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I. PURPOSE OF THE STUDY AND BACKGROUND

A. Purpose of the Study

The proposed study "Integrated Community-Clinical Linkage Model to Promote Weight Loss among South Asians with Pre-Diabetes" aims to test the effectiveness and assess the implementation process of an integrated intervention to support weight loss for South Asian patients at-risk for type-2 diabetes mellitus (T2DM) in primary care settings. The primary outcome is ≥5% weight loss among South Asian patients at-risk for T2DM. The integrated intervention involves:

1. An electronic health record (EHR) intervention for primary care providers (PCPs) utilizing embedded alerts to increase screening and identification of South Asian patients at-risk for T2DM with BMI >23 kg/m^2 and registries to track outcomes: and
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 PCPs enrolling 1040 South Asian patients at- risk for T2DM.

In addition, using a mixed-methods approach and the RE-AIM evaluation framework[23], 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:

3. 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.
4. Key Informant Interviews (n=100) with physician champions at each site and/or administrator of each site, 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 sites and insurer organizations.

Impact: The proposed study will inform efforts to prevent diabetes and promote weight loss in a high-risk population and generate a reproducible, scalable, and sustainable model for use with other insurer groups and clinical settings that work in immigrant 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 in the U.S. and NYC are a rapidly growing population. Asian Americans currently comprise 5% of the U.S. population and make up approximately 40% of the immigrants entering the country.[24] By 2050, the number of Asian Americans nationally is projected to grow to over 43 million.[25] In this proposal, we focus on the *South Asian community,* who are among the largest and fastest growing Asian subgroups in the U.S. and NYC. South Asian Americans are comprised of individuals from India, Bangladesh, Pakistan, Sri Lanka, Nepal, and Bhutan.[26-28] The NYC South Asian community grew by 49% during the years 2000 to 2010, from 216,179 to 323,675.(Asian American Federation, 2013a, 2013b, 2013c) Though there is substantial diversity in the socio-economic profile of South Asians across various subgroups, a significant portion of South Asians live in poverty (ranging from 17% of Asian Indians to 32% of Bangladeshis), have limited English proficiency (ranging from 25% of Asian Indians to 53% of Bangladeshis), and have access to fewer culturally appropriate community resources.[24] 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. Diabetes & Pre-Diabetes is significantly higher among South Asians compared with Non-Hispanic Whites. Among Asian Indians in the U.S., cardiovascular disease (CVD) is the leading cause of death, and mortality due to T2DM has been increasing over time.[29] Rates of T2DM and pre-diabetes in the U.S. South Asian community are high, with national data revealing the highest prevalence of diagnosed diabetes among Asian Indians compared to other Asian groups[16] and compared to Non-Hispanic whites.[5,6] In NYC, both population-based self-report and clinically measured rates of T2DM are high among South Asians. Rajpathak and colleagues report that foreign-born South Asians have a significantly higher prevalence of T2DM (35.4% vs 10.8%) compared to Whites, and had five times the odds of having T2DM compared to whites after adjustment for demographics and other potential confounders (AOR: 4.88, 95% CI (1.52, 15.66)).[30] Similarly Gupta et al found that prevalence of self-reported diabetes diagnosis among South Asians of normal weight (using adjusted-BMI guidelines for Asians) in NYC were more than triple the rates of diabetes among Whites of normal weight (10.2% vs 2.9%, respectively).[31] Estimates of clinically measured pre-diabetes in population-based studies and large community-based cohorts of South Asians in the U.S. have ranged between 16% to high as 33%.[30,32] Thus*, scalable and translatable interventions that promote the early identification and prevention of diabetes in this population have significant potential for public health impact.*

B3. South Asians develop diabetes at a lower BMI compared to other group. South Asians report some of the highest BMI levels compared to other Asian groups and other minority/ethnic groups,[33-39] ranging from 27% to 89% higher than the national average.[34] A recent analysis of National Health & Nutrition Examination Survey (NHANES) data revealed that the average BMI for all Asian Americans surveyed was ≤ 25 kg/m^2, and yet they had the highest proportion of undiagnosed T2DM among all ethnic and racial subgroups surveyed.[13] Due to these differences, in 2014 the American Diabetes Association (ADA) recommended lowering BMI cutoff points to ≥ 23 kg/m^2 for testing for T2DM in Asian American adults, including South Asians.[14,40] Lowering BMI cutoff points as advised by the ADA could result in earlier identification of pre-diabetes and T2DM in Asian Americans, leading to improved primary and secondary prevention in these communities.[21] *However, ADA recommendations have not been formally adopted in clinical settings for T2DM screening purposes despite compelling evidence for Asian American populations.[12,14,41]*

B4. Diabetes Prevention Program (DPP) is effective in in reducing incident diabetes in South Asians by achieving modest weight loss through behavior change. Results from the U.S. Diabetes Prevention Program (DPP) indicated that modest weight loss through dietary changes and increased physical activity significantly reduced the incidence of T2DM in study participants.[42] The Indian Diabetes Prevention Programme, modeled after the U.S. DPP, found that study participants who had modest weight loss ($\leq$5%) were more likely to achieve normal fasting glucose at 6 and 24-month follow-up, which was associated with a 75% lower risk of developing incident T2DM after 2 years. Similarly, weight loss interventions conducted among South Asian immigrants in the United Kingdom and US have reported lower rates of developing incident T2DM and lower rates of insulin resistance.[43,44] Though there have been few adaptations of DPP for the South Asian community, existing studies have demonstrated DPP's efficacy in increasing weight loss, diabetes knowledge, and positive behavioral changes such as healthful eating and/or engaging in physical activity.[22,44,45] Our own work has tested the efficacy, feasibility, and acceptability of a cultural adaption of DPP for Bangladeshis and Asian Indians, demonstrating significant weight loss and behavior change among study participants.[46]

B5. DPP adaptations have utilized Community Health Workers (CHWs) for program delivery. Numerous studies have adapted and translated the DPP to different settings and contexts, with specific efforts to tailor program delivery for varied racial and ethnic groups.[20,47,48] Many of these programs have adapted the original DPP structure and length, and have utilized CHWs or peer educators. These studies are typically less expensive and/or more feasible to administer in community-based settings[49-52] and some studies have demonstrated health improvement similar to the original DPP.[53] Our cultural adaptation of

DPP for South Asians also utilized and demonstrated high acceptability of the CHW model, *lending support to the concept of adapting DPP to be delivered by CHWs for this population*.

B6. Incorporating CHWs into clinical teams can improve patient health outcomes. The importance of CHWs in improving health outcomes for underserved communities has long been recognized by federal agencies and organizations,[54-56] and by the Patient Protection and Affordable Care Act,[57] in which CHWs have been identified as important members of the health care workforce.[57] By acting as bridges between the community and health care system, CHWs have the potential to address health disparities and disseminate efficacious interventions to underserved communities. With the advent of the patient-centered medical home model, primary care practices increasingly aim to work in an integrated manner to coordinate care for a patient.[58] There is a significant evidence base demonstrating the addition of CHWs to the primary care team can improve care for patients with chronic disease at low cost.[59-61] There have been recent efforts to reimburse clinical settings for referral of pre-diabetic patients to YMCA-led DPP programs[62,63]; *thus, the delivery of diabetes prevention by CHWs in clinical settings, coupled with reimbursement opportunities for this workforce, offers a unique opportunity for sustainable, scalable models for prevention.*

B7. Electronic health records (EHRs) can improve primary and secondary prevention of diabetes. The US Preventive Services Taskforce (USPSTF) recommends screening adults in primary care settings with known risk factors T2DM, including high-risk racial and ethnic minority populations.[64] Data available through EHRs can be used to identify candidates for needed follow-up[65], targeted risk-reducing interventions[66-68] and can be designed to allow primary care physicians (PCPs) to easily refer patients to counseling and other services.[69,70] 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.[71-73] EHRs can also assist providers in counseling patients through EHR-based goal-setting modules, intention exercises, and tailored reminders to encourage behavior change during clinical encounters with appropriate patients.[74] There have also been recent efforts to utilize EHRs to identify and refer patients to community-based diabetes prevention programs, though none in small primary care settings that target high-risk immigrant communities.[75-77] *The proposed project will build on this evidence-base by implementing EHR interventions to identify patients at-risk for T2DM using ADA adjusted BMI guidelines, and link them to CHW-led coaching to achieve weight loss.*

B8. The effect of integrating EHR and CHW interventions has not been well-tested. Despite the tremendous potential that both CHW and EHR-based interventions can have on improving health outcomes in minority communities, there have been few studies that have examined the impact of integrating the two interventions, and how best to engage both physician and non-physician members of the healthcare team, including CHWs,[66] in effectively integrating EHR-based interventions into care planning. Studies are now beginning to demonstrate 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, and no studies have been conducted in small primary care settings.[78-80] *However, scalable and sustainable models that assess the cost, adoption, and maintenance process of integrating EHR and CHW intervention in clinical practice settings are needed.*

Contributions

The goal of this study is to test the effectiveness and assess the implementation process of an multi-level, integrated intervention to promote weight loss among South Asians at risk of T2DM, including two components: an EHR-based alert and registry function to increase identification of South Asian patients who are at-risk of diabetes, and CHW-led health coaching of registered patients with pre-diabetes to increase weight loss. This study is innovative in four main areas. First, the proposed intervention will foster the uptake and adoption of an evidence-based ADA recommendation for diabetes screening at lower BMI[14] into clinical practice using HIT strategies (an alert and registry function) to enhance identification of pre-diabetes among South Asians, offering a scalable and replicable model to decrease disparities in a community with a high diabetes burden. Because the revised guidelines have not been systematically integrated into clinical practice, the implementation and testing of the proposed HIT

strategies represents an innovation of our project. Second, this is the first study to examine integration of a multi-level approach that combines EHR based tools to identify high risk patients, culturally adapted CHW-led coaching, and CHW-physician feedback to increase diabetes prevention in a high risk community. Though a limited number of studies have integrated EHR-CHW approaches and conducted referral to DPP programs, our study would represent the first to implement such a multi-level approach in small primary care practice settings in a high risk immigrant community. Our study uniquely assesses both effectiveness outcomes and implementation processes, thus informing the replication of integrated models in other primary care settings. Third, our culturally adapted DPP model has demonstrated efficacy, feasibility, and acceptability among South Asians at-risk for T2DM in community settings, and the proposed study offers a replicable model for clinical settings. Fourth, the project informs both the effectiveness and calculates costs of these interventions in team-based care approaches, thereby helping to develop potentially reimbursable and relevant sustainability strategies. Finally, given our partnership with a large payer organization and local health department, best practices for implementation of integrated EHR-CHW models at clinical sites will be generated that may be scalable to other insurer organizations and healthcare systems working with large immigrant populations facing a significant burden of chronic disease.

C. Study Design

C1. Overall Design/Site Selection/Site Enrollment

We will use a randomized controlled trial design with staggered-entry and a waitlist controlled group to compare the effectiveness of an alert and registry-driven CHW-led coaching compared with usual care among patients with BMI at baseline of $\geq$23 kg/m^2. Randomization will be at the individual-level and stratified by PCP, meaning eligible intervention 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 2 (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: 1 month for recruitment and enrollment of intervention 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 three times (baseline, 6 month, and 12 month) for each PCP. Randomization at each PCP will occur during the first round. Prior to allocation into treatment group, each treatment participant will be matched to a control participant based on age, gender, and BMI. Intervention 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. 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$\geq$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.

Figure 1. Recruitment, Enrollment, and CHW Intervention Timeline

Participant Accrual Projections	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		
Wave 1				**Round 1**			**Round 2**											
PCP1			Recruit/ Enroll N=48	CHW intervention			CHW intervention											
PCP2			Recruit/ Enroll N=48	CHW intervention			CHW intervention											
PCP3			Recruit/ Enroll N=48	CHW intervention			CHW intervention											
PCP4	PCP Recruitment		Recruit/ Enroll N=48	CHW intervention			CHW intervention										336 out of 960 target participants = **35%**	35%
PCP5			Recruit/ Enroll N=48	CHW intervention			CHW intervention											
PCP6			Recruit/ Enroll N=48	CHW intervention			CHW intervention											
PCP7			Recruit/ Enroll N=48	CHW intervention			CHW intervention											
Wave 2								**Round 1**		**Round 2**								
PCP8							Recruit/ Enroll N=48	CHW intervention		CHW intervention								
PCP9							Recruit/ Enroll N=48	CHW intervention		CHW intervention								
PCP10							Recruit/ Enroll N=48	CHW intervention		CHW intervention							288 out of 960 target participants = **30%**	65%
PCP11							Recruit/ Enroll N=48	CHW intervention		CHW intervention								
PCP12							Recruit/ Enroll N=48	CHW intervention		CHW intervention								
PCP13							Recruit/ Enroll N=48	CHW intervention		CHW intervention								
Wave 3												**Round 1**		**Round 2**				
PCP14											Recruit/ Enroll N=48	CHW intervention		CHW intervention				
PCP15											Recruit/ Enroll N=48	CHW intervention		CHW intervention				
PCP16											Recruit/ Enroll N=48	CHW intervention		CHW intervention				
PCP17											Recruit/ Enroll N=48	CHW intervention		CHW intervention		Analysis & Dissemination	366 out of 960 target participants = **35%**	100%
PCP18											Recruit/ Enroll N=48	CHW intervention		CHW intervention				
PCP19											Recruit/ Enroll N=48	CHW intervention		CHW intervention				
PCP20											Recruit/ Enroll N=48	CHW intervention		CHW intervention				

C2. EHR-CHW Intervention

The implementation and content of EHR and CHW components of the intervention at each PCP align with the Chronic Care Model.

EHR Components: The EHR component of the integrated EHR-CHW intervention will include: 1) An alert to identify South Asian patients with elevated BMI ($\geq$23 kg/m^2) and recommendation to PCPs to order an HbA1c test as part of standard of care; and 2) Generation of registry lists of individuals with A1C 5.7-6.4% (individuals with incident pre-diabetes). Building upon existing protocols the study team will coordinate the implementation of the proposed EHR modifications at each PCP. 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,[93-98] baseline workflow analysis will be conducted at each PCP. 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 PCP.

Implementation of System Requirements for the Intervention. System requirement definition and implementation ensures that various EHR systems across PCPs are configured to provide the functionality called for by the study design. The research team will work with a PCIP specialist 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 PCP, 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 eligibility criteria will be drawn from registry lists and randomized to intervention or waitlisted control. Patients assigned to the intervention 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 invite them to enroll into the study. Patients assigned to the waitlisted control group will be recruited and contacted in the same manner as intervention participants except after completion of intervention rounds.

Consenting and data collection with Intervention participants

Consent forms will be completed with intervention participants in an in-person meeting. Baseline surveys will also be conducted by NYU study staff with intervention participants within two weeks after consent. (See *CHW Participant Baseline Survey*). A CHW Participant Followup 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.

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 conditions and mental health was affected in during the pandemic and to understand how best to tailor remote intervention strategies to encourage vaccination among patients with overweight and pre-diabetes who are at higher risk for complications from COVID-19.

The CHW intervention includes a protocol that consists of 5 monthly 90-minute group health education sessions, providing the tools and strategies to prevent 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 in remotely via audio phone calls via telephone, MCIT NYU approved Webex and Zoom platform or in community spaces identified by partner agencies, and multiple sessions will be held weekly to accommodate patient's varying schedules. Links to the health education sessions will be created via NYU approved Webex and Zoom platforms that are provided for use across the institution. These NYU Webex and Zoom links will be shared to participants via text message through NYU MCIT secured phones(see Text Message Script). The study team has developed training materials on how to use the NYU Webex and Zoom platforms to provide to research participants. Use of the Zoom will be used solely for the purpose of delivering the health education materials and will not involve discussion of PHI. In order to maintain anonymity for Zoom, for each session, the study staff will create Zoom waiting rooms for participants to be renamed as "Participant 1, Participant 2, etc.) prior to individuals joining the larger session with other research participants.

In addition to these 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 Action Plan, *Progress Note Form for CHW Intervention*). In addition to phone calls, CHWs will also contact patients via a secure NYULMC phone through text messages to communicate study activities(see Text Message Scipt). 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.). 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 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 throughout the intervention to encourage ongoing attendance, and incentives will be distributed at program completion for individuals who attended all 5 sessions.

Consenting and data collection with waitlisted control participants

For control participants, the study will collect EHR data on clinical measures only that will be linked to a unique identifier housed at the primary care practices; there will be no survey data collection with control participants. In other words, the study will not be evaluating changes in study outcomes via non-EHR data among waitlisted control participants who receive the CHW intervention. For these reasons, we are requesting a waiver of authorization (see *Section IVb Process of Consent*). After completion of Round 1 intervention with intervention participants, CHWs will call contact waitlisted control participants regarding the group education sessions. Control participants will be offered the same content and dosage of education sessions.

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 (See *Provider Survey and Provider Survey – Follow-up*). The follow up provider survey will also include additional 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 overweight and pre-diabetes who are at higher risk for complications from COVID-19)
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: "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. Provider Surveys will be administered via online survey software or paper copy if requested. Surveys will take approximately 15 minutes to complete.

C5. Key Informant Interviews
Qualitative key informant interviews will be conducted with physician champions at each site and/or administrator of each site, Healthfirst representatives, community advisrory board members, study 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 interviews 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 overweight and pre-diabetes who are at higher risk for complications from COVID-19 (See Key Informant *Interview Guide - provider – remote intervention*). A member of the NYU study team will conduct the interviews. Questions will be adapted from existing validated measures on acceptability, feasibility, adoption, organizational culture, and scalability.[105-110] 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 1220.
This includes a total of 1040 participants in the EHR-CHW Intervention, 80 subjects who participate in the surveys and 100 particpants in the key informant interviews.

CHW Intervention
Inclusion Criteria: Participants will be eligible for study participation if they meet the following criteria: a) self identify as South Asian; 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) have a BMI of ≥23; and e) have incident pre-diabetes as determined by HbA1c test (last A1c test date in the last 12 months).

Exclusion Criteria: Patients under the age of 21 and older than 75 will be excluded. Individuals with a diagnosis of diabetes or pre-diabetes during the 12 months prior to intervention implementation will be excluded. Pregnant women and all visits with an obstetrician gynecologist are excluded.

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

Provider Assessment Surveys
The 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: participants who are unable to complete the survey in the English language.

Key Informant Interviews
The inclusion criteria for the interviews are as follows: adult (18 years and over); must be a provider, clinic manager, Healthfisrt staff, community advisory board member, study 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

PCP Enrollment
Practices that express interest in participating in the 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 elevated BMI (≥23 kg/m^2) and recommendation to order an HbA1c test
- Generation of registry lists of individuals with A1C 5.7-6.4% (individuals with incident pre-diabetes).
- 5 group-based health education sessions on diabetes prevention
- Provision of culturally and linguistically tailored health information and resources
- Up to 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.[78-80]
    - 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 site-specific and guided by input from the provider and workflow analysis findings in order to avoid provider burn-out.

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 • Prevention of diabetes • Myths and Facts about diabetes • Goal-setting	· Concept of prevention tied to South Asian core values (in religion/culture) · 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
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	· Discussion of physical activity as essential to physical and mental fitness (eg. encouragement to practice similar discipline in physical activity as in prayer)

balance • Benefits and types of exercise • Injury prevention • Incorporating routines • Overcoming barriers • Practice activity and goal-setting	· Home-based exercise/activities · Practice Activity · Incorporation of culturally appropriate images and language
Session 4: Diabetes Management and Complications • Diabetes complications • Heart disease and stroke • Staying motivated and goal-setting · 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 South Asian foods high in salt and fat and limiting these foods · Incorporation of culturally appropriate images/language
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 PCPs' EHR systems by an NYU staff member every 6 months. De-identified EHR data will be collected from both intervention and control participants. The process for collecting de-identified patient data is described here: This will entail NYU study 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, unique study identifiers will be assigned to 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 will be kept at each PCP 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, laboratory dates, and Alc readings.

Follow-up height and weight 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.

Extracted de-identified data on patients include the following::

i. De-identified EHR data will include the following:
   - Practice site 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: A1c, lipid profile during the study period, Month and year of measurement
   - All BP measurements (systolic and diastolic) during the study period, Month and year of measurement
   - Dates of clinic visits

De-identified claims data obtained from the Healthfirst data warehouse to be provided to the study team includes:

- All hospital admissions and ED visits during the intervention period (Study ID, Bill type, Encounter type, Admission Month/Year, Length of stay, DRG, Primary ICD 9/10 diagnosis code, Secondary diagnosis codes, if available, ICD 9/10 procedure codes, Attending physician specialty, Allowed Amount, Discharge status, Admit type, Admit source)
- Pharmacy claims (Study ID, Drug generic names, Drug class, Dates of Fill (month/year only), Total Drug Cost Amount
- Outpatient claims (Study ID, Primary ICD 9/10 diagnosis code, Secondary diagnosis codes (up to 5), if available, ICD 9/10 procedure codes, Allowed Amount, Month/year of claim, Physician specialty)
- Lab claims (Study ID, Allowed amount, Month/year of claim, Type of test)

B. Data Analysis and Data Monitoring

B1. Aim 1 Analysis

AIM 1: To compare the effect of the EHR/CHW intervention with usual care on weight loss. The primary outcome will be probability of eligible patients at a PCP to lose 5% or more of their body weight six months following the index office visit.

Secondary outcomes include: Average reduction in HbA1c, % sustained >5% weight loss at 12 months; improved lipids and blood pressure 6- and 12- months following the index office visit.

Hypothesis: Individuals receiving care during the implementation of the EHR/CHW intervention will be more likely to lose 5% of their body weight six months following the index office visit than individuals receiving care as usual. This will translate directly to a commensurate increase in the proportion of the study sample under the EHR/CHW intervention losing 5% of their body weight relative to the care as usual group.

The analysis of the effect of EHR/CHW on the outcome measure will be based on 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} site at time quarter t loses 5% or more her body weight six months following the index visit, $Y_{ijt} = 0$ otherwise. α_j is a random effect for site j with mean 0 and variance σ_b^2. θ_t is a time-specific effect a quarter t, $t \in (1, 2,...,12)$. C_i is an indicator variable, and $C_i = 1$ 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 $\alpha = .05$. 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 intent-to-treat protocol.

Power Calculation:

We conservatively estimate an 8% difference in effect size (i.e., >5% weight loss) comparing intervention and control group participants. Accrual of 1040 participants, evenly randomized to intervention or control groups, provide greater than 80% power to detect this difference, using a 2-sided, 0.05-level test (i.e., 52 participants (26 Intervention and 26 control participants per PCP). These calculations assume 15% loss to follow-up and enrollment of 20 PCP sites.

Sampling: Preliminary data from our practice needs assessment indicates that approximately 444 unique patients for every six months will have an office visit. Based on population estimates,[21,30] we estimate that 29% of those individuals will be ineligible due to a pre-study period T2DM or pre-diabetes diagnosis (n=129) and approximately 69% of remaining patients will have a BMI ≥23 kg/m2, making them eligible for the study (n=217). In our ongoing T2DM management CHW intervention among South Asians, screening to enrollment rate is 41%.[111] For this study, we apply a conservative estimate that 30% of patients will consent to be contacted by a CHW and receive an HbA1c test (n=65). Based on populations estimate[17], we anticipate that 43% of those individuals will have pre-diabetes (n=28). Based on retention rates from our CHW studies,[22,46,84] we conservatively estimate that approximately 85% of individuals assigned to a CHW will be followed up at six months (n=24). Thus, for each PCP, we will enroll approximately 24 patients every six months over a period of one year, resulting in total recruitment of 960 across 20 PCPs. This equates to an approximate CHW caseload of 13 patients per month for a part-time CHW, consistent with caseloads from our previous studies.[22,83]

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 PCPs as well as an estimate of the percentage of adoption in terms of patient visits for HbA1c screening. 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 testing of pre-diabetes at BMI ≥23 kg/m2? 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 prevention and weight loss?

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.[112] 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.[112] 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).[113] The coded transcripts will be analyzed with *Atlas.ti*, a software package for qualitative data analysis.[114] Analysis will be conducted to inform best practices for scalability that can be replicated by payer organizations and health care systems.

4. Cost-Effectiveness/Sustainability: What were the costs of the integrated intervention to the insurer organizations and physician practice and did these additional costs provide added value at patient and provider levels? What were the net costs and benefits of different combinations of CHW and EHR interventions?

Using average resource utilization and costs per patient (in first 6 and 12 months of follow-up), we will compare resources incurred by the trial arms during the follow-up period at each time point. Our outcome will be the incremental cost per person achieving 5% weight loss. Cost data will be used to inform HF leadership of program costs for consideration of sustainability of CHW models by payer organizations.

Provider Survey

The data will be tabulated and summarized descriptively to address research questions and to assess change in attitudes from baseline to 12 months. All quantitative data will be entered and analyzed in SPSS.

Key Informant Interviews

Interview data will be transcribed and analysis transcribed data will follow "constant comparison" analytic approach.[112] 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.[112] 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).[113] The coded transcripts will be analyzed with *Atlas.ti*, a software package for qualitative data analysis.[114] 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.

Intervention 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. On the baseline and follow-up surveys, the first page of the survey will ask 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 alldata will be housed on a secure MCTI managed network drives. Pages containing participants name and contacts information and logs linking subjects' identifying information to study numbers will be kept locked in in a subject file per IRB regulation in a 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-recordings and interview transcripts 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 Principal 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 NCT03188094

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 audiotapes. All interviews will be stored 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 preventing 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.

Donna Shelley, MD will serve as a co-investigator on this study. Her research has focused in the areas of implementation science with a specific focus on studying health care system change to improve the quality of tobacco use treatment across a wide range of health care settings and developing efficacious cessation treatments for underserved populations, including smokers with comorbid conditions. She was recently awarded an AHRQ grant that is part of the AHRQ EvidenceNOW initiative, to recruit 250 small primary care sites to study the effectiveness of practice facilitation on increasing adoption of Million Hearts guidelines for optimizing cardiovascular health. She will provide her experience and expertise in implementation research in clinical and other physician settings.

Heather Gold, PhD will serve as co-investigator and will implement the cost analysis component of the study. Specifically, she will oversee the development of cost-related data collection tools and databases, and oversee the analysis of claims and programmatic cost data. Dr. Gold is an expert in cost-effectiveness analysis and costing out comparative behavioral interventions, particularly with respect to chronic diseases.

Keith Goldfeld, DrPH is a biostatistician interested in health services research, cluster randomized trials, and causal inference for secondary data analysis. He will serve as co-investigator and will provide his biostatistical expertise.

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.

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.

Jennifer Zanowiak, MA is the Program Supervisor 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.

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 inPunjabi 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 Collaborators

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 recruitment and dissemination of education material.

Phoebe Laughlin, MS is the Healthfirst Program Coordinator for this study. She will be responsible for extracting individual level Healthfirst data from physician EMR systems and relationship management with the physician practices.

Hang Pham-Sanger, Pharm.D. will participate in the training and intervention implementation of the study activities. She will also manage the quality improvement team who assists practices in establishing standard and consistent processes to promote chronic disease care management. She is the Director of Quality Improvement within the Primary Care Information Project (PCIP) at the New York City Department of Health and Mental Hygiene.

VI. SUBJECT IDENTIFICATION, RECRUITMENT, AND CONSENT/ASSENT

A. Method of Subject Identification and Recruitment

CHW Intervention
Patients that meet eligibility criteria will be drawn from registry lists and randomized to intervention or waitlisted control. Patients assigned to the intervention group will be sent an invitation letter and recruitment flyer (See *Recruitment Letter for CHW Intervention and Recruitment Flyer*) to participate in the CHW intervention. Invitation letters and recruitment flyers 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 informant 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. Patients assigned to the waitlisted control group will be recruited and contacted in the same manner as intervention participants after completion of intervention rounds. CHWs will call waitlisted control patients a maximum of two times over a one-week period.

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 advisrory board members, study 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 NYU IRB Mandatory Tutorial and IRB HIPAA Training before commencing any data collection 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 and HIPAA authorization will be obtained via telephone from participants(see Waiver of Authorization and Documentation of Consent and Telephone Script Form, Consent Brochure for CHW Intervention). The CHW will review all the elements of informed consent over this call using the Telephone Consent Script to introduce the study and then going over the Consent Brochure in detail to review all elements of consent. (see Telephone Script Form and Consent Brochure) The Consent Brochure will be mailed to the study participant.

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; 3) social-distancing contraints at PCP offices where health education sessions were previously being conducted.

CHW Intervention Paticipants

All potential intervention 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.

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. Informed consent, HIPAA authorization and signatures will be obtained.

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.

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).

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

F. Consent Forms. Please refer to consent forms: *Consent Brochure/Signature Page for CHW Intervention and,Telephone Script,* and *Invitation and Elements of Consent* and *Verbal Consent Script* documents for the Provider Survey and Key Informant Interviews.

The subject will receive a mailed copy of the Consent Brochure/Signature Page. A translated verbal informed consent will be used for non-English speaking subjects, depending on their preferred language(upon approval of the Waivier of Authorization and Documentation of Consent, translated documents will be included in a subsequent modification).

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.

G. Documentation of Consent

Intervention Participants

Study staff will obtain consent and HIPAA authorization by reading the verbal informed consent script to the subject to introduce the study and will then proceed to obtain verbal consent by reviewing the Consent Brochure with the participoant. The participant will be given adequate opportunity to review and clarify questions before verbally consenting. The subject will receive a mailed copy of the Consent Brochure. A translated verbal Telephone script will be used for non-English speaking subjects, depending on their preferred language(upon approval of the *Waiver of Authorization and Documentation of Consent*, translated doucments will be uploaded via a subsequent modification).

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.

Patient survey data will be collected at baseline and at 6-months follow-up to evaluate the effectiveness of the CHW intervention. 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 intervention 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 study will only collect EHR data from control participants and will not collect survey data or claims data. A Waiver of Authorization is being requested for EHR data collected from control participants (see *Application for Waiver of Authorization for Consent Participant EHR data*). Without the requested waiver, the study could not be practically carried out and would adversely affect the scientific rigor of the study. Although control participants will be offered the full CHW intervention at a later time point (i.e., waitlist control), experience from similar studies have shown that recruitment and retention of control participants would dramatically increase the CHW caseload. The study is only collecting clinical outcomes from control participants through the EHR and this data will be de-identified. All variables for extraction will be pre-approved by all participating PCPs. MOUs between PCPs and NYU will explicitly outline the process of de-identification of the data and the list of variables for extraction.

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 not receive payment for participation in this 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. Additionally, participants that complete all five educational sessions will be eligible for a raffle cash prize to be given after each six month study period.

VII. APPENDIX

A. Recruitment Letter for CHW Intervention
B. Recruitment Flyer
C. Script for Telephone Screening for CHW Intervention
D. Telephone Screening Form for CHW Intervention
E. Action Plan for CHW Intervention
F. Progress Notes Form 1 for CHW Intervention
G. Progress Note Form for CHW Intervention Additonal Followup
H. CHW Participant Baseline Survey
I. CHW Participant Followup Survey
J. Enrollment Update Letter to Provider
K. Provider Survey
L. Key Informant Interview Guide
M. Consent Brochure and Consent Signature Page for CHW Intervention
N. Telephone Consent Script
O. Invitation and Elements of Informed Consent for Provider Survey
P. Invitation and Elements of Informed Consent Text for Key Informant Interview
Q. Verbal Consent Script for Key Informant Interview
R. Application of Waiver of Authorization for Control ParticipantsApplication for Waiver of Authorization for Telephone Screening Form
S. Application for Waiver of Documentation of Consent for Provider Survey and Key Informant Interview
T. Encounter Report
U. Rapid COVID Assessment
V. Rapid COVID Assessment – Repeating Form
W. Application for Waiver of Authorization and Documentation of Consent CHW Intervention
X. Text Message Script

Y. Key Informant Interview Guide – CAB
Z. Key Informant Interview Guide – CHW
AA. Key Informant Interview Guide – Staff
BB. Key Informant Interview Guide – Provider – Remote Intervention
CC.

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