gen Intern Med, 2013. **28**(4): p. 554-60.
55. Program, N.Y.C.P.H.I., *A Strategy for Expanding and Improving the Impact of the Medical Home Across New York City*. 2016.
56. Promotion, N.C.f.C.D.P.a.H., *Behavioral Risk Factor Surveillance System Questionnaire*. 2017, Centers for Disease Control and Prevention.
57. Rajpathak, S.N., et al., *Elevated risk of type 2 diabetes and metabolic syndrome among Asians and south Asians: results from the 2004 New York City HANES.* Ethn Dis, 2010. **20**(3): p. 225-30.
58. Riley, L., et al., *Mixed-Methods Evaluation of a Randomized Control-Trial Community Health Worker Intervention to Improve Diabetes Management in the New York City Bangladeshi*, in *Paper presented at: 142nd Annual Meeting & Expo, American Public Health Association* 2014: New Orleans, LA.
59. Scott, T., et al., *The quantitative measurement of organizational culture in health care: a review of the available instruments.* Health Serv Res, 2003. **38**(3): p. 923-45.
60. Sherwani, S.I., et al., *Significance of HbA1c Test in Diagnosis and Prognosis of Diabetic Patients.* Biomarker Insights, 2016. **11**: p. 95-104.
61. Shih, M., et al., *Stemming the tide: rising diabetes prevalence and ethnic subgroup variation among Asians in Los Angeles County.* Prev Med, 2014. **63**: p. 90-5.
62. Shrout, P.E. and J.L. Fleiss, *Intraclass correlations: uses in assessing rater reliability.* Psychological bulletin, 1979. **86**(2): p. 420.
63. Sinai Urban Health Institute, *Best Practice Guidelines for Implementing and Evaluating Community Health Worker Programs in Health Care Settings*. 2014, Sinai Urban Health Institute,: Chicago, IL.
64. Stellefson, M., *The chronic care model and diabetes management in US primary care settings: a systematic review.* Preventing chronic disease, 2013. **10**.
65. Tung, E.L., et al., *Racial and Ethnic Disparities in Diabetes Screening between Asian Americans and Other Adults: BRFSS 2012–2014.* Journal of General Internal Medicine, 2016: p. 1-7.
66. U.S. Census Bureau. *American Fact Finder: 2011 American Community Survey 5 Year Estimates, Selected Characteristics of the Native and Foreign-Born Populations (S0501)*. 2015 [cited 2017 5/1/17]; Available from: https://factfinder.census.gov.
67. U.S. Census Bureau. *Profile of general demographic characteristics: 2000 supplementary survey summary tables. Geographic area: United States*. 2004; Available from: www.factfinder.com.
68. Unertl, K.M., et al., *Traversing the many paths of workflow research: developing a conceptual framework of workflow terminology through a systematic literature review.* J Am Med Inform Assoc, 2010. **17**(3): p. 265-73.

69. Vandelanotte, C. and I. De Bourdeaudhuij, *Acceptability and feasibility of a computer-tailored physical activity intervention using stages of change: project FAITH.* Health Educ Res, 2003. **18**(3): p. 304-17.
70. Walker, R.J., B.L. Smalls, and L.E. Egede, *Social determinants of health in adults with type 2 diabetes—Contribution of mutable and immutable factors.* Diabetes Research and Clinical Practice, 2015. **110**(2): p. 193-201.
71. Walton, J.W., et al., *Reducing diabetes disparities through the implementation of a community health worker-led diabetes self-management education program.* Fam Community Health, 2012. **35**(2): p. 161-71.
72. Ye, J., et al., *Cardiovascular risk factors among Asian Americans: results from a National Health Survey.* Ann Epidemiol, 2009. **19**(10): p. 718-23.
73. Zahn, D., et al., *Making the Connection: The Role of Community Health Workers in Health Homes*, Health Management Associates, Editor. 2012.
74. Zimet G. D., D.N.W., Farley G. K. , *The Multidimensional Scale of Percieved Social Support.* Journal of Personality Assessment, 1988. **52**: p. 30-41.