PROTOCOL TITLE: Tribal Home-Based Kidney Care Study

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1. Objectives*

Recently, through Patient Center Outcomes Research Institute (PCORI) funded home based kidney care (HBKC), UNMHSC IRB 10-249, we (Shah) established a model for delivering kidney care in Zuni Indians with the following innovations: (1) it is the first HBKC system for the diagnosis and management of CKD in high risk minority populations that was designed in collaboration with tribal community leadership and local Indian Health Services (IHS) providers; (2) it prioritizes patient preferences in their health care by using individualized curricula for CKD intervention; (3) it has as its primary outcomes patient activation measures and adherence; (4) it combines community health representatives (CHRs) with point of care (POC) technology and text messaging to deliver state-of-the-art care; (5) it incorporates the culture and traditions of the community, and (6) it employs a patient-centered approach leveraged with CHRs, IHS physicians, and expertise from an academic medical center.

The HBKC study demonstrated that many of the Zuni patients with diabetes and CKD experience significant stigmatization when they are diagnosed. We demonstrated that a home-based, CHR-implemented educational intervention using POC testing and individualized therapeutic goals significantly improves compliance with care and metabolic parameters relevant to CKD and diabetes, including microalbuminuria, A1C, and lipid concentrations.

In order to test the HBKC model used in Zuni Pueblo, our OBJECTIVE is to extend our culturally specific, CHR-led evidence-based community screening and intervention model into other high-risk communities of Native Americans in New Mexico. We are partnering with the Albuquerque Area Southwest Tribal Epidemiology Center (AASTEC) and its parent organization the Albuquerque Area Indian Health Board, Inc. (AAIHB). Our proposed aims are to compare effectiveness of *multidisciplinary HBKC interventions* to bolster patient levels of kidney specific knowledge, self-efficacy and CKD self-management, enabling Native Americans to carry out the recommendations in a culturally sensitive way.

Aim 1: Screen 600 participants from *four different American Indian tribes* in New Mexico utilizing Point Of Care (POC) testing, to identify incident cases of CKD and identify participants for the proposed study of HBKC;

Aim 2: Conduct a 12 month study of HBKC among 240 Native Americans randomized in a 1:1 allocation to HBKC group versus *Delayed Intervention* (DI) group to demonstrate improvement in Patient Activation Measures (PAM) and adherence to treatment. We will demonstrate that CKD clinical risk profiles will improve with HBKC as compared to DI at 12 months and 4 months post intervention (16 months);

Aim 3: To demonstrate that HBKC will improve psychological factors that map onto important cultural variations in treatment efficacy and health outcomes. Specifically, we will show improvement in potential mediators (treatment engagement, self-efficacy, coping and increased knowledge) and moderators (stigma, and chronic stress, and depression) of health disparity and outcome.

Novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) OR COVID-19 related Addition: The aim of this addition activity is to track the impact of the COVID-19 epidemic on participants with diabetes and chronic kidney disease (CKD). We are requesting a modification to the HBKC Study protocol to expand data currently collected from study participants to include data in the following domains linked to the COVID-19 epidemic: symptoms of COVID-19 disease, access to healthcare, and impact on health related behaviors (such as medication adherence, physical activity, dietary behaviors, smoking, and alcohol use).

Specific Aims
Aim 1. Develop a phone-based and or mail based survey to understand the impact of COVID19 on patient-reported outcomes for adults with diabetes and CKD.
Aim 2. Test the feasibility and acceptability of this phone-based and or mail based survey in the HBKC cohort.

2. Background*

Health Promotion: The Institute of Medicine (IOM) landmark report, Unequal Treatment, provides compelling evidence that racial/ethnic disparities persist in medical care for a number of health conditions and services including chronic kidney disease (CKD) [1]. Furthermore, the IOM identified America's top 100 priorities for comparative effectiveness research[1]. Among the top 25 were the following two priorities that will be directly addressed by our current protocol: (#15) compare the effectiveness of various strategies (e.g., clinical interventions, selected social interventions, combined clinical and social interventions) to prevent chronic disease in at-risk populations such as the urban poor and American Indians (AIs), and (#22) compare the effectiveness of interventions (e.g., community-based multi-level interventions, simple health education, usual care) to reduce health disparities.

Furthermore, Healthy People 2020 identifies elimination of health disparities as an urgent need and features 467 science-based objectives and 10 Leading Health Indicators to address disparities[2]. This protocol will address three of the ten Leading Heath Indicators; including clinical preventive services such as routine disease screening, healthcare access and health activities / behaviors including physical activity, over-weight and obesity. Given the existence of firmly-entrenched and rapidly increasing health disparities, novel approaches are needed to improve the health of socio-economically disadvantaged minorities including American Indian communities. One innovative approach is to build community capacity to promote community-wide health activities and campaigns for healthier lifestyles[2]. Community leaders can lead the way by forming alliances between tribal programs, schools, youth groups, elders and traditional healers to advocate for community-friendly health programs, and by supporting health policies and programs that respect values and culture. Our protocol builds upon a strong existing partnership between Albuquerque Area Southwest Tribal Epidemiology Center (AASTEC), its parent organization the Albuquerque Area Indian Health Board, Inc. (AAIHB), –four tribal communities in the IHS Albuquerque Area, and the University of New Mexico Health Sciences Center to address paramount chronic disease priorities in the community.

Disruptive Innovation in Health Care: Significant changes are occurring throughout the healthcare industry. As hospitals and health systems develop their strategies, they need to determine how to adapt to these changes to be successful in an environment that is moving from fee-for-service payments to pay-for-performance models. Our proposal is engaged in disruptive innovation - a term coined by C Christensen and K Clark[3]. Disruptive innovation can transform an existing care delivery models or create a new health care models by making processes simpler and improving access. The patient activation as the primary out-come of our protocol focuses on engaging patients in their healthcare decisions whereby we will use a home-based kidney care (HBKC) model delivered by tribal community health workers to give us and patients access to patients' individual health information at the point of care. The HBKC model will help patients visualize their condition and treatment options and will encourage their involvement in their own care. For example, for a patient with diabetes or CKD, the tool would use the patient's data to estimate the likelihood of developing other health complications and the likelihood of different interventions to prevent these complications. The HBKC model "helps the patient understand what the patient's role is in shared accountability in a way that's not just general statistics; it looks at what is patient risk based on their data". It makes it more real, and the information more accessible. It helps take the dialogue in joint treatment planning between the tribal community health worker, commonly referred to as community health representatives (CHRs), and the patient to another level. Our disruptive innovations of HBKC delivered by CHRs with POC testing and patient preferences uproot existing systems in favor of new approaches that simplify processes and reach new understanding of patient care.

Chronic Disease Burden in Disparity Population of American Indians: The percentage of adults who do not participate in regular physical activity is higher among AIs (46%) than the US population as a whole (40%), and the prevalence of type II diabetes is 16.1% among AIs.[8] Prevalence of proteinuria is also higher among AIs than among the white population[9]. Furthermore, the incidence rate of diabetes related End-Stage Renal Disease (ESRD) is 3.5 times as high in AIs as in the general U.S. population[10]. AHRQ-funded research has shown that AIs with diabetes often face economic barriers to treatment and are reluctant to place their own medical needs over needs of family members. Other common barriers include: a distrust of insulin therapy; a preference for more familiar traditional remedies; and a fatalistic acceptance of the disease [11].

CKD is common, harmful, treatable and frequently unrecognized until its latter stages. CKD is a national health problem affecting over 31 million Americans [12] with 9 out of 10 people with stage 3 CKD unaware that they have it [13]. Racial and ethnic groups such as AIs are at greater risk for kidney failure. The risk for AIs is 2 times as high relative to non-Hispanic Whites[14]. Nearly 600,000 of these patients are being treated for ESRD[15]. ESRD, a debilitating disease associated with decreased quality of life, resulted in Medicare costs of $29 billion (6.7% of total Medicare budget spent on less than 1% of the patient population)[16]. Delayed referral of patients with progressive loss of kidney function increases health expenditures[17]. Our protocol directly addresses this important disparity in chronic disease, with emphasis on improving patient activation and adherence to prevent progression of CKD.

The prevalence of overweight, obesity and type II diabetes among the study population is disproportionately elevated. Specifically, among AI adults age 18 and over in the Indian Health Service (IHS) Albuquerque Area, 51.0% have a BMI > 30, which significantly exceeds the rate of obesity observed nationally (35.3%) and the Healthy People 2020 target of 30.5%[2,18]. Likewise, the rate of type II diabetes (22.8%) among the adult AI population in our area is almost three times the rate of the U.S. adult population (8.3%)[19], and the age-adjusted diabetes mortality rate for AI/ANs was 104.7 per 100,000 compared to 23.1 per 100,000 among non-Hispanic Whites (NHWs) in the region[20]. At the same time, the median age of diagnosis of type 2 diabetes among AI adults was much younger (42.2 years) than the national average (53.8 years)[18]. Poor management of type 2 diabetes is also common among AIs in the IHS Albuquerque Area, where only 44% of AIs with type 2 diabetes had their blood pressure under control (130/80) and only 33% had ideal glycemic control (HgA1C less than 7.0)[21]. AI adults in the IHS Albuquerque Area with type II diabetes also demonstrate extraordinarily high rates of chronic kidney disease (mean=16.9%, range by Tribe=10.0% - 38.3%), hypertension (mean= 69.4%, range by Tribe=65.3% - 75.7%), and BMI > 30 (mean=63.8%, range by Tribe=59.5% - 75.6%)[18]. Consequently, there is a critical need to intervene with AI in our service area to prevent complications such as CKD, slow the progression of CKD to ESRD, and improve the management of type 2 diabetes.

Innovation and Theoretical Aspects of Chronic Care Model**:** The Chronic Care Model (CCM) re-orients healthcare practice to promote a systematic, planned approach by emphasizing productive interactions between informed, activated patients, their families, and proactive healthcare teams.[31] A central tenet of this concept is that healthcare workers cannot achieve optimum outcomes when working alone. Rather, desired outcomes are achieved when communities and healthcare organizations work together toward shared goals, as proposed in this application. Our innovative educational / behavioral HBKC intervention hinges on the coordination of four key elements: (1) delivering healthcare that incorporates collaborative communication within the healthcare team and emphasizes greater autonomy in care, adherence to the medical regimen, and patient-centered goal setting, all while retaining the ability to address the needs of patients, family members, the healthcare team, and/or the healthcare system; (2) providing innovative educational and organizational approaches, as well as behavior change strategies, that will enhance adherence; (3) addressing health beliefs that reduce adherence by over- or under-predicting maladaptive thoughts (e.g., catastrophizing, minimizing, cognitive dissonance, invincibility, or fatalism) or that interfere with lifestyle changes; and (4) using technology to address barriers to achieving desired health outcomes. The proposed HBKC model described in this protocol is innovative in the following ways: (1) it is the only home based paradigm that has resulted from active collaborations with tribal community leadership and local providers for the diagnosis and management of CKD; (2) it prioritizes patient preferences and uses individualized curricula for CKD intervention; (3) it includes Patient Activation Measures and adherence as primary outcomes; (4) it uses Community Health Representatives (CHRs), who are provided with state of the art tools to achieve the desired outcomes, such as POC technology, text messaging and telemedicine, ultimately delivering evidence-based care to a very high risk population in a cost efficient manner; (5) it incorporates the culture and tradition of the participants; and (6) it may serve as a model

for other racial and ethnic groups in rural and urban locations that suffer from health disparities.

Preliminary data / experience: PI, Shah as a health services researcher for more than 17yrs has been involved with the Zuni Kidney Project (ZKP) and the Zuni Health Initiative (ZHI) funded consecutively by NIH and PCORI (RO1DK49347, 5UO1 DK57300, RO1 DK073665-01A1, 5UO1 DK066660, 2P20 RR016480 and 2P20 RR016480-09S1 - ARRA supplement, and PCORI)[59-68]. The ZKP conducted a population-based survey which demonstrated extremely high age-adjusted prevalence estimates for renal disease and related co-morbidities, including hypertension, obesity, T2D, albuminuria and low estimated glomerular filtration rate. The ZHI started in 2009 as an educational program to identify barriers to health care, evaluate knowledge and perception of diabetes and measure health literacy among Zuni Indians along with conducting patient activation in chronic diseases (obesity, diabetes, kidney disease) management. The PCORI funded pilot study of home-based kidney care is the latest on-going study of patient activation measure as primary outcome.

PCORI supported Home-base Kidney Care Study in Zuni Individuals with CKD: In our previous study of home-base diabetes care in Zuni, we demonstrated that an innovative, six month, patient-centered intervention of empowering T2D patients to become active participants in their care resulted in improved diabetes outcomes[28]. We reported increase in "patient activation measure (PAM)" by at least one level in 58% of T2D participants, while 40% of participants who started at higher baseline PAM score did not change. Six months after intervention, mean levels of A1C decreased by 0.7 ± 1.2%; fasting blood glucose by 24.0 ± 38.0 mg/dl; BMI by 1.5 ± 2.1 kg/m2; total cholesterol by 12.0± 28.0 mg/dl; and tri-glycerides by 52.0 ± 71.0 mg/dl. All of these changes were statistically significant ($p<0.05$).

3. Inclusion and Exclusion Criteria*

We will screen a total of 600 willing participants in four of the American Indian communities in New Mexico. We have presented the study to American Indian communities across New Mexico at meetings of the Albuquerque Area Indian Health Board, Inc. (AAIHB) Board of Directors and the Albuquerque Area Southwest Tribal Epidemiology Center (AASTEC) Executive Council. Four communities expressed interest in the study and possessed the necessary criteria for inclusion – tribal leadership approval to participate, direct access to a local Tribal/IHS health facility, and a large enough population (2,000 + tribal members and >150 members with T2DM) to ensure that the study is sufficiently powered. These four communities include Acoma Pueblo, Laguna Pueblo, Jicarilla Apache and Santo Domingo (Kewa) Pueblo. Formal documentation of tribal leadership approval from three of these communities have been obtained and the final supporting document will be submitted to the IRB upon receipt. We will measure blood pressure, height, and weight and waist circumference. We will determine the albumin: creatinine ratio in a spot urine sample and measure HbA1c and serum creatinine to classify patient for CKD.

Inclusion Criteria include: The study will incorporate male and female community members: (1) live in a household with ≥ 1 participant; (2) age 21 to 80 years; and (3) negative pregnancy test in women of child-bearing potential; diagnosed diabetics or HbA1c >7, (4) BMI >27 kg/m2 and UACR of >/= 30

Exclusion criteria include: (1) life expectancy < 1 year; (2) pregnancy or absence of reliable birth control in women of child-bearing potential; (3) malignancy except non-melanoma skin cancer; (4) blind; (5) ESRD and on dialysis; (6) kidney transplant recipient; and (7) unwilling or unable to give informed consent.

4. Study-Wide Number of Subjects*

We will screen 600 participants from four different American Indian tribes in New Mexico to identify incident cases of CKD and identify participants for the proposed study of HBKC.

We will also conduct a randomized controlled trial of home based kidney care (HBKC) versus control delayed intervention (DI) in 240 of eligible participants who live in a household that has ≥ 1 participant with CKD. We will randomize households in a 1:1 allocation to HBKC vs control DI. In the usual care arm we will measure blood pressure, height, and weight and waist circumference and determine the albumin: creatinine ratio in a spot urine sample and measure HbA1c and serum creatinine at the beginning and end of the 1-year intervention. In the HBKC and control arm we will measure the same variables plus lipid profiles and inflammatory markers at baseline, six months and 1 year.

Estimated number of potentially eligible study participants (describe how this number was determined [e.g., EHR, claims data, clinic logs, administrative data, other]):	Each Tribe's population averages 2,000 members and as per IHS database, >150 participants with T2DM will be eligible for the study.
Total number of study participants expected to be screened:	600 (150 in each Tribe)
Total number of study participants expected to be eligible of those screened:	306
Target sample size (use same number stated in milestones):	240
If applicable, total number of practices/centers that will enroll participants:	4
Projected month first participant enrolled (month after project initiation):	3
Projected month last participant enrolled (month after project initiation):	20
Projected rate of enrollment (anticipated number enrolled per month of enrollment period):	75/month for screening. 30/month for the intervention

5. Study-Wide Recruitment Methods*

We will use a combination of clinic and community-based approaches to inform Tribal members of the study. We will utilize the IHS Diabetes Audit to identify patients who are likely to meet the study eligibility criteria (i.e., age 21 to 80 years; and diagnosed diabetics or HbA1c >7, UACR > 30 and BMI >27 kg/m2.). These individual will receive a mailing with information about the study and a culturally appropriate brochure that highlights the relationship between diabetes and chronic kidney disease. Two follow-up letters will be mailed in 3 week increments and the CHR will also make home visits to non-responsive individuals. Clinic providers will also be encouraged to provide information about the study to potentially eligible tribal members who present at the clinic during the study period until full enrollment is achieved. Community-based approaches to inform other Tribal members about the study will include community meetings, posters, health fairs, and notices in the tribal newspapers/newsletters. As previously detailed, this study will employ a full-time CHR in each of the four participating Tribes, who will also serve as community-based messengers about the study and will be available to answer specific questions that emerge from tribal members in real time.

Study recruitment will proceed as follows within each selected Tribe. We will screen up to 150 potential enrollees for participation from each Tribe (n=4) and gather baseline data. We will screen participants for the study by measuring BP, height, weight, HgA1C, urinary albumin to creatinine ratio, and serum creatinine. For patients who are eligible by screening, we will randomize them to either receive the intervention immediately or to receive it on a delayed timeline in a 1:1 ratio. We will continue enrollment and randomization until we have randomized 30 individuals into each treatment arm within each Tribe. The individuals in the immediate intervention group will participate in the intervention program while those in the delayed intervention group will continue with their typical care in year 1. After the first 12 months, participants in the delayed intervention arm will be invited to continue in the study and will receive the same intervention as was supplied to participants randomized to the immediate intervention arm.

All participants participated in the screening will receive a $25 merchandise card and those that agree to participate in the study will receive payments of $50 at baseline, and $25 at 3 months, 6 months, 9 months 12 months and 16 months of the intervention.

6. Multi-Site Research*

Not Applicable

7. Study Timelines*

The study will last 36 months (12 Quarters).

Study Activity	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12
Formative Work, Prepare MOO,	X											

Translate Materials, Obtain IRB Approval and CHR training												
Community education	X	X	X	X	X	X	X	X	X	X	X	X
Recruitment and Screening		X	X									
Enrollment and HBKC intervention		X	X	X	X							
Enrollment and delayed group intervention						X	X	X	X			
Post Intervention Follow-up							X				X	
Analyze Data and Prepare Manuscripts						X				X	X	X
Disseminate Results												X

8. Study Endpoints*

In order to evaluate the degree to which the HBKC model influences CKD risk profiles, and potential mediators and moderators, of health disparity and outcome we will conduct a randomized trial of our intervention. The study will be conducted within four Native American communities in the IHS Albuquerque Area. A randomized block experimental design will be employed. The households will serve as the blocks, and individual participants will be randomized to either the immediate or delayed intervention arms in a 1:1 ratio.

Aim 1 – Primary outcome: The Patient Activation Measure (PAM) and adherence measures;

Aim 2 – Secondary outcome: Changes in clinical phenotypes, including UACR, A1c, body weight, BMI, fasting glucose, blood pressure (BP), plasma lipids;

Aim 3 – Secondary outcome: Changes in quantitative traits such as food intake and scores from mental-health, self-efficacy, and quality of life instruments.

9. Procedures Involved*

Aim 1: Screen 600 participants from four different American Indian tribes in the Southwest to identify incident cases of CKD and identify participants for the proposed study of HBKC. We will hold education sessions throughout the participating communities, including health fairs, Senior and Wellness Centers, Tribal Buildings and IHS facility to update the community on our home-based kidney care study. During these meetings we will offer to screen participants and measure BP, height, weight, HbA1c, UACR, serum creatinine and compute eGFR. All recipients who are screened will be educated about diabetes, hypertension and heart disease and CKD and counseled concerning healthy life styles and referred to the tribal providers including IHS for appropriate primary care and nephrology follow-up. The screening process will also help us identify potential participants for the study of HBKC, described in this application.

Aim 2: Conduct a 12 month study of HBKC among 240 Native Americans randomized in a 1:1 allocation to HBKC group versus Delayed Intervention (DI)

group to demonstrate improvement in Patient Activation Measures (PAM) and adherence to treatment. We will demonstrate that CKD clinical risk profiles will improve with HBKC as compared to DI at 12 months and 16 months post intervention:

Study Related Testing							
Testing	Screening- ($25)	Baseline Testing for CKD-($50)	3 months- ($25)	6 months - ($25)	9 months- ($25)	12 months- ($25)	16 months- Post-Follow up- ($25)
Consent and HIPPA	x						
Patient Activation (PAM)		x		x		x	
Adherence –Morisky 8		x		x		x	
Kidney Disease QOL -35		x				x	x
Medical History /demographics	x					x	x
Height and Weight	x			x		x	x
Blood Pressure	x	x	x	x	x	x	x
Clinical Labs	x			x		x	
POC testing A1c and UACR		x	x		x		x
hsCRP marker	x					x	
Waist-Hip Ratio	x			x		x	x
Acculturation survey		x				x	
Diet Questionnaire -24hrs survey		x				x	
Educational Group Sessions		x		x		x	
Medication List		x		x		x	
Education Material		x		x		x	x
Educational Intervention Every Alternate weeks only for HBKC with first 3 months of text messaging							

Conduct a 12 month study of HBKC among 240 participants from approximately 160 households randomized in a 1:1 allocation of households to HBKC versus DI to demonstrate that patient activation measure and CKD risk profiles (microalbuminuria, A1c, fasting glucose, plasma lipids, inflammatory markers, body weight, BMI, and blood pressure) will improve with HBKC as compared to DI care among community members with the highly prevalent chronic condition of CKD. DI arm participants will be treated with usual care. Participants randomized to the waiting list will enter the intervention group 12 months after entering the study. Both intervention groups will be followed longitudinally for total of 16 months.

Randomization: All participants who are eligible for the intervention after baseline testing and who consent to participate will receive either HBKC (intervention arm) or delayed intervention (control arm). A randomization list will be generated under the direction of Dr. Pankratz, the study's lead statistician as outlined in the Statistical Considerations section below. The unit of randomization will be the household, and all consenting and eligible members within a given family will be randomized as a block to avoid cross-group contamination. Study staff will not know to which arm a given household will be randomized until after assignment has been made.

Study Testing: All participants will receive study testing at baseline, 6 and 12 months of intervention, as well as at post-intervention follow-up at 16 months as depicted in the table. Testing will occur in the morning after a 10 hour overnight fast and will be conducted at the clinic facility by certified study staff.

Delayed Intervention: Participants randomized to the control group will receive standard lifestyle advice as determined by their provider. They will also attend one group class taught by CHRs in which they will learn basic information about diabetes prevention, weight loss, diet, and exercise consistent with current expert recommendations for a healthy lifestyle, including losing body weight, standard dietary recommendations to reduce calorie and fat intake, and performing at least 150 minutes of moderately vigorous

physical activity per week. DI participants will receive publicly-available literature that reinforces the information given in class, and they will have no other contact with study staff aside from during study data collection visits at baseline and 12 months. After the baseline visit, participants in the DI arm will receive usual care as provided by IHS and/ or other providing hospital. With the participant's consent, all screening and follow-up lab studies will be shared with the participant's primary care physician, and the primary care physician will be notified of any change in the participant's clinical status as noted at the 12 month follow-up visits.

Intervention Arm: For this study, we will train a small and dedicated cadre of four CHRs to implement the home-based intervention. As tribal members themselves, CHRs are especially well suited to aid community members in offering health education and patient navigation services, as well as study specific information, while acknowledging and respecting important cultural considerations. To promote consistent engagement between the CHRs and the study team, the program coordinator will conduct weekly web-based meetings with all 4 CHRs and will also conduct at least one monthly in-person visit with each participating Tribe throughout the intervention period. These meetings will not only maintain rapport between the study team and these critical community stakeholders, but will also provide opportunities to offer technical support and quality control throughout the study. The weekly web-based meetings and monthly in-person visits will allow us to build a cohort effect among the CHRs working across 4 communities. Meeting content will entail 1) review of data collection methods and feedback on any data entry errors noted through our data records checking, 2) refreshers on the study protocol, 3) reinforcement of procedures for maintaining participant confidentiality, 4) review of upcoming modules for home education sessions, 5) debriefing on successful strategies, lessons learned and challenges experienced, 6) troubleshooting any unexpected challenges and/or CHR burdens that emerge during the prior week; 7) offering tangible and social support to all CHRs; and 8) identification and replenishment of needed supplies and resources.

CHRs will make regularly scheduled home visits, described below, and they will have a laptop computer with internet access and telemedicine contact with study faculties for ongoing review of care plans, and management of hypertension, dyslipidemia, and CKD. In a collaborative manner, the participant and healthcare team will set appropriately realistic treatment goals.

All subjects randomized to the HBKC arm will be visited by a CHR in their home at least every two weeks for the duration of the 12 month intervention. All enrolled members of a household unit will attend these visits. Each CHR will be responsible for all eligible participants and up to 60 home visits per month, although this latter estimate is high given that rolling enrollment will occur over a 12 month period. Each visit will last 30 minutes to one hour and will cover curriculum materials agreed upon by the study team and prioritized by the participants. Household visits will occur after-hours if necessary to maximize household participation. Other members of the household who do not have CKD or who are not enrolled in the study will also be allowed to participate in the sessions if they wish, and all subjects will be encouraged to keep their clinic appointments.

Participant preference will be incorporated into the HBKC intervention arm by allowing participants to prioritize the order in which curriculum topic areas will be

emphasized by the CHRs. Topics from currently available NIDDK and IHS kidney education materials will include: (1) Kidney 101, (2) weight management, (3) exercise, (4) healthy eating, (5) medication management, (6) coping with stress, (7) risk factor management (i.e.- blood pressure, hyperlipidemia), (8) alcohol and substance abuse, (9) smoking cessation, and related health concerns. Given the interrelated nature of these topics, we will ensure that each of the curriculum areas will be covered in each household during the course of the 12 month intervention, but topics will be covered in differing order based upon participant preference and relevance to the participant's current situation. Priority lists will be collected from subjects for later analysis as a covariate to determine if attention to "preference" facilitates the successful attainment of therapeutic goals. All sessions will include a brief coaching segment with a personalized review of progress made, problem-solving and goal-setting, as well as a safety assessment. CHRs will implement the intervention in the native language if preferred by the participants. Sessions will typically employ a problem solving approach with specific referral to community resources, as appropriate. We will also employ low-literacy tailored goal-setting and self-monitoring worksheets.

In compliance with COVID-19 safety measures, the study has obtained approved by the funder and our community advisory board for adaptation to a telephone-based intervention model (i.e., delivering the educational sessions via telephone instead of in-person home visits) in communities where tribal leadership has imposed restrictions on home visiting.

Components: Aside from regularly scheduled home visits, participants in the HBKC group will be involved in activities actively promoted by the study investigators and incorporated into individualized treatment plans:

a. Text Reminders & Participant Text Responses*:* CHR generated text message reminders and participant text responses will be utilized to promote adherence to both medical and lifestyle interventions. Participants in the HBKC group will receive weekly text messages from the CHR and be requested to send a text response within 24 hours. Response will be noted in a database. Text message content will be individualized and will offer adherence reminders in cultural- and language-appropriate formats.

b. Peer Support Groups*:* Participants will be offered peer support groups of 4-6 people. This type of "buddy system" has been shown to increase compliance in intervention studies and cross-sectional studies of exercise participation, and it enhances the sustainability of the intervention.

c. Group Didactic Sessions*:* Group sessions will be offered three times during the intervention of 12 months for 30 minutes and will be directed by the investigators, study coordinators and CHRs. The sessions may incorporate components of cognitive-behavioral therapy for weight loss, including self-monitoring of eating and exercise, behavioral goal setting, stimulus control techniques, cognitive restructuring, assertive communication skills, stress management, and relapse-prevention. Group discussions will focus on active problem solving and weight loss maintenance. Sessions will include culturally popular activities (e.g., traditional food, bingo games, eating together as a family, etc.) and will promote group cohesion, modeling of desirable behaviors, and peer support for change.

Group meals will include discussions around taste of the food prepared, the ease of food preparation, and strategies for implementing the recipes at home, acceptability to family and friends, and steps towards trying new eating styles at home. Participants will be provided with handouts for future reference.

In compliance with COVID-19 safety measures, the study has obtained approval from the funder and our community advisory board to conduct the group educational sessions via videoconference. Participants will also have the option to call in if videoconferencing technology is not available or internet connections are unstable.

COVID-19 related enhancement study – methods:
Study population: The study will include all HBKC participants screened.
a. Inclusion Criteria
Inclusion criteria: Willingness to participate in the phone-based and or mail based survey.
Exclusion criteria: none
b. Risks/Benefits
This is a very low risk study. However, there is always the risk of loss of confidentially. Some of the questions may cause some discomfort to the participants.
Participants will not directly benefit from participation in the study.

Methods
1. The attached instrument will be administered to all enrolled study participants by telephone and or mail. This will occur with an initial phone call to all participants in the near future. In addition, for tracking the impact of the COVID-19 epidemic on this study population we will return to the participants later to repeat completion of this survey. In some instances, the telephone contact to implement this survey will be bundled with a previously planned CRIC study visit. If it is not possible to do this at the time of a previously planned visit, the telephone contact to administer this survey will be an additional contact. It is estimated that this survey will take approximately 20 minutes to complete by telephone, a time, which has been found to be acceptable to HBKC Study participants, based on other telephone interactions conducted for the study.
2. Each of the sites will attempt to recruit all active HBKC participants at their site.
3. Study data will be collected and managed using RedCap data system currently in use.

10. Data and Specimen Banking*

All data collected will be deposited into local tribal clinics and patient files kept at the tribal/IHS health facility. All patients will receive copy of their clinical data and anthropometric measurements. A REDCap folder will be created to enter all qualitative (demographics and anthropological measures) and quantitative data set.

We are not banking any biological material for this protocol.

11. Data Management* and Confidentiality

We plan to utilize the REDCap application for data management. REDCap (Research Electronic Data Capture) is a secure, web-based application designed exclusively to support data capture for research studies. REDCap provides: 1) an intuitive interface for data entry (with data validation); 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages (SPSS, SAS, Stata, R); 4) procedures for importing data from external sources; and 5) advanced features, such as branching logic and calculated fields. We recognize the need for strict protection of confidentiality. Participants will be assigned a unique identifier (study ID number). The study ID number will be included on all research records for that study participant. Participants will have the option of having their study results of clinical meaning entered in their medical records. Participant tribal affiliation will also be assigned a unique identifier to ensure equal protection of individual and community identifiers. All staff members will be trained to handle participants' data with confidentiality. Staff will have controlled access to data. Each staff person will be assigned a user ID and a password. Access will be in layers, with appropriate fire walls in place. We will employ a web-based strategy with advanced security techniques. Data entry personnel will be certified. Server, CD, and secure hard copy storage will be available for each site. Information on study participation and study results for individual participants will not be released without the written consent of the participant.

Precautions will be exercised in order to maintain the highest standard of anonymity. Each patient data/blood sample will be given a unique study number that will not be linked in any way to standard HIPAA-related personal identifiers (including tribal affiliation), and importantly, the datasets we receive and will work with are Limited Data Sets in accordance with HIPAA guidelines (stripped of standard identifiers). All data undergo extensive QA/QC before being sent to us from each participating community. No reference to subject name or other personal identifiers that could jeopardize their privacy will appear in the database, or blood samples, in abstracts, scientific papers or other documents that emanate from this study. Importantly, random anonymous identifiers will be used to label blood samples.

We will inform participants of their Point of Care test results (UACR, serum creatinine and HbA1C) verbally and in writing at the time of testing. After the participant has given HIPPA consent, a copy of all testing and clinical measurements (height, weight waist circumference and blood pressure) will be given to medical records at the local tribal/IHS health facility to be placed in the patient's medical record, to the attention of the patient's primary provider.

12. Provisions to Monitor the Data to Ensure the Safety of Subjects*

All CHRs will be provided with mobile tablets to display educational videos during home visits with participants and to administer the scales (Patient Activation Measure, Adherence, Kidney Disease QOL, Diet Questionnaire) at baseline, 6 months and 12 months as outlined in the table on p.10. All mobile tablets will be password protected. The scales will be administered via REDCap, a secure, web-based application designed to support

data capture for research studies. No data will be stored on the tablet, rather all data is inputted directly into the online REDCap platform, which possesses secure web authentication, data logging, and Secure Sockets Layer (SSL) encryption. CHW field staff in each community will perform the initial data entry on recruitment and questionnaire information. The database in REDCap will have automated error checks, such as range checks, during data entry. Data error reports including checks for consistency, logic, and structural & relational integrity will be run monthly. These reports will consist of identified problems and include cross-tables for assessment and comparison of the data entries, with identification of errors. Records will be randomly sampled (10%) for completeness, consistency, and logic by the project coordinator and database manager. CHW Field staff will provide corrections based on the monthly reports and random samples of reviewed records. All de-identified clinical data received electronically in a password protected file from the labs once every month will be adjudicated with the hard copies.

The proposed research involves minimal risk only. However, we will continuously monitor the data. There are potential minor risks to the participant's health if they take part in the study. Only trained and certified staff will perform venipuncture. Participants may get mild pain when we draw the blood. There is a small risk of bleeding, bruising (less than 10%) and infection (less than 1%) in the area where we put the needle. There is no risk from donating a urine sample.

Our protocol includes sharing all clinical and anthropological data electronically with the local providers /clinics (mainly run by I H S). Working along with those local providers we will make sure to have physician assigned to a participant if he/she is not in a system. Participant with the abnormal / critical values will be referred right away to local provider along with the assistance by our CHRs to bring the participant to the local clinic.

We will report the interim and completed project findings to all participants, their health care provider, the funding agency, IHS, IRBs, community advisory panels and tribal council. This reporting will be at least annually (i.e., progress report) with quarterly updates to the community advisory panel.

13. Withdrawal of Subjects*

There are no criteria for study withdrawal other than a participant voluntarily requesting to withdraw.

14. Risks to Subjects*

There are some small risks to participant's health if they take part in the study. Participants may have mild pain when we draw their blood. There is a small risk of bleeding, bruising (less than 10%) and infection (less than 1%) in the area where we put the needle. There is no risk when giving a urine sample. We have established mechanism to protect the confidentiality of participant information. Nevertheless, accidental disclosure of study data may occur. There are no alternative treatments appropriate for this protocol and no circumstances for terminating the study other than declining to participate in the study.

15. Potential Benefits to Subjects*

There may be no direct benefits to the participants. However, participants in this study may benefit individually from earlier diagnosis of Chronic Kidney Disease (CKD). Home based kidney care may result in better control of blood pressure, diabetes and cholesterol. Improving these items could slow down kidney disease. This study may also help future generations and other tribal communities by identifying new ways to manage diabetes and kidney disease. This study may help the participants to be able to make changes in their life-style by educational intervention and get medical care sooner.

16. Vulnerable Populations*

Not Applicable

17. Community-Based Participatory Research*

Valuable tribal input and engagement has already been secured in the conceptualization of this study. The AASTEC Executive Council has established type II diabetes as its top health priority for the 2012-2017 period, and has charged AASTEC with the task of researching innovative, sustainable interventions to ameliorate existing disparities in this health priority area. Likewise, sustainable partnerships have already been established between AASTEC, UNM HSC and the IHS Albuquerque Area Tribes through prior activities in the areas of health research, public health surveillance, community health assessment, program evaluation, and health promotion/disease prevention intervention. These partnerships will be leveraged and strengthened throughout this 3-year project.

The first month of this project will focus on formalizing, strengthening and further developing existing relationships, as well as fostering trust between project partners and developing structures that will guide and support the project. This practice is aligned with established tribal protocols for conducting health research in AI/AN communities. Within each Tribe we will conduct meetings with clinicians, health administrators and CHR program directors to promote broad understanding of the study protocol and recruitment procedures. Because this study is a new initiative, it will be necessary to fully outline the purpose and benefits of the research to the participating Tribes, the study protocol and key activities associated with participation, protocols for data sharing and maintaining confidentiality, and dissemination plans for project data and reports. The AASTEC PI (Dr. English) and project coordinator from AAIHB will travel to each intervention site on a routine basis during the first several months of the intervention period to strengthen rapport and finalize plans for the intervention.

The study team will also receive invaluable guidance from a community advisory panel which will include 2 stakeholders from each of the 4 participating tribes and meet on a quarterly basis (2 in person meetings and 2 virtual meetings). This approach will ensure that our tribal partners are included in the research process from its inception and that

important cultural considerations are taken into account with study activities in each community.

18. Sharing of Results with Subjects*

We will prepare the clinical lab data and some of the anthropometric measures such as blood pressure and give a copy directly to the participant and offer to share them with their doctor. We will also, transfer a hard copy of the lab results into participant's case file at the tribal/IHS health facility.

19. Setting

The patient population for this study will include **four** of the 27 IHS Albuquerque Area Tribes. We have already obtained verbal commitments from the 4 communities and will provide documentation of formal Tribal leadership approval to the IRB upon receipt.

Each of these tribes currently operates a tribal/IHS health clinic/hospital, a CHR program, and a Special Diabetes for Indians Program (SDPI). We will partner with each of these entities in each participating community to identify and recruit potential subjects and implement the intervention.

In addition to the UNM Health Sciences Center IRB, IRB approval will be sought from the Southwest Tribal IRB to further ensure that the study team adheres to all tribal protocols for research.

20. Resources Available

PI Dr Shah is a Molecular Epidemiologist with Health Services Research experience for more than 25 years. He has broad background in basic system biology science research and clinical translational and community based participatory studies in minorities including Native Americans and Hispanics. He has carried out the original cross sectional research in the Zuni Kidney Project with many secondary data analyses on disparity aspects of chronic diseases, in particular diabetes and CKD and its complications. He has served as a PI and or Co-PI on several NIDDK funded grants including: (1) Cytokine gene polymorphism in the CRIC Cohort Study; (2) Zuni Kidney Project; (3) Zuni component of FIND; (4) Genetics of Kidney Disease in Zuni Indians. Currently he is the PI on the UNMHSC component of the NIGMS funded NM INBRE grant and obtained an ARRA supplement to work with minority kids and young adults in educational intervention of life style, diet/nutrition and obesity in preventing chronic disease. In 2013 Dr Shah received a 3yrs pilot funding from PCORI in developing effective measures of chronic diseases among Zuni Indians and delivering home based kidney care in randomized group of participants with CKD.

The community–based PI of this proposed research, Kevin English, DrPH, directs the Albuquerque Area Southwest Tribal Epidemiology Center, which was established in 2006 and is the only tribal research entity that serves all of the 27 Albuquerque Area Tribes. AASTEC is one of twelve Tribal Epidemiology Centers across the country, and is committed to serving the AI/AN population in the Southwest in several core areas, including: health research, tribal community health assessment, public health surveillance, and capacity development. AASTEC is housed within the Albuquerque Area Indian Health Board, Inc. (AAIHB), an intertribal, non-profit organization established in 1977. For the past three decades, AAIHB has been a leader in the provision of culturally appropriate health services research (including cancer control research), health promotion/disease prevention intervention, technical assistance/capacity building and specialized clinical services including audiology and HIV/AIDS prevention education. The AAIHB also operates the Tribal Institutional Review Board (IRB) for all research that occurs among the 27 Albuquerque Area Tribes. The AAIHB offices are located in Albuquerque, which is centrally located among the Tribes it serves and affords access to numerous resources and partners such as the Indian Health Service (IHS) Albuquerque Area Office, the University of New Mexico Health Science Center (UNM HSC), and the State of New Mexico Department of Health. In addition to the aforementioned community advisory panels, the well-established AASTEC Executive Council, which includes tribal representatives from all 27 Albuquerque Area Tribes and two intertribal organizations – AAIHB and the All Indian Pueblo Council (AIPC) – will also provide tribal-specific oversight and guidance throughout all facets of this proposed research. Dr. English also possess vast experience in CHR intervention research, including the design, implementation and evaluation of health promotion/disease prevention intervention research with American Indian Tribes in the Southwest for over a decade. Dr English earned my Doctor of Public Health Degree from Columbia University in February 2013 and was awarded the Marisa De Castro Benton Award for distinguished scholarship and research, and outstanding contribution to the Sociomedical Sciences, worthy of special recognition in a doctoral dissertation entitled " An Exploration of Determinants that Impact Tribal Community Health Worker (CHW) Capacity to Engage in Breast and Cervical Cancer Health Education, Outreach and Patient Navigation Services". In his present position as the Director of the Albuquerque Area Southwest Tribal Epidemiology Center (AASTEC), he leads the design and implementation of a national demonstration program aimed to build the capacity of tribal community health workers to engage in health education, outreach and patient navigation to promote cancer screening in American Indian communities. Dr English's leadership at AASTEC has also entailed the establishment of collaborative partnerships between AASTEC, 27 Southwest Tribes and researchers at the UNM Health Science Center. He possess high standing within each of these environments. Working directly for American Indians within the context of an intertribal organization has allowed him to establish significant rapport and trust with this population where the discovery of culturally appropriate, innovative and sustainable interventions to address persistent health disparities is sorely needed.

21. Prior Approvals

Not Applicable

22. Recruitment Methods

We will use a combination of clinic and community-based approaches to inform Tribal members of the study. We will utilize the IHS Diabetes Audit to identify patients who are likely to meet the study eligibility criteria (i.e., age 21 to 80 years; and diagnosed diabetics or HbA1c >7, UACR > 30 and BMI >27 kg/m2.). These individual will receive a mailing with information about the study and a culturally appropriate brochure that highlights the relationship between diabetes and chronic kidney disease. Two follow-up letters will be mailed in 3 week increments and the CHR will also make home visits to non-responsive individuals. Clinic providers will also be encouraged to provide information about the study to potentially eligible tribal members who present at the clinic during the study period until full enrollment is achieved. Community-based approaches to inform other Tribal members about the study will include community meetings, posters, health fairs, and notices in the tribal newspapers/newsletters. As previously detailed, this study will employ a full-time CHR in each of the four participating Tribes, who will also serve as community-based messengers about the study and will be available to answer specific questions that emerge from tribal members in real time.

Study recruitment will proceed as follows within each selected Tribe. We will screen up to 150 potential enrollees for participation from each Tribe (n=4) and gather baseline data. We will screen participants for the study by measuring BP, height, weight, HgA1C, urinary albumin to creatinine ratio, and serum creatinine. For patients who are eligible by screening, we will randomize them to either receive the intervention immediately or to receive it on a delayed timeline in a 1:1 ratio. We will continue enrollment and randomization until we have randomized 30 individuals into each treatment arm within each Tribe. The individuals in the immediate intervention group will participate in the intervention program while those in the delayed intervention group will continue with their typical care in year 1. After the first 12 months, participants in the delayed intervention arm will be invited to continue in the study and will receive the same intervention as was supplied to participants randomized to the immediate intervention arm.

All participants participated in the screening will receive a $25 merchandise card and those that agree to participate in the study will receive payments of $50 at baseline, and $25 at 3 months, 6 months, 9 months 12 months and 16 months of the intervention.

23. Local Number of Subjects

The table below describes the total subjects screened and CKD cohort identified with the intervention at each site.

Estimated number of potentially eligible study participants (describe how this number was determined [e.g., EHR, claims data, clinic logs, administrative data, other]):	Each Tribe's population averages 2,000 members and as per IHS database, >150 participants with

	T2DM will be eligible for the study.
Total number of study participants expected to be screened:	600 (150 in each Tribe)
Total number of study participants expected to be eligible of those screened:	306
Target sample size (use same number stated in milestones):	240 (60 per community)
If applicable, total number of practices/centers that will enroll participants:	4
Projected month first participant enrolled (month after project initiation):	3
Projected month last participant enrolled (month after project initiation):	20
Projected rate of enrollment (anticipated number enrolled per month of enrollment period):	75/month for screening. 30/month for the intervention

24. Confidentiality

We recognize the need for strict protection of confidentiality. Participants will be assigned a unique identifier (study ID number). The study ID number will be included on all research records for that study participant. Participant tribal affiliation will also be assigned a unique identifier to ensure equal protection of individual and community identifiers. Participants will have the option of having their clinically relevant study results entered in their medical records. All staff will be trained to handle participants' data with confidentiality. Staff will have controlled access to data. Each staff person will be assigned a user ID and a password. Access will be in layers, with appropriate firewalls in place. We will employ a web-based strategy with advanced security techniques. Data entry personnel will be certified. Server, CD, and secure hard copy storage will be available at each site. Information on study participation and study results for individual participants will not be released without the written consent of the participant.

Precautions will be exercised to maintain the highest standard of anonymity. Each patient data/blood sample will be given a unique study number that will not be linked in any way to standard HIPAA-related personal identifiers, and importantly, the datasets we receive and will work with are Limited Data Sets in accordance with HIPAA guidelines (stripped of standard identifiers). All data undergo extensive QA/QC before being sent to us. The primary database will have some personal identifier in order to link the participant with their data. However, no reference to subject name or other personal identifiers that could jeopardize their privacy will appear in the abstracts, scientific papers or other documents that emanate from this study.

25. Provisions to Protect the Privacy Interests of Subjects

Participation in research will involve a loss of privacy, but information about subjects will be handled as confidentially as possible. Representatives of the University of New Mexico Health Sciences Center Human Research Review Committee that oversees human subject research, t or other regulatory agencies such as Indian health Services will be permitted access to subjects' records. Also, subject's participation in the study and information in their study records may be disclosed to their doctors, and may be disclosed as otherwise provided by law. However, subjects name will not be used in any published reports about this study. Hard copy of all study results will be kept in locked cabinets. Electronic copies of study results will be kept in pass word protected files in computers located in offices of study personnel. Only authorized study personnel, representatives of the Southwest Tribal and the Human Research Review Committees of the UNMHSC and participating Tribes and community advisory panels will have access to study results. Study related results and their reporting and publications will be presented to the tribal leadership before dissemination.

26. Compensation for Research-Related Injury

Not Applicable - Minimal risk only

27. Economic Burden to Subjects

Not Applicable – NONE

28. Consent Process

We will conduct screening evaluation which includes (1) personal interview; (2) physical exam; (3) anthropometric measurements (5) serum chemistries; (6) biomarkers. The consent form will be administered to all participants in English, however local CHRs may use the tribal language to describe the content of the consent document. We will not create separate consent form in the tribal language. The consent process will be:

Introduction of field representatives (CHRs) takes 5 minutes.
10 minutes - summary of the project.
3 minutes to explain HIPPA.
15 minutes to explain Consent Form.
35 minutes for completing the Questionnaire.
5 minutes to take client's Vitals.
5 minutes for Blood Draw.
3 minutes for Urine sample.

29. Process to Document Consent in Writing

Not Applicable

30. Drugs or Devices

Not Applicable