Addressing Social Determinants of Health & Diabetes Self-Management in Vulnerable Populations

STUDY PROTOCOL

NCT# 03802825

Revised: 01.09.2020

1. Protocol Title

Addressing Social Determinants of Health & Diabetes Self-Management in Vulnerable Populations (Bridge to Health Study)

2. Objectives

The purpose of this R34 is to study the feasibility of a large-scale, pragmatic, randomized trial designed to compare the effectiveness of navigation only to navigation + diabetes self-management training on A1C reduction among racial/ethnic minority and low-income patients with poorly managed diabetes. In the first phase of this pilot, we will conduct a data only study to determine the number and clinic service area of eligible patients from Kaiser Permanente Northwest (KPNW) and use this information to inform recruitment strategies and materials for the second phase randomized clinical trial.
For Phase 2 of the study, we will use the electronic health record (EHR) system at KPNW to identify and recruit 100 participants that meet eligibility criteria. We will randomize 50 participants to one of two study arms: 1) patient navigation only; or 2) patient navigation + diabetes self-management training.

Phase 1
Aim 1: *Determine the number and clinic service area of eligible patients for Phase 2 (RCT) based on: A1C ≥ 8; African American, Hispanic, and/or Medicaid recipient (all race/ethnicities); and poor follow-up in primary care.*

Phase 2
Aim 1: *Determine feasibility of the trial based on: a) recruitment and retention rate; b) proportion of participants who actually connect with a Community Health Worker (CHW) and/or navigator after referral; c) mean length of time to connect participants to navigators and CHWs; and d) proportion of patients whose medical, social, and/or economic needs are met after the 6-month intervention based on patient self-report questionnaire and intervention process measures.*

Aim 2: *Assess intervention acceptability and determinants of implementation by conducting semi-structured qualitative interviews with patients, navigators, CHWs, providers, and health care system senior leadership.*

Aim 3: *Assess preliminary effectiveness by comparing the two study arms on the following outcomes at 6-months post-randomization: a) proportion of patients with A1C < 8%; b) proportion of patients with an A1C test; c) number of emergency department visits; d) primary care visit no-show rate; and e) percent of on-time pharmacy refills for diabetes-related medications.*

Phase 3
Aim 1: Extract clinical data on Asian American, Pacific Islander, Native Hawaiian, and Alaska Native populations in KPNW from the EHR as preliminary data for a future grant proposal including these populations in a large-scale, pragmatic, randomized trial aimed to address disparities in diabetes management in relation to socioeconomic needs.

3. Background

Racial/ethnic minorities and low-income individuals in the U.S. are less likely to achieve diabetes-related clinical targets. *Only 42% of African Americans and 38% of Hispanics with diabetes have hemoglobin A1C*

levels at target (≤7%), compared to 58% of Whites.[1] In addition, individuals with low socioeconomic status (of all racial/ethnic backgrounds) are also more likely to have suboptimal diabetes management.[1,2] This is troubling because poor diabetes management leads to an increased risk for diabetes complications including cardiovascular disease events, contributing to the disparities in the rates of these major diseases.[3] As such, pragmatic, multifactorial interventions to address these disparities in diabetes management are sorely needed.

Disparities in diabetes management have been linked to social determinants of health. *Social and economic needs, including food insecurity, housing instability, and trouble paying for medical care, are common among racial/ethnic minorities and low-income populations.[3] These needs interfere with adequate diabetes self-management behaviors, including healthy eating, physical activity, self-monitoring of blood glucose, and medication adherence,[4-9] and are associated with high diabetes-related health care utilization.[4,10-12] A recent meta-analysis indicated that diabetes self-management interventions are effective for reducing A1C by an average of 0.31% among racial/ethnic minorites,[13] but access to these interventions is limited partly due to social determinants of health such as lack of transportation to attend sessions or access to the internet for online programs.[14,15]*

Racial/ethnic disparities in diabetes management and social and economic needs are prevalent among insured patient populations. *Based on recent population health data, across several Kaiser Permanente Northwest (KPNW) primary care clinics, there are disparities in achieving the clinical target of A1C < 8% between Hispanic and non-Hispanic White members (3% - 15% gap) as well as African American and non-Hispanic White members (2% - 9% gap). In January 2017, Kaiser Permanente instituted the Your Current Life Situation (YCLS), a 9-item screener for social and economic needs. Over the past year, the YCLS was administered to 2,406 KPNW patients (6% African American, 12% Hispanic, and 20% Medicaid) because of high emergency department utilization, Medicaid coverage, or referral to a patient navigator. Among these patients, 11% had a diabetes diagnosis and 16% had multiple chronic conditions. In a recent study, our team administered the YCLS as an online REDCap survey to the ~30,000 adult members on the KPNW Diabetes Registry. Among the 3,805 (13%) responders, ~25% endorsed one or more social and/or economic need. Most common needs included trouble paying off debts, food insecurity, and trouble paying for medical needs; all issues that can interfere with optimal diabetes self-management. Furthermore, a significantly higher percent of patients who endorsed one or more social and/or economic need compared to those with no needs had a most recent A1C ≥ 8 (28% vs. 16%). This previous work underscores the high prevalence of social and/or economic needs among the insured KPNW patient population as well as the interplay with diabetes.*

The most effective approach for integrating lay health workers in efforts to improve diabetes management among vulnerable populations is not clear. *There is a growing body of evidence that lay health workers, such as patient navigators and community health workers (CHWs), can effectively address medical, social and economic needs by connecting patients to medical and community-based services.[16-19] However, it is not clear if solely addressing navigation and access to social and economic resources is sufficient for improving long-term diabetes management. For this proposed study, we define patient navigators as lay health workers that are embedded in the health system and whose primary role is to connect patients with medical services and/or community-based resources. In contrast, CHWs are lay health workers embedded in the community and their role is to provide psychosocial support, connect patients to community-based resources, and deliver self-management training.*

Several studies that have utilized patient navigators[16,17] or CHWs,[20-22] have generally demonstrated a reduction in A1C and in some cases a decrease in the number of emergency department visits,[21] and an increase in utilization of primary care among racial/ethnic minorities.[17] However, the roles of patient navigators and CHWs across these previous studies have been mixed including connecting patients to

medical and social services only, providing diabetes self-management training only, or both. Thus, the optimal role of lay health workers is unclear in terms of diabetes management. Also, methodological limitations including lack of randomization or a comparison group, limit the conclusions that can be drawn from several of these studies. Determining the optimal role of lay health workers is key to translating effective diabetes management interventions into clinical practice in a pragmatic, sustainable way. To our knowledge, there has been no rigorous trial to compare the effectiveness of a patient navigation only versus patient navigation + diabetes self-management training intervention. A trial to address this issue may help health systems determine how to best use their resources to improve diabetes outcomes long-term among high risk, high cost populations.

Findings from this comparative effectiveness trial will generalize to other health care settings. *Because of limited staff or access to community-based resources, we expect it would be difficult for a solo-practitioner or a rural clinic to implement navigators or connect patients to a community-based organization with a CHW. However, if successful, findings from this trial could provide a model of care for community health centers, integrated health systems, and specialty clinics that already have access to or would like to embed navigators and/or CHWs, but struggle with fully integrating these personnel into clinic workflow, tracking community-based referrals, and sustaining reimbursement. Furthermore, several states, including Oregon, are currently exploring billing Medicaid to reimburse services provided by lay health workers to low-income patients. Thus, our study is also well-positioned to inform payers about implementation cost and contribute to the discussion about possible payment models.*

Why is a pilot feasibility study needed prior to the full-scale clinical trial? *The challenges of engaging, enrolling, and retaining racial/ethnic minorities and low-income individuals in randomized clinical trials are well established.[23] In the future, full-scale trial, in particular, we plan to recruit patients who are also disengaged from care (i.e., missed one or more scheduled primary care visits in the past year). Therefore, it will be important to test the feasibility of recruiting from this high risk, hard-to-reach population using: the electronic health record; recruitment study staff trained in cultural competence, sensitivity, and motivational interviewing; and care coordinators within the health system who primarily work with this patient population. Furthermore, the proposed study would involve a new partnership between the health system and community-based organizations. The feasibility and acceptability of referring patients to community-based agencies to address social and economic needs and deliver diabetes self-management training while maintaining communication with the health system about patient progress also needs to be determined. Finally, determinants of implementation and sustainability of this model of care need to be explored with various stakeholders to inform the final design of the interventions to be compared in the full-scale clinical trial.*

4. Study Design

We will evaluate the feasibility of a large-scale, pragmatic, randomized trial designed to compare the effectiveness of navigation only to navigation + diabetes self-management training on A1C reduction among racial/ethnic minority and low-income patients with poorly managed diabetes. In this pilot, we will randomize 100 African American, Hispanic, and/or Medicaid (all race/ethnicities) patients from KPNW with A1C ≥ 8 and poor follow-up in primary care to one of two 6-month interventions: 1) patient navigation only; or 2) patient + diabetes self-management training.

Treatment Arms

Patient Navigation

Participants randomized to the patient navigation only arm will be referred to a KPNW patient navigator using a standard EHR-based referral process. Once the participant has completed the YCLS assessment with study staff, the navigator will receive the referral and follow-up with the participant to address the social and

economic needs identified. The patient navigator will follow-up with the participant 2-3 times over the 6 months by phone or in-person about progress with the referral and help address additional needs that may develop during the 6-month intervention. Diabetes educational materials from the American Diabetes Association (available in English and Spanish) will be mailed to the participants monthly to keep them engaged in the study.

Patient Navigation + Diabetes Self-Management Training
In addition to receiving patient navigation as described above as well as educational materials from the ADA mailed at the beginning of treatment, participants in this arm will also be referred to Project Access NOW by study staff via an encrypted email sent via REDCap with a secure link to REDCap. As part of the partnership with KPNW, Project Access NOW will be provided with participants' contact information and other PHI via REDCap to facilitate the referral to a certified CHW within a community-based organization. Project Access NOW will connect participants to a community-based organization based on their preference, previous experience with an agency, geography, and capacity.

Project Access NOW will receive the following private health information only about participants randomized to the intervention arm:

- *Patient contact: name, phone number, address, zip code*
- *Patient demographics: date of birth, race, ethnicity, gender, primary language*
- *Patient clinical data: diabetes diagnosis, most recent hemoglobin A1C levels*
- *Patient health care utilization: assigned Primary Care Provider, clinic service area, KPNW patient navigator*
- *Patient insurance: type of coverage*
- *Social and economic needs endorsed on the YCLS*

Sharing of PHI with Project Access NOW

CHR runs its own private instance of REDCap, which is housed at CHR. REDCap is hosted on a web server which is located in the CHR computing center. This web server uses a SHA 2 SSL certificate to encrypt the data transferred between the server and the end user's web browser. The database backend of REDCap is located behind the CHR firewall. Both web and backend servers are protected and are monitored for any unusual or malicious activity. REDCap uses user rights settings that uniquely identify each user and log their activities. These internal security settings determine the access and privileges of the signed in user. The study team has also obtained a Data Transfer Agreement with Project Access NOW, which covers the above-mentioned data points and was executed by CHR and Project Access NOW on Nov. 9, 2018. KP PHI may be stored on Project Access NOW-owned devices, which are encrypted, or will be stored on Clara, a HIPAA-compliant cloud-based storage. PHI will not be stored on devices that are not behind a firewall or hard copy file format. In the rare circumstances that KP PHI needs to be stored in a hard copy file format, it would be stored per policies and procedures of Project Access NOW. Transmission of KP PHI will occur via telephone or encrypted email communication between Project Access NOW and community-based agencies that house the community health workers to facilitate the referral that is currently already happening as clinical practice within the Regional Community Health Network, which KPNW is a member. Project Access NOW policies and procedures prohibit the use of removable storage media and PHI will not be transported in a hard copy file format. Project Access NOW also has policies and procedures in place to address the minimum necessary rule as well as controls in place to limit access. They also have mechanisms for determining if PHI has been inappropriately or illegally accessed, used, disclosed, or modified. Project Access NOW staff may remotely access KP PHI on their owned devices, which are encrypted.

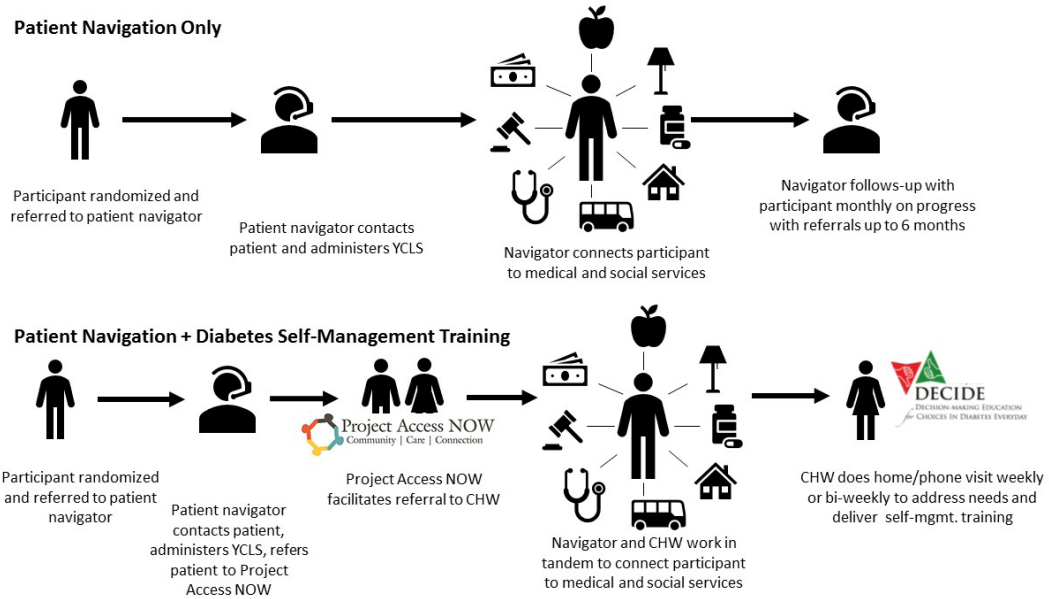
The CHW will follow-up with the participant to conduct a home visit and follow-up on community-based referrals already placed by the KPNW patient navigator and assess for additional needs. The timing of the

diabetes self-management training will be based on the needs of the participant. The Decision-making Education for Choices in Diabetes Everyday (DECIDE) program is a nine-module, literacy adapted diabetes and cardiovascular disease education and problem-solving training program. Participants are taught the five steps of problem solving with each module going in depth on a single step: 1) identify the problem; 2) brainstorm possible strategies for problem resolution; 3) select the most appropriate strategy; 4) apply the strategy; 5) evaluate the effectiveness of the strategy. During the six months, CHWs will have weekly or bi-weekly contract with participants in-person or by phone to deliver the DECIDE modules and address social and economic needs. Based on the participant's availability or preference, the modules may also be administered via video (e.g., Skype or other video conferencing program used by the CHWs agency) or over the phone. There may be cases when a CHW may not be able to continue meeting with a participant in-person or via phone. For those instances the participant will be provided hard copies of the intervention material and a designated study staff member will conduct monthly check-in calls to review the material and address any questions that the participant may have.
For training and quality assurance purposes, CHWs will be randomly identified by study staff to audio-record their sessions with study participants. The selected CHW will be provided with an audio recorder and asked to record the entire session. The CHW will also confirm that the study participant agrees to being recorded. Once the recording is complete, the CHW will keep the audio recorder in a bag carrier marked 'confidential' and physically deliver the recorder back to study staff in a secure manner within 48 hours of conducting the recording. These audio recordings will not be transcribed and only be reviewed by pertinent study staff. Relevant feedback from the recording will be provided to the CHW for training purposes. Any documentation drafted related to the recordings will be de-identified. When the study is complete, the recordings will be destroyed and removed from the audio recorders.

Qualitative interviews will be conducted with various stakeholders to assess intervention acceptability and several implementation domains including intervention burden, professional interactions (referral processes and communication across different levels of care), and capacity for organizational change. Preliminary

effects on A1C, diabetes-related care gaps, health care utilization, and medication adherence will also be examined.

The two treatment arms are summarized in the figure below.



5. Study Population

For Phase 1, using the electronic health record system at Kaiser Permanente Northwest (KPNW), we will identify patients that meet eligibility criteria.

Inclusion criteria:

- *Diagnosis of diabetes*
- *Current Kaiser Permanente Northwest member*
- *African American, Hispanic/Latino (English, Bilingual, or Spanish speaking only), and/or a Medicaid recipient (from any racial or ethnic background)*
- *Age 18 or older*
- *Most recent hemoglobin A1C ≥ 8%*

Phase 2 Inclusion criteria:

- *Diabetes diagnosis*
- *Current Kaiser Permanente Northwest member*
- *African American, Hispanic/Latino (English, Spanish-speaking, or bilingual), and/or a Medicaid recipient (from any racial or ethnic background)*
- *Age 18 or older*
- *Most recent hemoglobin A1C test of ≥ 8*
- *Endorses 1 or more social and/or economic need on the YCLS*

Because patient-level socioeconomic status (SES) is not captured in the EHR, we will identify eligible patients based on SES using their health insurance coverage type, Medicaid.

Exclusionary criteria:

- *Patients who are unable to provide verbal informed consent due to cognitive or psychiatric impairment*
- *Patients with a HIV+ diagnosis*

Phase 3 Inclusion criteria:

- *Current Kaiser Permanente Northwest member*
- *Age 18 or older*
- *Identifies as Asian American, Pacific Islander, Native Hawaiian, and Alaska Native*
- *Most recent hemoglobin A1C ≥ 8%*

a. Vulnerable Populations

African Americans, Hispanics, and Medicaid recipients with poorly managed diabetes who will be recruited for this study certainly meet the general definition of 'vulnerable population' given that they represent the disadvantaged sub-segment of the community requiring high quality care and special considerations and protections in research. We will follow a strict protocol in terms of confidentiality. We will not intentionally target or include data from members of other vulnerable populations such as children, pregnant women, prisoners, or employees.

b. Setting

KPNW is a non-profit, group model integrated health care system that provides comprehensive prepaid health care to its more than 550,000 members in southwest Washington and northwest Oregon. It owns and operates two hospitals, contracts with six other local hospitals, and maintains 22 medical clinics (17 with primary care). All patient contacts within the system and all services referred outside are recorded in a single, comprehensive electronic health record (EHR, KP HealthConnect, based on Epic®) that has been in place since 1996. Health and health care utilization data is stored in the Virtual Data Warehouse (VDW), which is maintained by the Kaiser Permanente Center for Health Research. The VDW provides a standardized, distributed data warehouse for the EHR and other clinical and administrative informatics systems employed by the health system. The VDW includes files for all encounters (outpatient and inpatient), vital signs, pharmacy fill data, problem lists and encounter diagnoses, procedures, and laboratory results.

c. Informed Consent Waiver and HIPAA Privacy Rule Waiver of Authorization

Because Phase 1 is a data-only study, we request a waiver of written and signed consent as well as HIPAA authorization for the study to extract participant data from the EHR (e.g., demographics, primary language spoken, contact information, clinic paneled to, vital signs, labs, diagnoses, encounters). At enrollment KPNW members are informed that their medical records may be used for research and that they may choose to opt out of such research; CHR maintains a registry of members who have asked not to be included in research or to have their records used, or both.

For Phase 2, we also request a waiver of written and signed consent as well as HIPAA authorization. Verbal informed consent by the participant will be captured and recorded in REDCap by study staff during the initial recruitment call and after study eligibility has been determined. No study activities or data collection will be gathered until after verbal informed consent has been obtained.

For Phase 3, we are also requesting a waiver of written consent as well as HIPAA authorization for the study to extract participant data from the EHR (e.g., demographics, clinic, primary language spoken, medical diagnosis, most recent A1C, most recent blood pressure measurement, BMI, insurance coverage, existing YCLS data, and social diagnosis codes).

6. Procedures

For Phase 1, the study team will conduct a data-only study to determine the number of eligible patients from Kaiser Permanente Northwest (KPNW) and the most common clinic service area where these patients receive primary care. Results from this data-only study will inform Phase 2, which is a RCT. We plan to extract the following variables from the EHR:

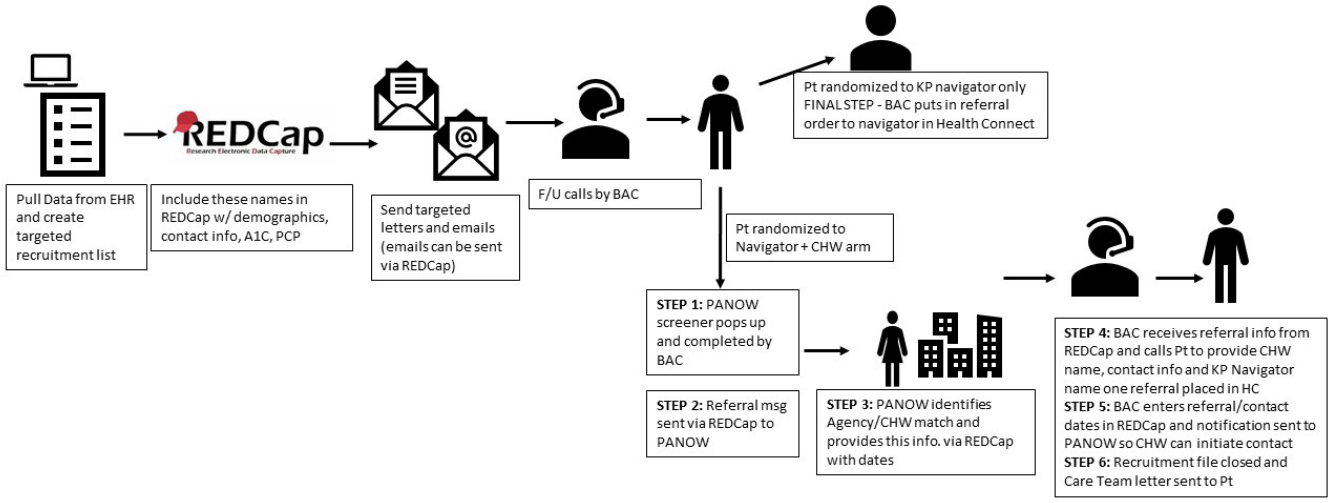
- *Demographics*
- *Contact information*
- *Zip code*
- *Clinic paneled to*
- *Primary language spoken*
- *Any Mental health diagnoses*
- *Health care utilization*
    - *Outpatient encounters*
    - *Inpatient encounters*
    - *ED visits*
    - *Navigator visit*
- *Vital Signs*
- *Labs*
- *Medical diagnosis*
- *Existing YCLS data from the VDW*
- *Social diagnosis codes*
- *Insurance coverage*

For Phase 2, the study team will utilize the KPNW EPIC system to identify potentially eligible patients who meet study criteria. The study team aims to enroll 100 participants and randomize 50 participants to each study arm. After eligible patients have been identified, using REDCap, we will send targeted emails and for those who do not have an email address listed, we will send targeted letters via regular mail. The email/letter will provide an overview of the study and provide the study number for potential participants to call-in and enroll if eligible. One week after sending the emails/letters, bilingual recruitment staff will contact potential participants by phone to follow-up on the email/letter and describe the study and enroll those interested. If study staff are made aware that an interested participant will be unreachable (i.e., out of town) after randomization, the individual will not be randomized until their schedule permits availability to participate in the study, applicable for both study arms. After consent has been captured, enrolled participants will be randomized to one of the study arms. Enrolled participants will receive a thorough explanation of what the randomization process entails, as well as the differences between the two study arms. Data collection, which consists of the administration of the Your Current Life Situation (YCLS) will occur at the Baseline and 6-month follow-up calls. During the Baseline call, study participants will also be provided with contact information to the 211info organization to serve as an additional contact for helping individuals navigate and connect with local resources.

The study team is partnering with Kaiser Permanente Northwest to ensure that we are also targeting those KPNW members who meet study eligibility criteria and have been identified by the Region as being high-risk/ high utilizers in need of intensive case management. To ensure that we are aligning our efforts with similar initiatives simultaneously occurring in the Region, we will share our list of identified eligible KPNW members with the Kaiser Permanente Northwest analyst. The analyst will in turn provide us with the saber score (indicator of high-risk/ high utilization severity) and probability of their diabetes being out of control in the next month (i.e., A1C ≥ 8%) We will use this additional information to prioritize these members for recruitment in Bridge to Health as we try to align with

similar initiatives in the Region. The study team has already submitted a Data Transfer Request form and received approval to share the dataset via the CHR Secure File Transfer site. We also want to ensure that the KPNW region is aware of which members are participating in the study, so they do not receive duplicate services or are contaminated by any clinical interventions being rolled out. At the end of recruitment, the study team will send a designated health system staff a list of enrolled participants who are either African American or receiving Medicaid coverage via the CHR Secure File Transfer site.

The recruitment and randomization process are summarized in the figure below.



For Phase 3, the study team will extract data from the EHR on KPNW members who identify as Asian American, Pacific Islander, Native Hawaiian, and Alaska Native. Data to be extracted includes demographics, clinic, primary language spoken, medical diagnosis, most recent A1C, most recent blood pressure measurement, BMI, insurance coverage, existing YCLS data, and social diagnosis codes. Because racial/ethnic identity information is often missing in the EHR for individuals with this background, we will also work with KP Community Health to get a list of Compact of Free Association (COFA) members who receive premium assistance from KPNW.

7. Privacy, Confidentiality, and Data Security

All KPNW employees receive extensive annual training in privacy protection and HIPAA rules. CHR follows strict procedures to assure the security and integrity of all study data. All research databases include only study ID and no personal identifiers; the medical record number is not included in either study databases or the main CHR research data warehouse; only selected analysts can link back to the medical record. Access to project data is restricted to authorized personnel, password-protected, and closely monitored for intrusion. All CHR staff, and any outside investigators working with CHR data, are annually required to review CHR's

policies on data confidentiality and research ethics and to sign a statement saying that they agree to abide by these policies.

In addition, to reduce any risk of disclosure of confidential information, participants' privacy and confidentiality will have been ensured by:
(1) securely storing all identifiable data in password-protected files and directories on investigator computers within firewall-protected networks.
(2) removing or obscuring participant names and identifying features prior to any presentation, publication, or other sharing of data outside the research team, except with the express written consent of the subject(s).
(3) granting access to unmodified data (containing identifying data or features) only to members of the research team or the patient's care team working under the direction of the investigators for the duration of the project.

EHR data for eligible patients will be accessed and utilized for verifying study eligibility and recruitment purposes. A crosswalk will be created to link the patient names and MRNs with a unique study identification number that will be tracked in REDCap. The crosswalk linking the patient names and MRNs with the study IDs will be kept in a secure study file.

For the qualitative component of the study, patient interviews will be recorded on encrypted devices. All media files will be downloaded to a secure file service and the recordings will be deleted from the password-protected audio recorders.

8. Risks and Benefits

a. Risks to Subjects

The most serious risks for Phases 1,2 and 3 is a breach of confidentiality. This could happen if, for example, confidential information, collected by CHR staff or extracted from the electronic health record during the course of the study was inadvertently disclosed to personnel other than the study staff. All persons employed by KPNW Center for Health Research (CHR) sign a written pledge every year not to reveal information about individual records that is any way traceable to a specific person or group of persons participating in research studies. Since its founding 50 years ago, CHR has had an excellent record of using these data systems for research without breach of confidentiality. No individual-identifying data will be published or released, and data will be summarized and presented in public forums only in de-identified or aggregate form. CHR actively monitors for signs that the data systems have been infiltrated.

<u>Phase 2</u>. Because the purpose of the two intervention arms, patient navigation only and patient navigation + diabetes self-management training, is to connect patients to social services and educate them about how to better manage their diabetes, we believe that these interventions carry no incremental health risks. That is, we believe the study carries no individual level health risks above and beyond what might be expected as part of usual care. Indeed, usual care can include referral to similar services and programs; the difference is the extent and ongoing nature of navigation and support.

b. Potential Benefits to Subjects

There are no potential benefits to participants for Phase 1 and Phase 3 of this pilot.

<u>Phase 2</u>. Participants assigned to either intervention arm will benefit from connection to services to address medical, social, and/or economic needs as well as the opportunity to improve their diabetes management and reduce risks for complications. As previously mentioned, we believe that these interventions carry no incremental health risks and the potential benefits of participating far outweigh any possible risks.

9. Costs to Participants

There are no cost to participants in this study.

10. Compensation to Participants

For Phase 2, participants who complete the YCLS assessment at both Baseline and 6-month follow-up, as well as complete an A1C test near the 6-month follow-up, will receive a $50 gift card as an incentive for their participation. For participants who do not complete the YCLS at the 6-month follow-up, but complete their A1C test or vice versa, we will provide them with a $25 gift card. For those participants who complete a qualitative interview, a $25 gift card will be provided for their participation.

PROPOSED STUDY TIMELINE – Anticipated Start Date 09/20/18

	Year 1				Year 2			
	Q1	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
SET UP PERIOD								
IRB approval to begin team meetings and develop study protocol, tracking systems for recruitment, and recruitment materials								
Develop study protocol and tracking systems for recruitment and other process data								
Develop recruitment materials (e.g., targeted emails, fliers, phone scripts)								
Full IRB approval								
RECRUITMENT (Goal = 100 participants)								
RANDOMIZATION								
INTERVENTION DELIVERY (6 months)								
DATA COLLECTION								
Qualitative interviews								
Obtain 6-month A1C measure in health system clinic lab; completion of YCLS at 6-month follow-up								
Data extraction of utilization measures from electronic health record								
DATA ANALYSIS								
WRITING/PUBLICATIONS								
PREPARE R18 SUBMISSION								

YCLS = Your Current Life Situation

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