Study Title: Scaling Telehealth Models to Improve Co-morbid Diabetes and Hypertension in Immigrant Populations

I. BACKGROUND AND SCIENTIFIC RATIONAL

A. Background

A1. Hypertension (HTN) and diabetes co-morbidity represents a significant public health concern, particularly among South Asian communities. Over two-thirds of United States (US) adults with diabetes have HTN, and half are not meeting blood pressure (BP) goals despite having antihypertensive treatment.[14] HTN is associated with a two times greater risk for cardiovascular disease (CVD) events and mortality among adults with diabetes.[15] Diabetes disparities are pronounced among South Asians. National studies indicate US South Asians have the highest age-adjusted prevalence of diabetes (23%) compared to whites (6%), Chinese Americans (13%), Latinos (17%), and African Americans (18%).[16] Further, among South Asians with diabetes, 72% also have co-morbid hypertension.[9]

A2. South Asians are a rapidly growing population across the US.
Asian Americans currently compose 5% of the US population and approximately 32% of the immigrants entering the country.[17] 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.[18,19] In (New York City) 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 from25% of Asian Indians to 53% of Bangladeshis), and have poor access to culturally appropriate community resources.[20-23] Similar expansive growth has been experienced among South Asians in areas of the Southeastern US, including Atlanta, Georgia. The Atlanta metropolitan area has the 10th largest South Asian population in the US, with an estimated 105,000 South Asians living in or around Atlanta in 2015.[24] South Asians make up the largest Asian population and the second largest immigrant group in Atlanta.[25] The South Asian community in Atlanta is concentrated in the northern suburban areas of Gwinnet, Fulton, and Dekalb counties (>100,000 in the Atlanta area identify as Asian Indian).26,27 However these are likely underestimated, given there is no specific data on other South Asian groups, for example, those from Bangladesh or Pakistan.

A3. The Southeastern region of the US faces disproportionate disparities in risk factors, and the racial/ethnic make-up of disparities is complex. The stroke belt, comprised of eight southeastern states (**Figure 1**), is defined by its disproportionately high and persistent stroke mortality rates despite overall decreases in stroke mortality.28 Stroke is more frequent in non-Hispanic blacks (OR 1.4, 95% CI 1.1–1.7) compared to non-Hispanic whites.[29]

Though stroke belt disparities are characterized as differences between black and white populations, persistent problems in the collection, reporting, and analysis of data in other minority communities may mask a more complex experience of disparities in this region.[30,31] This issue is particularly true for Asian American populations, who have historically suffered from under-reporting of disaggregated health data that masks disparities across subgroups. Recent calls in the last decade to disaggregate data across Asian

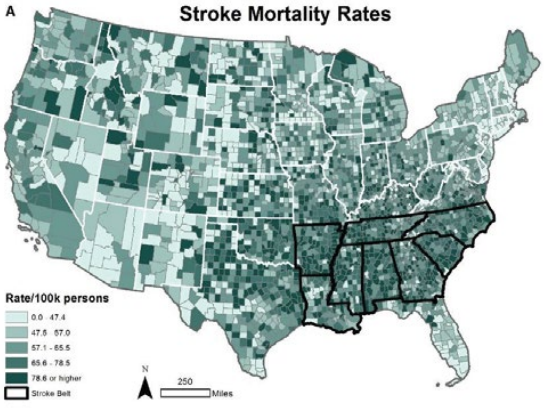

Figure 1. Stroke Mortality in the Stroke Belt

American subgroups and by geographic region, have demonstrated that South Asians experience stroke and heart disease. For example, a national study of mortality records found that the leading cause of death for Asian Indians was heart disease and temporal trends showed increased stroke mortality in Asian Indians.[32] Similarly, mean age at death due to ischemic heart disease is lowest for Asian Indian men compared to all other Asian male groups and White men.[33] As a result of the growing evidence of CVD risk among South Asians, the American Heart Association (AHA) and other medical groups issued updated guidelines to consider ethnicity when determining a patient's CVD risk and treatment options.[34] The unique disparities faced by South Asians has been highlighted in the mainstream media[35] and calls for specific legislation and national campaigns to engage this population have been made by both policymakers and national associations.[36,37] *However, despite rapid population growth of South Asians in the Southeastern region where there is a known density of stroke, there is a lack of intervention strategies tailored by geography and ethnicity to improve the efficacy of existing therapeutic interventions and mitigate risk for CVD.[38]*

A4. South Asians face disproportionate diabetes and HTN disparities. Diabetes prevalence in the US South Asian community are high, with national and regional data revealing the highest prevalence of diagnosed diabetes among Asian Indians compared to other Asian groups[39] and compared to non-Hispanic whites.[2,3,5,7,8,4,6] 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]).[40] 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).[41]

Similar disparities have also been uncovered among South Asians living in the Southeastern region of the US. In a community-based survey of Asian Indians in Atlanta, the self-reported prevalence of diabetes was18.3%, nearly four times as high as Non-Hispanic whites and twice as high as Hispanics.42 Among those who reported diabetes, there was a >3.5 odds of having co-morbid HTN. This population further had higher prevalence of stroke (2.77%) compared to whites (2.12%).[43] *Thus, scalable and translatable interventions that promote diabetes management and hypertension control in this population may have significant potential for public health impact and reducing disparities in the Southeastern US.*

A5. Addressing HTN and diabetes co-morbidities requires a multi-level, patient-centered approach
Several groups have published guidelines regarding the comorbid management of HTN and diabetes, including the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, the American Diabetes Association (ADA), and the World Health Organization (WHO).[44] Strong evidence from clinical trials and meta-analyses supports targeting BP reduction to at least 140/90 mmHg; most recently, the American College of Cardiology (ACC) and AHA have recommended targeting BP to 130/80 mmHg in most adults with diabetes.[45,46] *Though clinical and lifestyle recommendations are in place to promote HTN control for individuals with diabetes, there is a gap in the implementation of evidence-based strategies to address co-morbidities, particularly among minority communities that may face unique social and cultural barriers to optimizing chronic disease management*.

A6. Incorporating Community health workers (CHWs) into healthcare teams can improve diabetes *and* HTN outcomes.
A substantial body of evidence demonstrates that CHWs can be a natural bridge and effective strategy to disseminate efficacious interventions between underserved communities and the health care system.[47] The addition of CHWs to primary care teams is a low-cost and cost-effective approach to improve care and adherence for patients with chronic disease.[48-51] 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.[52,53] Similarly, the Centers for Disease Control and Prevention (CDC)'s Community Guide recommends team-based care to improve BP control,[54] including CHWs.[54-56]
A systematic review including twenty-six US-based CHW interventions designed to reduce CVD risk among vulnerable populations reported significant effects in sixteen (62%) studies, with similar findings supporting team based care for CVD risk reduction in low and middle income countries.[57,58] A health coaching intervention among African Americans with comorbid diabetes and HTN demonstrated weight loss and a reduction in systolic BP (SBP) and diastolic BP (DBP) compared to participants receiving usual care.[59] Similarly, an evaluation of a team based care coaching and case management model among Latino patients with diabetes demonstrated increased odds of SBP control among patients following implementation.[60]

A7. CHWs demonstrate efficacy in improving HTN and diabetes related outcomes in South Asians.
Our work has demonstrated culturally adapted CHW-led interventions in community and clinical settings are acceptable and efficacious in improving HbA1c control, weight loss, self-efficacy and social support, and health behaviors for South Asian patients with diabetes, and improved BP control and medication adherence among Filipino and South Asian individuals with HTN.12,13,61-63 A substantial proportion of South Asian individuals in our HTN and diabetes management intervention13,64 (total n=640) had co-morbid diabetes and hypertension (56%, n=358), and among this subgroup, 75% had uncontrolled HTN at baseline. A combined analysis across to randomized control trial studies examining the impact of CHW-led coaching for individuals with comorbidities found that individuals in the treatment group were more likely to achieve BP control (using the ADA defined140/90 mmHg) at study follow-up, compared to individuals in the control group (72% vs 57%, p<0.012). Mean SBP decreased from 136.2 to 129.9 (p<0.001) and mean DBP decreased from 82.8 to 78.5 (p<0.001) in the treatment group, while the control experienced a small, non-significant change in DBP and no change in
SBP. The differences between groups were statistically significant (p<.05).[65] *Our study findings offer a promising model to address HTN control among South Asian individuals with diabetes that can be replicated to address disparities among South Asians living in the Southeast.*

A8. Scale and replication of culturally tailored CHW-led programs remains a challenge.
Despite the potential demonstrated for CHW approaches to reduce CVD disparities in general and comorbidities in particular**,** the scale and replication of culturally tailored CHW-led programs remains a challenge, with inconsistent implementation driven by community, organizational, provider and patient challenges.[66-74] Such challenges may be mitigated through a rigorous process of cultural and local adaptations, guided by implementation science frameworks, that retain the fidelity of an intervention's goals while increasing "fit" between the intervention, target population, and service system where it is delivered.[75,76] Further, models that offer technical assistance and capacity building for sites and settings by factoring in local contextual considerations have demonstrated promise in enhancing program effectiveness across settings.[77] *To date, there have been limited efforts to replicate efficacious interventions to address co-morbidities, particularly in South Asian communities. Given the geographic and ethnic disparities, careful attention to implementation processes is critical to ensuring evidence-based strategies are optimized for success.*

A9. Scientific Premise and Impact
The proposed project, "Scaling Community-Clinical Linkage Models to Address Diabetes and Hypertension Disparities in the Southeastern United States," builds upon the evidence base of the effectiveness of culturally tailored CHW interventions and proposes to replicate and scale a CHW intervention to improve HTN control among South Asian individuals with diabetes in the Southeastern US. Our past work used rigorous methods and a randomized design, demonstrating efficacy in improving BP control and other CVD risk factors for individuals with diabetes. Given the rapid growth of South Asians in this region and their high burden of diabetes and HTN, a critical need exists to tailor, translate,

and disseminate evidence-based CHW interventions to maximize impact in ameliorating co-morbid CVD disparities.

II. OBJECTIVES

A. Purpose of the Study

The proposed project takes place in two parts: part one builds upon the evidence base of the effectiveness of culturally tailored CHW interventions and proposes to replicate and scale a CHW intervention. A critical need exists to tailor, translate, and disseminate evidence-based CHW interventions to maximize impact in ameliorating co-morbid CVD disparities. Part two describes the variation of cardiovascular disease risk across South Asian populations in the US derived from electronic health records. Our study takes a first step towards filling this gap in the literature, by characterizing the burden of disease among two South Asian communities. This project will facilitate bidirectional collaboration by building this data set across two sites in the United States. This will complement ongoing work by the investigative team to replicate an efficacious intervention program delivered in NYC in Atlanta.

B. Study aims

Specific Aim 1: Provide research training, technical assistance, and capacity-building to community and clinical sites in Georgia for implementation of culturally tailored, evidenced-based CHW programs to improve HTN and diabetes management for South Asians.

Specific Aim 2: Use a multi-theoretical framework to test the effectiveness of a CHW-led intervention compared to usual care among South Asian individuals with diabetes and uncontrolled HTN in Atlanta.

Specific Aim 3: Apply RE-AIM and CFIR frameworks to delineate factors influencing reach, appropriateness, fidelity, adoption, and maintenance of the intervention within clinical and community settings to optimize intervention replication.

Sub-Aim3a: Serve as a national information and dissemination resource in the adaptation of evidence-based strategies to reduce geographic disparities in HTN and diabetes across Asian American groups.

B. Study Outcomes

Phase 1: See below: this is the planning and technical assistant phase of the proposal.

Phase 2: The primary outcome of interest is proportion of patients that achieve BP control, defined as less than or equal to 130/80 mmHg, at 6 months. The secondary outcomes of interest include changes in HbA1c, SBP and DBP, and BMI at 6 months.

Phase 3: The outcomes for the provider surveys, informant surveys, and EHR will be descriptive data to inform with to facilitate the development of intervention strategies within the larger healthcare system

III. STUDY DESIGN

A. PHASE 1: During the first six months of the intervention, we will be conducting Specific Aim 1 of the study, which does not involve human subjects research. Phase 1 is a planning and technical assistance

phase, where we will work with Atlanta-based partners to develop survey instruments and refine the intervention protocol. The project leverages established community partnerships in Atlanta. Established in 2016, the Atlanta South Asian Health Alliance (ASHA) is a community-academic partnership that brings together a diverse coalition to address the growing burden of cardio-metabolic disease in the South Asian community in Atlanta. The advisory board of ASHA includes patients with diabetes, family members, small business owners, religious leaders, cultural organizations, physicians, and health services researchers. ASHA was consulted in the development of this project proposal. ASHA will serve as advisors on the proposed study and provide cultural competency in study design, recruitment and implementation to ensure the research is adapted to meet the target population's social, cultural, and linguistic needs.

B1. PHASE 2: Overall Design for PHASE 2:

The integrated intervention involves:

1. A randomized controlled, community health worker-led coaching trial which aims to enroll 652 South Asian participants (326 treatment and 326 control) with comorbidities of hypertension and Type 2 Diabetes Mellitus (T2DM).
2. Linkage to culturally relevant community-level resources

A randomized control design will be used to test the efficacy of the CHW intervention to improve HTN control among South Asian individuals with diabetes in Atlanta. The intervention will recruit participants from three clinical sites in Atlanta, GA: 1) The Emory Family Medicine Clinic is located in North Atlanta and serves approximately 1,200 unique South Asian patients annually; 2) Grady Clinic at Brookhaven is a safety net county clinic that sees a high volume of low-income South Asians (approximately 6,000 per year; 3). The Shifa Free Clinic is a community-based free clinic coordinated by the Islamic Circle of North America, Atlanta branch, to serve uninsured and under-insured South Asians in Georgia.. On average, they see 200 unique South Asian patients per month at each site. Both Emory Family Medicine Clinic and Grady Clinic utilize EHR systems which will be used to generate lists of eligible patients for the intervention. Shifa Clinic is currently transitioning to an EHR system, thus patient data will be electronically accessible for patient recruitment and follow-up outcome data. Each of the sites has expressed interest and commitment to participating in the study. The community centers will not be engaged in research, all consenting and procedures will be completed by Emory study staff.

We also anticipate enrolling participants from community-based recruitment with the CHWs referring participants that they meet at South Asian community events and advertising the study. The proposed research design is a modified stepped wedge design, whereby 2 groups will implement the intervention in phases. The time prior to the intervention will serve as the comparison group. Enrolled patients will be randomized to treatment (Group A) and wait-list control (Group B) groups within each site.

There are five primary research groups for this study: 1) 326 treatment participants who will receive the CHW intervention; 2) 326 control participants who may receive the CHW intervention as a point of service at a later point; 3) 10 subjects who will participate in provider surveys; 4) 25 subjects who will participate in qualitative key informant interviews; 5) a retrospective EHR review of characteristics of South Asians seen at Emory Healthcare and NYU hospital system between 2014 and 2019; and 6) 50 subjects who will participate in focus groups.

B2. CHW Component:

1. *Data collection and consenting with treatment participants*

After letters from the provider practices of the 3 participating clinical sites have been mailed to eligible patients or they have been notified of the study by their provider, CHWs will contact patients via mailing and phone calls to invite them to enroll into the intervention. CHWs will call patients a maximum of ten times over a two-week period at varying times of day to invite them to enroll into the study. In addition, list of eligible treatment participants will be shared with primary care physicians who will be encouraged to refer patients to contact CHWs during routine visits. CHWs will also table at primary care provider (PCP) clinics and community events to enhance recruitment and enrollment. During the recruitment call, CHWs will conduct a brief screening to confirm eligibility (see Screening Form). If eligible, patients will be invited to complete an in-person consent form (See Consent Brochure and Consent Signature Page for CHW Intervention) and survey (see Participant Survey) that assesses baseline demographic and logistical information, such as preferred language and session availability. Participants must sign a consent form in order to participate, which will be administered by the CHW or bilingual study coordinator.

Surveys will be collected from all participants at baseline and 6 months. Baseline surveys will be conducted by a CHW or bilingual study coordinator immediately following consent. Six-month surveys will be conducted in person by a study staff within two weeks of completion of the CHW coaching component of the intervention. Survey measures will be developed based on their 1) brevity; 2) presence of domains with face validity for Asian American or low literacy communities; and 3) valid psychometric properties, thus enhancing scientific rigor. Survey measures include weight and blood pressure measurements, as well as questions about self-efficacy, medication adherence, and referrals to social services.

Patient-engagement measures: Contact with eligible treatment group participants will be collected in REDCap or on paper-based CRFs, including phone contact attempts, patients' intervention status (declined, enrolled, not reached etc.), completion of intervention activities (such as health education sessions and phone-based health coaching), and completion of data collection, referrals, and intervention activities across sites and CHWs.

Participants enrolled in the intervention will receive monthly text and phone call reminders (See Text Script) in addition, multiple sessions will be hosted at varying times/days of the week to accommodate schedules of both working individuals and at-home caretakers. Finally, small incentives will be provided at each session to encourage ongoing attendance.

Templates will be created that CHWs can complete to help keep track of each participant's progress. 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.

C1. Overall Study Design for PHASE 3
Provider Survey

At the end of each 6 month period, brief surveys will be administered to all participating physicians (n=10) by the Emory Study team to capture data on: information sources before and after intervention, acceptability of and satisfaction with the integrated intervention, and barriers and facilitators of care coordination tools. (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."

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 Emory School of Medicine's databases and will only be accessible through a unique secure link sent to an individual provider through REDCap's secure database by Emory study staff. Surveys will take approximately 15 minutes to complete.

C2. Key Informant Interviews and Focus Groups

At the end of the each 6 month period, interviews with study staff and CHWs will be completed for the purpose of program evaluation, and focus groups will be completed with a random sample of existing enrolled CHW intervention participants will assess current satisfaction and usage of CHWs. Questions will also assess barriers and facilitators to the implementation and adoption process of the integrated intervention appropriates, fidelity to the interventions and the solicit recommendations for the replication and scalability of the intervention to other sites. Satisfaction and outcomes from the partnership and capacity building process will also be assessed. Questions will be adapted from existing validated measures on acceptability, feasibility, adoption, organizational culture, and scalability and other previous work.
The key informant interviews as part of the Phase 3 implementation evaluation will include NYULH employees. NYU CHWs served as mentors to the external implementation site, and thus their inclusion in the research is unavoidable, as inclusion of these NYU staff members in the research is important for achieving Specific Aim #3. The unique knowledge obtained from the NYULH employees regarding the training and mentorship they provided to the external site will allow us to delineate factors influencing reach, appropriateness, fidelity, adoption, and maintenance of the intervention within clinical and community settings to optimize intervention replication.

C3. Characterizing the Prevalence of Type 2 Diabetes and Prediabetes

To better characterize differences, similarities, and reach for implementation of the intervention, retrospective analyses will be conducted by extracting variables from the EHR using samples of South Asians aged 18+ years living in the greater Atlanta area and the New York City area from two large healthcare systems. These variables include: 1) study population characteristics (i.e age, gender); 2) prevalence of diabetes and prediabetes; 3) diabetes risk factors (i.e. smoking, BMI), comorbidities (i.e. blood pressure, lipids), 4) diabetes complications (i.e.. neuropathy, nephropathy, and retinopathy); and 5) diabetes/CVD medications among South Asians.

IV. METHODS and PROCEDURES

A. Methods and Procedures

A1. Integrated CHW Intervention
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:

Intervention Components
A minimum set of proposed intervention components will be implemented including:

- 5 group-based health education sessions on hypertension and diabetes management
- Provision of culturally and linguistically tailored health information and resources

- Two one-on-one in-person meetings that can be at the participants home or at the participants clinical site and 7 follow-up phone calls 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.

CHW Curriculum

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

Curriculum Session Title & Content	**Tailored cultural components**
Session 1: Hypertension and Diabetes Overview • Diabetes and Hypertension information • Myths and Facts about diabetes/Myths and Facts about Hypertension • Signs of Symptoms of Diabetes • Signs and Symptoms of Hypertension • Goal-setting • Blood Glucose Levels • Basics on Eating Healthy • Staying motivated and goal-setting	· Concept of prevention tied to South Asian core values (in religion/culture) · Discussion of hypertension and diabetes prevalence and increased risk of diabetes in Asians · Discussion of hypertension and 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 hypertension, 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: Hypertension and Diabetes Management • Chronic disease 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. Characterizing the Prevalence of Type 2 Diabetes and Prediabetes

Understanding differences/disparities across South Asian populations may help disentangle issues related to genetics, health services, and/or immigration. Given the rapid growth of South Asians in New York and Atlanta and their high burden of diabetes and HTN, a critical need exists to tailor, translate, and disseminate evidence-based interventions to maximize impact in ameliorating co-morbid CVD disparities. Tables 2 and 3 below describe the data to be collected from the electronic health records.

Study Design. Cross-sectional analyses will be conducted using samples of Asian Indians aged 18+ years living in the greater Atlanta area and the New York City area from two large healthcare systems.

Study Sites. Emory Healthcare is based in Atlanta, Georgia and serves over 611,000 unique patients annually; we conservatively estimate that 1% will be of South Asian origin.

Measures. Variables that will be extracted from the EHR include: 1) study population characteristics (i.e age, gender); 2) prevalence of diabetes, prediabetes, and hypertension; 3) diabetes risk factors (i.e. smoking, BMI), comorbidities (i.e. lipids), 4) diabetes complications (i.e.. neuropathy, nephropathy, and retinopathy); and 5) diabetes/CVD medications among South Asians.

Data Sources and Collection.

Analysts at each site will associate a specific study number with a specific medical record number in the EHR system. Each study site will maintain the table of study identifiers in RedCap and corresponding

medical record numbers for the duration of the study. After the data extraction, study staff will match the data extract file to the table by medical record number. The medical record number will then be stripped from the extract file and be sent by secure server to NYU. All other potentially identifying data (e.g., zip code, day and month of birth, date of visit) will also be stripped from the dataset prior to storage on the NYU server. The table necessary to link patient identifiers and the study ID will remain at practice sites to ensure that patient confidentiality is maintained.

Analysis. We will conduct cross-sectional analyses, using EHR-based samples South Asians aged 18+ years living in the greater Atlanta and New York City areas from two large healthcare systems. Prevalence values and 95% CIs will be estimated by study site, sex, age-group, and BMI category. Participant characteristics will be stratified by sex and compared by study using x^2 test or ANOVA as appropriate. The non–normally distributed variables of fasting and 2-h plasma glucose will be log transformed. The effect of location of residence (Atlanta or New York) on the risk of diabetes and prediabetes will be assessed using standardized polytomous regression. Initially, an unadjusted regression model will be created to compare the individual association between study location and prevalence of diabetes and prediabetes. Subsequent multivariable models were then created to adjust for covariates including age, sex, blood pressure, BMI, and educational status. All analyses will be performed using SAS, version 9.4 (SAS Institute, Cary, NC).

Table 2: Eligibility and measurement of items in Atlanta and New York City

Construct	Atlanta	New York City
Inclusion criteria	• Last name or spoken language	• Last name or spoken language or race/ethnicity
Exclusion criteria	• • Type 1 diabetes or diabetes secondary to other conditions (e.g. gestational, steroid-induced, pancreatic insufficiency, or chemotherapy-induced).	• Type 1 diabetes or diabetes secondary to other conditions (e.g. gestational, steroid-induced, pancreatic insufficiency, or chemotherapy-induced).
Age	18+ years old	18+ years old
Spoken Language		Bengali, Gujarati, Hindi, Kannada, Kashmiri, Malayalam, Nepali, Pakistani, Punjabi, Sindhi, Sinhalese, Tamil, Urdu
Native country		
Sex/Gender		
Education level		
Income level		
Body Mass Index		
Smoking Status		
Prediabetes diagnosis		Having 2+ encounters with a diagnosis of prediabetes† *or* having 2+ abnormal A1C levels (5.7% to 6.4%)** and 1+ encounters with a diagnosis of prediabetes and no diabetes diagnosis***
Diabetes diagnosis		Having 2+ encounters with a diagnosis of diabetes† *or*

		have a diabetes medication prescribed* (excluding Acarbose/Metformin) *or* having 2+ abnormal A1C levels (≥6.5% and ≤30%)** and 1+ encounters with a diagnosis of diabetes***
Years since diagnosis		
Hemoglobin A1C		
Hypertension diagnosis		Having 3+ BP readings of systolic BP ≥130 mmHg*** or diastolic BP ≥80 mmHg*** *or* 2+ encounters with a diagnosis of hypertension† *or* had anti-hypertensive medication prescribed*
Systolic Blood Pressure		
Diastolic Blood Pressure		
Total Cholesterol		
LDL Cholesterol		
HDL Cholesterol		
Glomerular Filtration Rate		
Neuropathy		
Nephropathy		
Retinopathy		

† See table 3 for outcome definition criteria
*in past calendar year
**in past two calendar years
*** ever in medical record

Table 3. Participant Characteristics by Study Site.

Condition	**ICD-10 Diagnostic codes**	**Medications**	**LOINC Codes**
Prediabetes	R73.03		
Hypertension	I10, I11.0, I11.9, I12.9, I13.0, I13.10, I67.4, H35.031-H35.033, H35.039	Therapeutic or pharmaceutical class/subclass of thiazide, calcium channel, beta-blocker, ACE I, or angiotensin	Not Applicable
Type 2 Diabetes Mellitus	E11.00, E11.01, E11.21, E11.22, E11.29, E11.311, E11.319, E11.321, E11.329, E11.331, E11.339, E11.341, E11.349, E11.351, E11.359, E11.36, E11.39, E11.40-E11.44, E11.49, E11.51, E11.52, E11.59, E11.610, E11.618, E11.620-E11.622, E11.628, E11.630, E11.638, E11.641, E11.649, E11.65, E11.69, E11.8, E11.9, E13.00,	Therapeutic class of Antihyperglycemic, excluding medication names of Metformin and Acarbose	**A1C:** 4548-4, 7426-0, 4549-2, 17856-6, 59261-8, 71875-9, 62388-4, 4637-5, 55454-3, 41995-2, 17855-8

	E13.01, E13.10, E13.11, E13.21, E13.22, E13.29, E13.311, E13.319, E13.321, E13.329, E13.331, E13.339, E13.341, E13.349, E13.351, E13.359, E13.36, E13.39, E13.40-E13.44, E13.49, E13.51, E13.52, E13.59, E13.610, E13.618, E13.620, E13.621, E13.622, E13.628, E13.630, E13.638, E13.641, E13.649, E13.65, E13.69, E13.8, E13.9		

V. STUDY ENROLLMENT

A. Characteristics of the research population

The overall number of subjects expected to participate in this study is 737. This includes a total enrollment of 652 participants in the CHW Intervention (326 treatment participants and 326 control participants, accounting for 10% attrition), 10 subjects who participate in the provider surveys, 25 participants in the key informant interviews and 50 focus group participants.

CHW Intervention
Inclusion Criteria: Participants will be eligible for study participation if they meet the following criteria: a) are of South Asian ethnicity (identified through a race and language code in the EHR or at screening); b) are at least 21 years of age and younger than age 85, c); d) a diagnosis of diabetes in the EHR or self-reported through community recruitment and e) a diagnosis of hypertension or self-reported diagnosis through community recruitment; f) an uncontrolled BP reading(>130/80mmHg) in the last 6 months or at screening.

Exclusion Criteria: a) Patients under the age of 21 and older than 85 will be excluded. b) Women who are pregnant at the time of screening. c) Type 1 diabetes or diabetes secondary to other conditions (e.g. steroid-induced, pancreatic insufficiency, or chemotherapy-induced), d) inability to perform unsupervised physical activity.
No children will be enrolled in this study.

This study includes the recruitment of a subset of community health workers participating in the project who are NYULH employees, which are considered a vulnerable population given the additional risks of coercion and undue influence that are inherent in research studies conducted in the workplace. Including these employees who are involved in the project in the research is not a matter of convenience; rather, it is essential for program evaluation purposes in order to understand their attitudes toward the mentorship and technical assistance provided to the Emory site in Atlanta. NYU CHWs served as mentors to the external implementation site, and thus their inclusion in the research is unavoidable, as inclusion of these NYU staff members in the research is important for achieving Specific Aim #3. The unique knowledge obtained from the NYULH employees regarding the training and mentorship they provided to the external site will allow us to delineate factors influencing reach, appropriateness, fidelity, adoption, and maintenance of the intervention within clinical and community settings to optimize intervention replication.

NYULH employees recruited as research subjects are more vulnerable to undue influence or coercion because of the possibility that they may perceive employment or other benefits as dependent upon their participation in research. In addition, NYULH employees may experience increased risk of invasion of privacy or loss of confidentiality. To minimize these risks, a study team member with no direct supervisory or evaluation responsibilities will be involved in enrolling the CHWs who are NYULH employees who wish to participate in the key informant interview as well as conducting the interview. At

time of enrollment, the study team member will emphasize that participation is voluntary and refusal to participate will not affect employment or job performance evaluation. Supervisors of these staff will not be involved in any capacity and will not have access to review any identified transcripts or recordings. All identifying information for employees will be kept strictly confidential following the data security provisions outlined in this protocol.

Provider Surveys
Inclusion criteria for the surveys are as follows: adult (18 years and over); clinicians employed by one of the participating clinic sites 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, or community health worker.

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

Focus Groups
Inclusion criteria: Participant previously enrolled in and participated in the CHW intervention (meeting all criteria listed for CHW intervention participant above).

Exclusion criteria: Unwilling to consent to participate

Characterizing Prevalence
Inclusion criteria: a) of South Asian ethnicity (identified by a combination of using natural language processing to identify common South Asian surnames in the EHR, race/ethnicity, and language preference); b) 18 years of age or older; and c) had appointment with a physician for routine non-emergent primary care in the last twelve months.

Exclusion criteria: a) pregnant at time of visit; or b) type 1 diabetes or diabetes secondary to other conditions (e.g. steroid-induced, pancreatic insufficiency, or chemotherapy-induced).

VI. STUDY SCHEDULE

A. Method of Subject Identification and Recruitment

CHW Screening Period
There will be a 1-month recruitment period. All participants 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 (See Application for Waiver of HIPAA). 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. Once the participants agree to enroll in the study, they will come into the Emory Dunwoody

Clinic to sign the consent form and complete the baseline survey. Control participants will not be contacted during the intervention and will only be contacted once the intervention with treatment participants has been completed; those who were control in the first wave of recruitment can then be enrolled in the second wave. Due to the study funding period, those in the second wave control arm will be offered education sessions as a point of service and not as part of research.

CHW Intervention Period
There is a 6-month intervention period immediately following recruitment. Each session will be held multiple times throughout the month to accommodate a variety of schedules by the treatment participants. Month 1 has participants coming to Session 1 followed by one follow-up phone call. Month 2 has participants coming to Session 2 followed by one follow-up phone call and then one in person visit at the participant's home or at local meeting point used for a session. Month 3 has participants coming to Session 3 followed by two follow-up phone calls within the month. Month 4 has participants coming to Session 4 followed by one follow-up phone call and then one in person visit at the participant's home or at local meeting point used for a session. Month 5 has participants coming to Session 5 followed by two follow-up phone calls within the month. Month 6 concludes the intervention period with an endpoint survey and completion certificate.

Provider Surveys
Over the course of 2 months, providers at participating practices will be invited to complete the Provider Survey 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 Script and Elements of Informed Consent for Provider Survey).

Key Informant Interviews
Over the course of 2 months, participating providers and community health workers will receive an invitation to participate in the interview (See Invitation Script 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).

The interviews will be completed in-person or virtually via Zoom (Emory University has HIPAA compliant Zoom accounts which have been institutionally approved for telemedicine, see supporting documentation) to accommodate the current COVID-19 situation. The method (face-to-face vs. virtual) will be determined at the discretion and preference of the participants, while following institutional regulations for COVID-19. Recordings will only include audio (not video).

NYULH employees recruited as research subjects are more vulnerable to undue influence or coercion because of the possibility that they may perceive employment or other benefits as dependent upon their participation in research. In addition, NYULH employees may experience increased risk of invasion of privacy or loss of confidentiality.

To minimize these risks, a study team member with no direct supervisory or evaluation responsibilities will be involved in enrolling the CHWs who are NYULH employees who wish to participate in the key informant interview as well as conducting the interview. At time of enrollment, the study team member will emphasize that participation is voluntary and refusal to participate will not affect employment or job performance evaluation. Supervisors of these staff will not be involved in any capacity and will not have access to review any identified transcripts or recordings. All identifying information for employees will be kept strictly confidential following the data security provisions outlined in this protocol.

Focus Groups
A random sample (n=50) of less engaged and more engaged previously enrolled treatment group participants of the CHW intervention will receive an invitation to participate in the focus group (See Invitation Script and Elements of Informed Consent for Focus Group). No undue pressure will be given to subjects for participation as the participation is entirely voluntary (See Verbal Consent Script for Focus Group).

The focus group will be completed in-person or virtually via Zoom (Emory University has HIPAA compliant Zoom accounts which have been institutionally approved for telemedicine, see supporting documentation) to accommodate the current COVID-19 situation. The method (face-to-face vs. virtual) will be determined at the discretion and preference of the participants, while following institutional regulations for COVID-19. Recordings will only include audio (not video).

Characterizing South Asian population
During the study period, the research team will be performing a retrospective chart review of South Asians, using surnames to identify patients of South Asian origin. We will submit a waiver of consent to obtain these records.

VII. DATA COLLECTION AND ANALYSES

A. PHASE 2: Data collection and implementation of the CHW intervention (recruitment, consenting, CHW led education sessions) will be led by Emory University. All participants will attend Session 1. Everyone who attends will receive a unique study identifier that will associate a specific study number with the participant. This information will then be downloaded onto the NYU servers into R statistical software for randomization. We will use stratified randomization by age and gender to assign patients to intervention or control arms.. The table necessary to link patient identifiers and the study ID will be maintained by the Emory-based study coordinator to ensure that patient confidentiality is maintained.

Treatment Participants
The study ID will be used for all implementation activities and reporting on CRFs. Thus, patients who are observed more than once will have the same study ID in each extract, which is necessary for the planned analyses. Study data will be collected in the form of a survey at baseline and at endpoint. Follow up calls and visits will also be recorded in REDCap, or paper-based CRFs and kept in locked boxes until transport back to the Emory Dunwoody offices for input into REDCap and secure storage.

A random sample (n=50) of less engaged and more engaged previously enrolled treatment group participants of the CHW intervention will receive an invitation to participate in the focus group This will be a one-time anonymous audio-recording with no follow-up; no names or identifying information will be collected at the time of the focus group.

The focus group will be completed in-person or virtually via Zoom (Emory University has HIPAA compliant Zoom accounts which have been institutionally approved for telemedicine, see supporting documentation) to accommodate the current COVID-19 situation. The method (face-to-face vs. virtual) will be determined at the discretion and preference of the participants, while following institutional regulations for COVID-19. Recordings will only include audio (not video).

Control Participants
The control participants will all participate in baseline and endpoint surveys with the CHWs. They will also complete a Session 1 educational session. Control participants will not be contacted during the rest of

the 6-month intervention phase and will be contacted by the clinic staff only when the intervention is complete among treatment participants. Those in the first wave will be offered the intervention in the second wave. The second wave control group will be offered educational sessions as a point of service and not as part of research (i.e., wait-listed control study design).

B1. Data Analysis and Monitoring

The NYU site will lead the data analysis portion of the study, with input and feedback from Emory research staff.

Specific Aim 2 Analysis.

Specific Aim 2: To compare the effect of the intervention with usual care on achieving BP control among individuals with diabetes. The primary outcome will be the proportion of eligible patients at a practice site to achieve BP control (130/80 mmHg) six months following the index office visit. *Hypothesis*: Individuals receiving care during the implementation of the intervention will be more likely achieve BP control six months following the index office visit than individuals receiving care as usual. The primary outcome of interest is the proportion of patients who achieve BP control. The secondary outcomes of interest include changes in HbA1c, SBP and DBP, and BMI at 6 months. For analyses of both primary and secondary outcomes, a logistic regression model will be used to estimate the CHW effect on outcomes (see equation 1):

$$(1) \qquad logodds\left[P\left(Y_{ij}\right)\right] = \beta_0 + \gamma_j + \beta_1 H$$

Using the primary outcome, HTN control, as an example, Yijk indicates state of HTN control at the end of the 6 months for patient *i*, in clinic site j. Y_{ijk} =1 if patient achieved HTN control, Y_{ijk}=0 if otherwise. Hi =1 if patient i was randomized to the CHW intervention, H_i =0 if otherwise (i.e., control group). y_j is a fixed effect for clinic site. $\mu + b_j$ is the log odds of HTN control for patients randomized to the control group in the first 6 months. β1 represents the log odds ratio of HTN control for those randomized to the CHW intervention compared to those randomized to the control group. A test will be conducted with the following null and alternative hypotheses: H0 : $\beta 1 = 0$ vs.HA : $\beta 1 \neq 0$ to assess whether or not the CHW intervention had an effect on HTN control after 6 months. We will conduct exploratory, secondary subgroup analyses to see which subgroups may achieve greater benefit from the intervention. In addition, we will assess an alternative measure of HTN control, using an ADA BP control definition of 140/90 mmHg to evaluate the effect of the CHW intervention. And finally, we will compare the findings from this Atlanta-based study with our ongoing trials in the NYC area. The datasets from each respective study will not be combined; they will be analyzed separately. Sex as a biological variable will be addressed by exploring gender as a potential moderator of intervention effects.

Specific Aim 3: Analysis

We will conduct cross-sectional analyses, using EHR-based samples South Asians aged 18+ years living in the greater Atlanta and New York City areas from two large healthcare systems. Prevalence values and 95% CIs will be estimated by study site, sex, age-group, and BMI category. Participant characteristics will be stratified by sex and compared by study using x2 test or ANOVA as appropriate. The non–normally distributed variables of fasting and 2-h plasma glucose will be log transformed. The effect of location of residence (Atlanta or New York) on the risk of diabetes and prediabetes will be assessed using standardized polytomous regression. Initially, an unadjusted regression model will be created to compare the individual association between study location and prevalence of diabetes and prediabetes. Subsequent multivariable models were then created to adjust for covariates including age, sex, blood pressure, BMI, and educational status. All analyses will be performed using SAS, version 9.4 (SAS Institute, Cary, NC).

B2. Power Calculation.
We conservatively estimate a 20% difference in effect size (i.e., BP control) when comparing intervention and control group participants. Our power calculation was based on our previous studies. Based on results from these studies, at six-month follow-up we conservatively assume a 15% BP control rate for the control group and 35% BP control rate for the treatment group. In our previous work, BP control rates at baseline varied; however, in the proposed study all participants will have uncontrolled BP at baseline. Further, in our past work control group participants experienced almost no change in BP control at follow-up; here we conservatively estimate a 15% BP control rate at follow-up. Accrual of 162 participants, evenly randomized to intervention or control groups, will provide greater than 80% power to detect this difference, using a 2-sided, 0.05-level test (i.e., approximately 81 intervention and 81 control participants). These calculations assume a 10% loss to follow-up.

B3. Sampling. Across the three clinical sites, there will be approximately 3,600 unique South Asian patients that have had an office visit in the last year. Based on preliminary analysis of Dr. Shah's patient panel, we estimate 30% of those individuals will have a Type II Diabetes diagnosis (n=1080), and estimate that 60% will have co-morbid diabetes and HTN (n=648), 75% of these individuals will have uncontrolled HTN (n=486), and additional 5% will be excluded due to not meeting other eligibility criteria, leaving 462 individuals eligible for the study. Of these individuals, approximately 50% will be randomized to the treatment group, and we estimate based on our previous studies that 40% of patients will be interested in the study and consent to enroll into the study (n=326). Based on retention rates from our CHW studies,[12,95,96,98,128,129,131] we estimate that approximately 90% of individuals in control and treatment quarters will be followed up at six months (n=83). Thus, across sites, we will enroll approximately 652 patients per six-month period, resulting in total recruitment of approximately 326 treatment group participants across 3 practice sites. Treatment group participants will be matched to 326control group participants. Approximate CHW caseload over a six-month period is 16 participants for a full-time CHW.

Specific Aim 3 Analysis.

B4. Analysis to address this aim will be guided by the questions in **Table 4**.

Table 4: Guiding Questions

Utilization Patterns	• How frequently do clinicians utilize the intervention? • What is the percentage of adoption? • Does the utilization pattern change over time?
Physician Attitudes Regarding the Integrated Intervention	• What are physicians' attitudes regarding CHW approaches to diabetes and HTN management? • How satisfied are the physician's with the integrated intervention tools? • What are the barriers and facilitators of using the CHW integration components? • How does the intervention affect clinicians' satisfaction with workflow around T2DM management?
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 each team member? • How did this organization customize the intervention to better serve its own local needs? • How were users involved in design and implementation? • Did CAB member feel ownership in the partnership process? • What are recommendations for replicating this model for other clinical settings and communities?

1. Utilization Patterns. Data from REDCap tracking forms will be used to analyze utilization patterns of the intervention (e.g. referral to CHW, receipt of CHW feedback on patients' progress and referrals). These data will yield descriptive trends for frequency of utilization across the participating clinic sites.

2. Physicians 'Attitudes Regarding the Integrated Intervention. Physician attitudes will be primarily assessed 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 1=strongly agree to 5=strongly disagree) to the following statement: “CHWs are helpful tome”. The survey data come from a small sample (n=approximately 10) and are only intended to quantify descriptive information and not for extensive statistical analyses. The data will be tabulated and summarized descriptively to assess change in attitudes from baseline to 12 months.

3. Barriers and Facilitators to Implementation Adoption and Implications for Scalability. Using a qualitative approach, interview data will be transcribed and analysis will follow "constant comparison" analytic approach.[146] The “constant comparison” approach is a method of explanation building in which the findings of an initial case are compared to a provisional category, 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.[146] Using "thematic" coding, we will develop an initial set of codes, which will be reviewed by the CAB to ensure they are relevant and complete. For each core code, we will ultimately develop one or more "secondary codes".T he 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).[147] The coded transcripts will be analyzed with *ATLAS.ti*, a qualitative data analysis software.[148] Dr. Islam will lead this component of the project.

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 (NYU) and Dr. Megha Shah (Emory)

CHW Intervention

All patient data will be de-identified and stored on the Emory and NYU servers via a secure site. All computer systems are protected from possible external access. No internet access is possible with the research systems. All of the case report forms and study activities will be kept in locked file cabinets at the Emory Dunwoody Clinic.

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. 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 an Emory study staff. All potentially identifying data (e.g., zip code, day and month of birth, date of visit) will also be stored on the Emory server.. 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 at the Emory site. Baseline and follow-up 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 / Focus Groups

Unique study IDs will be assigned to each key informant or focus group participant in Excel, and these unique study IDs will track interview/focus group logistics (including date/time/location), audio file names, and = transcripts. The audio-recordings and transcripts will be stripped of all identifying data before being

transferred to NYU where it will 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 de-identified, and subject names will not be collected or included in interview transcripts. Audio-recordings will be discarded once the interviews have been transcribed.

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 access 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 is submitted to clinicaltrials.gov (in process) and will be updated as necessary in accordance with study development.

VIII. RISK/BENEFIT ASSESSMENT

A. Risks and protection against risks

The proposed study poses minimal risk to participants. Loss of confidentiality is the greatest potential risk to study subjects.

Data from CHW intervention participants: Locked file cabinets will be used to store materials with identifying information at Emory University. All computer systems are password-protected from possible external access. The data collected for this study will be used strictly for the purposes stated in this application and will only be available to Emory and NYU research staff.

Data from key informant interviews and provider surveys: We will 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 be stored on password protected documents housed within MCIT managed network drives upon transfer of data from Emory. 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.

B. 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.

IX. INVESTIGATOR'S QUALIFICATIONS AND EXPERIENCE

NYU Personnel

Nadia Islam, PhD will serve as PI of the proposed study. Dr. Islam is an Associate 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.

Jeannette Beasley, PhD is a Co-Investigator and will guide adaption efforts to the local Atlanta community. She has conducted randomized, controlled trials and epidemiological studies to better understand relationships between nutrition and health. Working as a nutrition researcher for the research firm PICS, She recruited participants from the community and conducted several randomized, controlled trials to evaluate novel dietary assessment and intervention tools. Since joining NYU in 2015, she has worked with the Department for the Aging and five senior center directors to recruit participants for several research studies, resulting in three publications and two grants as PI.

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.

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 health workers 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.

External collaborators

Megha Shah, MD, MSc will serve as the Site PI in Atlanta. She is an Assistant Professor in the Department of Family and Preventative Medicine at Emory School of Medicine. She is a family physician and health services researcher with substantial experience partnering with the local South Asian community in Atlanta. Her clinical practice is in Dunwoody, GA, where 20% of her patient population is South Asian. Dr. Shah will oversee all Emory EHR data extraction at the Emory site in collaboration with **Drs. Joyce Ho**, a data scientist, and **Unjali Gujral**, an epidemiologist.

Christina Gibbs, MS is the Project Coordinator in Atlanta. She works in the Department of Family and Preventative Medicine at the Emory School of Medicine. She will supervise the community health workers, coordinate with each clinical site, and oversee the implementation of the intervention. Christina graduated with MS in Global Health. She has previous experience working in research specializing on South Asian populations.

Sakila Nasrin, Zohra Amin, and **Nazneen Akhter** are community health workers in Atlanta, working in the Department of Family and Preventative Medicine at the Emory School of Medicine.. They are fluent in Bengali and will provide in-language culturally tailored health education and coaching to intervention participants.

X. SUBJECT CONSENT/ASSENT

A. 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 has been created by the NYU School of Medicine Office of Science and Research in accordance with Federal guidelines, including the Health Insurance Portability and Accountability Act (HIPAA).

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 and Key Information Sheet). 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.

Consent processes will be conducted in a manner that maximizes confidentiality and privacy and allows questions to be asked. Eligible patients demonstrating interest in participating in the project will meet with a study team member who will explain the intervention and consent form and invite them to sign a consent form. Consent will be obtained in a closed room, 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.

Provider 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 participants wish to complete a paper-based survey, the study team will obtain verbal consent (See Invitation Script 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)**.** The language in the recruitment and verbal consent materials for NYU employees which details their risks (coercion, invasion of privacy or loss of confidentiality) and specific protectons as a vulnerable population will always apply specifically because they are the individuals involved in the methods under study. This language does not apply to research subjects who are involved in the interviews who are not NYU employees.

Focus Groups
A Waiver of Documentation of Consent is being requested for the random sample of participants previously enrolled in the CHW intervention invited to participate in the Focus Group (n=50) (See Application for Waiver of Documentation of Consent for Focus Group). 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 subject's name to the focus group component (meaning that they were part of the random sample of treatment group participants who also participated in the focus group, which is a smaller sample than that of the CHW intervention. This will be a one-time anonymous audio-recording with no follow-up; no names or identifying information will be collected at the time of the focus group. Verbal consent will be obtained prior to start of the focus group, but we will not collect any personal information or identifiers. No names of individuals will be recorded or appear in notes. Participants will be free to withdraw from the focus group 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 focus group participants prior to beginning (See Verbal Consent Script for Focus Group)**.**

B. 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).

C. Subject/Representative Comprehension
To determine that the subject or his/her authorized representative understood the information presented, they will be given opportunity to ask questions before giving consent to participate. They can also choose at that time not to be in the study. The individuals authorized to obtain consent will do so by presenting to the subjects the consent form and will verbally read along with the subject and explain the study. The individuals will explain the purpose of the study, the procedures, possible risks and anticipated benefits, that it is voluntary, and how to withdraw if they choose to at a later time. Limited English speaking individuals will be given a translated consent form, and Bengali/Urdu/Punjabi-speaking speaking personnel will obtain consent from them.

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

E. Consent Forms. Eligible treatment patients will be consented and enrolled to participate in the study (see Consent Brochure/Signature Page for CHW Intervention).

F. Documentation of Consent
Informed consent will be documented by the use of a written consent brochure/signature page to be signed and dated by the subject or the subject's legally authorized representative at the time of consent (See Consent Brochure and Consent Signature Page for CHW Intervention) for all those participants enrolled in the CHW intervention. Individuals authorized to obtain consent will read the consent form to the subject or the subject's legally authorized representative, and the subject or representative will be given adequate opportunity to read it and clarify questions before it is signed. The subject will receive a copy of his/her signed consent form. A translated written consent form will be used for non-English speaking subjects, depending on their preferred language. The informed consent will outline elements of the EHR data collection, CHW group education, one-on-one counseling and survey data collection.

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

A waiver of consent will be submitted to obtain Emory and NYU EHR data to characterize to obtain the data points characterizing South Asians in these two areas.

G. 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.

H. Payment for Participation
Participants will need to travel to the clinic or community-based sites to participate in the group-based health education sessions. Participants will receive compensation for their time, effort, and travel. Participants will receive $10, in the form of a gift card upon completion of each of the health education sessions. Small prizes such as pedometers will be given at educational sessions. The participants will also receive compensation of $25 for the completion of the final survey. Participants of the focus groups will receive a $10 gift card.

XI. APPENDIX

A. Recruitment Letter for CHW Intervention
B. Script for Telephone Screening for CHW Intervention
C. Telephone Screening Form for CHW Intervention
D. Participant Survey Baseline
E. Participant Survey Followup
F. Provider Survey(baseline and followup)
G. Key Informant Interview Guide(baseline and followup)
H. Consent Brochure and Consent Signature Page for CHW Intervention
I. Key Information Sheet
J. Key Information and Verbal Consent for Provider Survey
K. Key Information and Verbal Consent for Key Informants
L. Application for Waiver of HIPAA for Telephone Screening

M. Application for Waiver of Documentation of Consent for Provider Survey and Key Informant Interviews, and EHR Characterization
N. Text Message Script
O. Action Plan
P. Progress Note
Q. One-on-One Form #1
R. One-on-One Form #2
S. Encounter Report
T. Recruitment Flyer
U. Focus Group Topic Guide (Template and Site-Specific)
V. Interview Guide – Implementing CHW (Template and Site-Specific)
W. Interview Guide – NYU CHW (Template and Site-Specific)
X. Key Information and Verbal Consent Script for Focus Group
Y. Application for Waiver of Documentation of Consent for Focus Groups