Home-based Conservative Care Model for Advanced Kidney Disease

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Abstract

Objective(s) and Hypotheses:
Conservative care (CC) is an important therapeutic option for Veterans who do not wish to pursue maintenance dialysis for their advanced chronic kidney disease (CKD) and offers a whole-person, multidisciplinary approach to care that is focused on slowing disease progression, active symptom management, advance care planning, and provision of appropriate palliative care. Recent evidence from observational studies of CC programs in other developed countries indicate that for older patients (aged ≥75 years) with significant comorbidity and functional limitation, dialysis may not meaningfully lengthen survival or improve quality of life beyond what can be achieved with CC. Although 1 in 7 Veterans with advanced CKD do not pursue dialysis, there are no formal CC programs within the VA and few, if any, concerted efforts to establish these programs in non-VA settings. While formal CC programs do not currently exist in the VA, many of the elements of CC programs found in other developed countries and that are desirable to Veterans, families, and healthcare providers can be found in the VA's Home-Based Primary Care (HBPC) program. HBPC provides home-based multidisciplinary primary care to Veterans with multimorbidity and functional limitation with the goal of supporting Veterans' quality of life and mitigating the complications of illness through to the end of life. The investigators hypothesize that HBPC serves as the ideal starting ground to build the VA's first CC program for Veterans with advanced CKD.

Research Design:
The investigators will conduct a randomized pilot trial of 30 Veterans with advanced CKD, their caregivers, and clinicians to assess the feasibility and acceptability of a novel CC Program, called "Kidney Care at Home Program" for advanced CKD delivered through the existing infrastructure of the HBPC program at VA Puget Sound Health Care System (VAPS).

Methodology:
The investigators will use implementation science and ethnographic research methods, including field observations, interviews, medical record review, and serial surveys to assess the feasibility and acceptability of the Kidney Care at Home Program vs. usual care among Veterans, caregivers, and clinicians.

List of Abbreviations

BEDSCN: bed section

CC: conservative care

CKD: chronic kidney disease

HBPC: Home-based Primary Care

MDC: Multi-disciplinary care

UW: University of Washington

VAPS: VA Puget Sound Health Care System, Seattle WA

VACOIN: VA Center of Innovation for Veteran-centered and Value-driven Care, Seattle WA.

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1.0 Study Personnel

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2.0 Introduction

Chronic kidney disease (CKD) is a progressive life-limiting illness that afflicts 1 in 3 older Veterans aged ≥65 years.[1] The care needs of patients with advanced CKD exceed those of most other patients with chronic illness[2] and are attributable to their high burden of comorbidity[3] and symptoms,[4] frequent hospitalization[5] and progressive loss of physical and cognitive function.[6,7] Although maintenance dialysis can extend survival in many patients with advanced CKD, dialysis also often demands significant lifestyle changes and frequent interaction with the healthcare system to manage the complications of illness and the treatment itself.[5]

Conservative care (CC) is a multidisciplinary approach to caring for patients with advanced CKD who do not wish to pursue dialysis that focuses on slowing the decline in renal function, active symptom management, advance care planning, and the provision of appropriate palliative care.[8] Recent evidence from observational studies of formal CC programs in other developed countries indicate that for older patients (aged ≥75 years) with significant comorbidity and functional limitation, dialysis may not meaningfully lengthen survival[9] or improve quality of life[10] beyond what can be achieved with CC.

There are no formal CC programs within the VA and few, if any, concerted efforts to establish such programs in non-VA settings.[11] In this context, it is not surprising that, regardless of age or comorbid burden, the vast majority (85.5%) of Veterans with advanced CKD are preparing for or are treated with dialysis.[12] When decisions to forgo dialysis do occur, they tend to unfold in a chaotic manner, late in the illness trajectory, and with only a minority (38.7%) of Veterans enrolling in hospice.[13,14]

Many of the elements of CC programs found in other developed countries[8] and considered desirable by Veterans, their families and nephrologists[11,15] can be found in the VA's Home-Based Primary Care (HBPC) program. HBPC provides Veterans with multidisciplinary (MDC) primary care in their home through to the end of life.[16] HBPC enrollees are not necessarily home-bound, but do have the kind of complex multimorbidity and functional limitations that are common among Veterans with advanced CKD.[16] HPBC may reduce Veterans' hospital, nursing home and emergency room use and increase their satisfaction with VA care.[17] Missing from available data is guidance on how HBPC can improve CKD-specific outcomes.

The investigators hypothesize that the MDC framework of HBPC serves as the ideal starting ground to build our nation's first CC program for Veterans with advanced CKD.

3.0 Objectives

The investigators aim to assess the feasibility and acceptability of a novel CC program, called the Kidney Care at Home Program, delivered through the HBPC infrastructure at VAPS among Veterans with advanced CKD, their caregivers and clinicians and explore preliminary outcomes of this CC Program. The investigators hypothesize that our HBPC-based CC model will be feasible and acceptable to Veterans, their caregivers, and clinicians.

4.0 Research Sites

This study will involve VAPS. Study subjects will be recruited from VAPS. Original study data will be stored at the VACOIN. All data analyses will occur at VACOIN.

5.0 Study Procedures

5.1 Study Design

The investigators will conduct a randomized pilot study of Veterans with advanced CKD receiving care at the VAPS, their caregivers and VA clinicians to assess the feasibility and acceptability of usual care versus the Kidney Care at Home Program in caring for patients who do not wish to pursue maintenance dialysis. The investigators will use the RE-AIM implementation science

framework and ethnographic research methods, including field observations of clinical encounters related to their kidney disease, qualitative interviews, serial surveys, and document review. Implementation science frameworks facilitate identification and understanding of the factors that promote uptake, practice, and effectiveness of an innovation (i.e. CC). RE-AIM categorizes factors into 5 domains: 1) Reach; 2) Effectiveness; 3) Adoption; 4) Implementation, and; 5) Maintenance.[18] Ethnography is an immersive form of qualitative inquiry that supports a comprehensive "insider's" understanding of a phenomenon as it is experienced and the "ecosystem" in which care is delivered through multiple data sources and perspectives.[19] It also supports elucidation of processes, such as Veteran-caregiver-clinician dynamics, clinical workflow, and workgroup cultures, that are difficult to capture using objective measures but that are crucial to understanding the pros and cons of different care approaches and environments that might lead to observed health outcomes.

5.2 Recruitment Methods

Veterans: The investigators will access the electronic medical records of patients to identify eligible Veterans for this study and to obtain their name and contact information to contact eligible patients for recruitment purposes. A study team member will pre-screen medical records to identify those for documentation in clinical progress notes indicate that the Veteran does not wish to pursue dialysis. The investigators will contact patients' VA primary care +/- nephrology to inform them that their patient has been identified as eligible for the study and to arrange a time to discuss the study, confirm whether the Veteran does not wish to pursue dialysis, and to inquire whether they agree to the Veterans' participation in the study. If the provider judges that the Veteran is not suitable for the study, the investigators will not approach the patient. Patients will not otherwise be informed about the study, and would not be able to indicate their wish to join the study. Using flyers and faculty meetings, the investigators will also notify VA primary care providers and nephrologists about the study and invite them to refer any eligible Veterans not identified through chart review. The investigators will mail all potential Veterans a letter that introduces the study followed by a phone call to schedule a phone or in-person appointment at VAPS or Veteran's home, per their preference, to discuss the study. During this initial call, the investigators will confirm with Veterans their desire not to pursue maintenance dialysis or kidney transplant. The investigators anticipate recruiting up to 30 Veterans

Caregivers: The investigators will obtain the name and contact information of up to 1 caregiver from each enrolled Veteran to participate in the study. Similar to Veterans, the investigators will mail all potential caregivers a letter introducing the study followed by a phone call to discuss the study and to schedule a phone or in-person appointment at VAPS or Veteran's home per their preference, to discuss the study. The investigators anticipate recruiting up to 30 caregivers.

Interviewed Clinicians: From each enrolled Veteran, the investigators will obtain the names of VA clinicians whom the Veteran has identified as important to their CKD care throughout the duration in the study. The investigators will initially approach clinicians by encrypted email informing them of their Veterans' participation in the study and to arrange a time to discuss the study and invite them to be interview about their perception of the enrolled Veterans' kidney care experience. Based on our prior similar research, Veterans name 1-3 clinicians who are important in their kidney care,[20] therefore the investigators anticipate recruiting up to 90 clinicians for interviews. The investigators also anticipate that interviewed clinicians might include those in the Kidney Care at Home Program if Veterans assigned to the intervention arm desire this. Investigators will not be involved in any recruitment or intervention activities. Only study team members unassociated in a supervisory relationship with HBPC clinicians will be involved in recruitment or study interventions such as interviews or encounter observations.

Observed Clinicians: For enrolled Veterans, the investigators will perform field observations of their clinical encounters related to care for advanced CKD. Patients will choose which encounters they wish observed by a study team member. The investigators will review upcoming scheduled clinical encounters with each Veteran and inquire whether they pertain to care of their advanced CKD and if a member of the study team can observe the encounter. The investigators will also ask Veterans to inform us at their earliest convenience of any ad hoc clinical encounters scheduled that they wish to be observed. Whenever possible, the investigators will contact clinicians at least 2 days in advance of the encounter to inform them of their patients' participation in the study and of the Veteran's decision to have study staff accompany him/her to observe the encounter. The investigators will also add a read receipt notification to emails and secure messages to help ensure that clinicians received our notification about clinical observation. Researchers will speak with clinicians just before the encounter to let them know about the clinical observation and to confirm that they agree with the observation. Given our prior experience with similar research, we anticipate that Veterans will identify encounters from a range of 1-5 different medical specialties that are relevant to their kidney care.[20] The investigators also anticipate that observed clinicians might include those in the Kidney Care at Home Program if Veterans assigned to the intervention arm desire that the investigators observe these encounters. Investigators will not be involved in any recruitment or intervention activities. Only study team members unassociated in a supervisory relationship with HBPC clinicians will be involved in recruitment or study interventions such as interviews or encounter observations.

5.3 Informed Consent

Veterans and Caregivers: During recruitment, the investigators will provide Veterans and caregivers the option of reviewing the study in greater depth in-person at VAPS of subject's home. The investigators will use the consent form as a guide to explain the goals of the study, the study procedures, and potential risks and benefits.

To ensure informed consent, the investigators will use a "teach-back" method in which, after reviewing the study, The investigators will ask Veterans and caregivers a series of true/false questions about key aspects of the study aims, procedures, and potential risks and benefits. Any responses that are incorrect or incomplete will be reviewed with Veterans and caregivers, and they will be asked for responses to missed statements for a second time. The investigators will repeat this teach-back approach a second time if there are aspects of the study that are still not understood by patients and close person. For a Veteran who is unable to provide correct answers after teach-back, the investigators will contact their legal surrogate to seek informed consent to participate in the study on behalf of the Veteran. Caregivers whose responses to statements are still incorrect after 3 rounds would be considered to have inadequate understanding of the study and to be ineligible to participate. Patients whose caregivers fail the informed consent process can still participate in the study, as Veterans can have multiple caregivers and the caregiver whom the Veteran nominates for the study is not necessarily the Veteran's primary caregiver or legal surrogate. If study staff identify any concerns about a Veteran's safety at home, they will be advised to raise this with the PI, who will then inform the patient's primary care provider. Veterans and caregivers who demonstrate understanding of the study through teach-back will be asked to provide their written informed consent.

Veterans and caregivers will be informed that participation is fully voluntary. Throughout the study, the investigators will verbally confirm Veterans' and caregivers' informed consent to participate before engaging in each study procedure. Prior to starting field observations, the investigators will also ask Veterans and caregivers if they agree to either audio-recording and/or note-taking during the encounter or if they agree to only observation with note-taking after the encounter has finished.

Interviewed Clinicians: For clinicians identified by Veterans who are involved in their CKD care, the investigators will conduct in-depth interviews with them about their perception of the care that enrolled Veterans receive for their advanced CKD. The investigators will ask for their verbal consent to participate in up to 2 interviews during the duration that Veterans are participating in the study. Verbal consent will be captured at the start of the interview audio-recording.

Observed Clinicians: For enrolled Veterans, the investigators will perform field observations of their clinical encounters related to care for advanced CKD. At the start of the clinical encounter, the investigators will remind clinicians about the Veteran's decision to have study staff accompany him/her to observe the encounter and inform clinicians of what form of observation that the Veteran prefers (i.e. audio-recording and/or note-taking during the encounter or only observation with note-taking after the encounter has finished). The investigators will ask for clinicians' verbal consent to observe the encounter. After the encounter and as needed, the investigators will request clinicians' permission to ask clarifying questions regarding conversations or interactions during the encounter.

If Veterans prefer audio-recording and/or note-taking during the encounter but clinicians are not agreeable to this, then the investigators will only observe the encounter and record notes after the encounter has finished. If clinicians do not agree to being observed, the investigators will inform the Veteran of this preference and will not observe the encounter.

Other Persons: It is possible that during field observations of clinical encounters, persons other than enrolled participants, such as medical staff and Veterans' acquaintances, may unexpectedly join the encounter and be present during conversations or interactions. If this should occur and if it does not disrupt the encounter, the investigators will notify the other person during the encounter that it is being observed by a study team member and what kind of observation is being performed (i.e. audio-recording and/or note-taking during the encounter or only observation with note-taking after the encounter). If introducing the study and study team member to the other person would disrupt the encounter, the investigators will notify the other person immediately after the encounter has been finished that it was observed by a study team member and what kind of observation was performed. The investigators will ask for other persons' verbal consent to retain any de-identified data collected during the encounter.

5.4 Inclusion/Exclusion Criteria

Patients:

Inclusion Criteria

- Receives primary +/- nephrology care from VAPS as defined as having at least 1 outpatient primary or nephrology visit in the prior year
- Adults aged ≥18 years
- Advanced CKD as defined as defined as having ≥2 outpatient measures of an eGFR ≤20 ml/min/1.73m^2 separated ≥90 days
- Unsure or do not wish to undergo maintenance dialysis
- Agreement by their VA primary +/- nephrology care provider that patients can participate in the study

Exclusion Criteria

- Unable to complete "teach-back" method of informed consent
- Currently receiving maintenance dialysis
- Currently enrolled in HBPC Program

Caregivers:

Inclusion Criteria

- Adults aged ≥18 years
- Nominated by enrolled patient as a caregiver whom patient agrees to participate in the study

Exclusion Criteria

- Unable to complete "teach-back" method of informed consent

A Veteran who does not identify a caregiver or whose nominated caregiver does not wish to participate in the study, the Veteran is still eligible to participate in the study. If a Veteran withdraws from the study, their caregivers' participation in the study is also terminated at that time.

Clinicians:

Inclusion Criteria

- Employed at VAPS
- Identified by enrolled Veterans as important to their CKD and nominated by the Veteran to be interviewed for the study

Exclusion Criteria

- None

For a Veteran who does not identify a clinician or whose nominated clinician does not wish to participate in an interview, the Veteran will still be eligible to participate in the study. If a Veteran withdraws from the study, their clinicians will no longer be eligible to participate in interviews.

5.5 Interventions

For each consecutively enrolled Veteran, the investigators will randomly assign the Veteran and their caregiver to either usual care (i.e., control arm) or to the Kidney Care at Home Program (i.e., intervention arm). Randomization to each study arm will be computer generated with a 1:1 allocation.

Usual Care: Veterans with advanced CKD are typically cared for by a VAPS primary care provider. Additionally, they might receive specialty nephrology care at the VA. Enrolled Veterans who are assigned to usual care will continue to receive the care they had been receiving for their CKD by their primary care +/- nephrology provider.

Intervention: Enrolled Veterans and their caregivers who are assigned to the intervention will be enrolled in the Kidney Care at Home Program. The Program will be delivered through the existing HBPC infrastructure at VAPS. The HBPC Program at VAPS is comprised of 8 HBPC teams, and each team is comprised on a lead physician or nurse practitioner, nurse, pharmacist, nutritionist, social worker, psychologist, therapist, and chaplain. Veterans will be assigned to the HBPC team serving their residential area. As is the standard of care for HBPC services, each member of their HBPC team that will perform an initial assessment of each Veteran within 3-months of randomization. This includes review of each Veteran's medical history and assessment of unmet medical and psychosocial needs. Additionally, the HBPC team will perform a focused CKD symptom assessment. On a monthly basis, the entire HBPC team will conduct MDC meetings to review each Veteran's active medical issues, recent hospitalizations, and emergency room visits, psychosocial needs, and medical plan.

At a minimum, subsequent clinical encounters and assessments for each Veteran will be scheduled no less than on a quarterly basis and more often as needed based on the HBPC team's clinical judgment. The HBPC team will also treat identified problems and make appropriate referrals according to their discretion and clinical judgment. The HBPC Team will

also have the freedom to change the frequency of their visits and the different team members involved in a patient's care according to their clinical judgement.

All clinical encounters, phone contact, and correspondence between a Veteran and any HBPC team member as part of the Program will be documented in the VA electronic medical record. Notes from monthly MDC meetings will also be documented in the medical record. The investigators will also be available between MDC meetings for urgent patient care-related questions.

Because the Program will provide both primary and nephrology care, enrolled Veterans will transfer their primary +/- nephrology care to the CC Program. The CC Program will also continue to follow Veterans through hospital and nursing home admissions and to care for Veterans if they should change their minds and start dialysis and/or return to CC after a trial of dialysis so as to support care flexibility and continuity. Should Veterans withdraw from the study, the Program will assist the Veteran with returning to their original primary care +/- nephrologist. After Veterans complete the study, they will be given the option to continue with the Program for ongoing primary and CC until they no longer desire it or to return to their original primary care +/- nephrologist.

The investigators will oversee implementation of the Program. In addition to the usual primary care provided by HBPC services, the Program will provide CC to enrolled subjects. The Program will incorporate the following CC care: patient-centered, whole-person and team-based care, shared decision-making, active symptom management, advance care planning and end-of-life care.[15] Specific care items reflecting these CC elements will draw from the clinical expertise of the investigative team, CC educational materials prepared by the investigative team, international consensus statements on CC best practices,[21] publicly available provider and patient resources on CC, and existing patient resources on related topics of kidney disease, self-care, and home and community-based resources that support Veterans' independence at home from the VA Kidney, Whole Health, and GEC Programs.

5.6 Study Evaluations

The investigators will use a combination of surveys, interviews, field observations, and medical record review to compare usual care and the Kidney Care at Home Program. Subjects will be followed through death, study withdrawal, or 1-year follow-up, whichever comes first. Subjects will be asked to complete the following procedures at enrollment and every 3 months (+/- 1 month) following randomization. Veterans and caregivers will receive a $40 incentive for each study visit that they complete (total of $200). Clinicians will not be provided compensation for their participation.

Surveys:

Demographic survey: At enrollment, Veterans and caregivers will be asked to complete a brief survey to collect information about their age, race, ethnicity gender, educational background, marital status, employment status, and annual household income. Each caregiver will also be asked their relationship to the Veteran, hours spent caregiving for the Veteran per week, and types of caregiving provided to the Veteran. For clinicians who participate in interviews, The investigators will ask their age, race, gender, professional role, year in clinical practice, and medical specialty.

Health Outcomes Prioritization Scale: At each study visit, The investigators will ask Veterans about their preference for care to be directed at maintaining independence, maximizing longevity, reducing or eliminating pain, and reducing or eliminating dizziness, fatigue, and shortness of breath using the Health Outcomes Prioritization Scale.[22] Veterans will also be asked whether they view the care they receive for their kidney disease as focused more on independence, longevity, pain relief, or relief of other symptoms. The language using in the Scale will be slightly

adapted to support a 7th grade literacy level. The investigators will slightly adapt the Scale for caregivers to inquire their perception of patients' healthcare priorities and the kind of care that patients receive.

Zarit Burden Interview: With caregivers at each study visit, the investigators will administer a 12-item survey that asks caregivers to rate the frequency with which they experience different forms of caregiver strain (nearly always).[23]

Consultation Satisfaction Questionnaire: With Veterans and caregivers at each study visit, The investigators will administer a 17-item survey that asks raters about their level of agreement with statements about overall care, professionalism, communication, time spent and depth of the relationship with the clinicians involved in their kidney care, based on the last clinical visit.[24] For Veterans and caregivers randomized to usual care, participants will be asked about care provided by their primary care provider and/or nephrologist. For Veterans and caregivers randomized to the intervention, participants will be asked about care provided by their Kidney Care at Home Program clinician.

Edmonton Symptom Assessment Scale: At each study visit, Veterans will be asked about 10 common physical and emotional symptoms of advanced CKD.[25]

EuroQol 5D: At each study visit, Veterans will be asked to complete a 5-item survey inquiring difficulty with mobility, self-care, usual activities, pain/discomfort, and anxiety/depression on 5-point scale. A 6th item asks patients to rate their overall health along a 0-100 visual analogue scale (higher scores indicating greater perceived health).[26]

Clinicians important to kidney care: At each study visit, the investigators will ask each Veteran the names of VA clinicians whom they perceive as important to their kidney care and whom they would allow us to interview to learn more about their experiences caring for the Veteran. The investigators will use the local VAPS address book to obtain their contact email and phone number.

Enrollment and attrition: The investigators will record reasons why eligible Veterans' primary care +/- nephrology provider did not agree to recruitment of Veterans to participate in the study. The investigators will also record reasons for refusal to participate in the study by eligible Veterans. The investigators will ask enrolled subjects who withdraw from the study their reasons for withdrawal.

Interviews:
Veteran and caregiver interviews: At each study visit, Veterans and caregivers in each study arm will be invited to complete a 45- to 60-minute interview to ascertain their experiences with and perspectives on their kidney care. Approach to inquiry will be informed by the RE-AIM Framework and will follow a structured guide intended to elicit participants' perspectives on: 1) reach; 2) effectiveness; and 3) implementation of respective approaches to care. Distinct interview guides will be used for participants initial interview, subsequent interviews, and final interviews during the study period. Non-specific probes will be used to prompt subjects to elaborate on their responses for greater depth and detail. Veterans and caregivers will be interviewed separately, in private, and in-person or by phone according to each person's preference. All interviews will be audio-recorded then transcribed without personal identifiers.

Clinician interviews: For clinicians who were nominated by enrolled Veterans to participate in interviews, the investigators will ask clinicians to complete a 30-minute interview by phone or

securing messaging to ascertain their experiences with and perspectives on the Veterans' kidney care using an interview guide similar to that for Veterans and caregivers. All interviews will be audio-recorded then transcribed without personal identifiers.

Field Observations: At each study visit, the investigators will review with Veterans their upcoming VA clinical appointments and ask if they are related to their kidney disease and if the investigators can observe the clinical encounter. These clinical encounters can include face-to-face, telephone, and video encounters. The investigators will also remind Veterans that they may contact us between study visits about any ad hoc clinical appointments related to their kidney disease that were scheduled and that they wish to be observed.

For each observed encounter, the investigators will record the date of the encounter, encounter setting (e.g. home, clinic), and duration of the encounter. The investigators will also record persons present during the encounter based on their professional (e.g. nephrologist) or personal (e.g. caregiver) relationship to the Veteran. During the encounter, study staff will either digitally audio-record and/or note-take conversations and interactions or only observe and note-take after the encounter per each subject's preference. After the encounter is complete, the investigators will debrief with subjects about the encounter and ask subjects clarifying questions about the encounter as needed using a semi-structured guide. Notes will be transcribed into a Word document without any personal identifiers. Audio files will also be transcribed verbatim onto a Word document without personal identifiers.

Medical Record Review:
Progress Notes: The investigators will review all the clinical progress notes entered into each Veteran's electronic medical record during follow-up and abstract passages documenting care considerations regarding CKD. Any abstracted text will be purged of personal identifiers and recorded into a Word document. The investigators will record the date, note title, clinical setting (e.g. emergency room), and provider type (e.g. nephrologist) from which passages were abstracted. The investigators will also review scanned healthcare documents, including advance directives, portable medical orders (e.g. POLST forms), and outside medical records, available in Veterans' medical record that were completed during the study period and transcribe any relevant text without personal identifiers into a Word document. The investigators will record the date, note title, clinical setting (e.g. emergency room), and provider type (e.g. nephrologist) from which passages were abstracted.

Clinical characteristics: The investigators will abstract relevant diagnoses in the year prior to enrollment to calculate a Charlson comorbidity index score.[27] During follow-up, the investigators will record all measures of Veteran's eGFR, hemoglobin, serum albumin, weight, blood pressure, and electrolytes and the dates during which they were measured.

Healthcare utilization: The investigators will record all hospital, nursing facility, emergency room use, and palliative care consultations documented in the medical record during follow-up. The investigators will also record any hospice, social work, nutrition, pharmacy, therapist, mental health, and chaplaincy referrals and visits during follow-up.

Dialysis status for advanced CKD: The investigators will record whether Veterans changed their mind about CC and received dialysis during follow-up.

5.7 Data Analysis

Feasibility and acceptability: As the primary aim, the investigators will perform an inductive thematic analysis[28] of all qualitative data collected through interview transcripts, observational field notes, and passages from reviewed documents to ascertain the feasibility and acceptability

of approaches to caring for Veterans who are do not wish to forgo dialysis with usual care vs. the Kidney Care at Home Program. The investigators will triangulate the qualitative research findings with quantitative measures collected that also reflect feasibility and acceptability of care approaches. The investigators will describe enrollment and attrition rates, the reasons for refusal and withdrawal of study, and care satisfaction scores using proportions and means where appropriate. HBPC providers will not actively be sought as the primary target for interviews or observed encounters. However, if they are identified as being important to a Veteran's CKD care, acceptability and feasibility from the perspective of HBPC clinicians may be ascertained. Participation of HBPC clinicians would be based upon identification by Veterans, rather than their role within HPBC.

Exploratory analyses: The investigators will describe healthcare utilization, caregiver burden, healthcare goals, perceived care, quality of life, and treatment with dialysis during follow-up using proportions and means where appropriate. Level of agreement in perception of healthcare goals and goal concordant care between Veterans and caregivers will be reported using the kappa statistic.

5.8 Withdrawal of Subjects

Subjects may withdraw from the study at any time. The investigators will inform subjects that any de-identified data collected prior to their withdrawal will be included in analyses. For Veterans who withdraw from the study, The investigators will facilitate their transfer back to the VA primary care +/- nephrology provider caring for the Veteran prior to the study. The lead physician or nurse practitioner of the HBPC team will contact the Veteran's prior primary care +/- nephrology provider to review the Veteran's clinical course during their participation in the study, and discuss any active clinical issues that requires close follow-up.

5.9 Potential Risks and Benefits

Anticipated Risk:

Discontinuity in care: Veterans randomized to the Kidney Care at Home Program will transfer their primary +/- nephrology care from their existing primary care +/- nephrology provider to the Program. It can take time for Veterans to become comfortable interacting with a new clinical team and for the clinical team to get to know Veterans and familiarize themselves with Veterans' clinical history. This can lead to delays in addressing health problems. To minimize this risk, the investigators will arrange that each patient have their first visit with the Program clinicians within 3-months of enrollment in the Program. The lead physician or nurse practitioner of each Veteran's HBPC team will also contact each Veterans' primary care +/- nephrology provider to inform them of the date of their first visit with the Program clinicians and to obtain any pertinent history or active medical issues that require close monitoring at the outset of patients' participation in the Program. These measures will help to ensure continuity in care for patients.

Emotional or psychological unease: Subjects might feel uncomfortable during interviews discussing their care experience or when observed during encounters. To minimize this risk, throughout the course of the study and with each study visit, The investigators will verbally confirm their consent before undertaking each interview and survey and being observed. The investigators will assure subjects that they can choose not to answer any questions or complete any study procedure that they are not comfortable with. The investigators will also assure subjects that they can choose not to be observed.

Potential Benefits: The Kidney Care at Home Program will be the first evidence-based CC program for Veterans with advanced CKD in the VA, if not the nation. Veterans and caregivers randomized to receive care through the Program may derive benefit from receipt of CC.

Clinicians involved will receive formal training in CC, which may enhance clinical services for Veterans beyond those who participate in this study. The findings of this study will also inform how usual care services could also be improved for Veterans who do not wish to undergo dialysis and the caregivers and clinicians who support them. Completion of surveys and participation in interviews may encourage Veterans, caregivers, and clinicians to reflect on the meaning of their own care experiences which may be beneficial to them in and of itself.

6.0 Reporting

The investigators do not anticipate any adverse events that might occur. However, any and all unanticipated problems, serious adverse events and protocol deviations will be recorded and reported immediately to the study Principal Investigator. Any serious adverse events and/or serious problems will be reported to the IRB within 5 business days
.

7.0 Privacy and Confidentiality

The proposed work requires the collection of protected health information.

All study personnel who will have access to protected health information and/or will be involved in obtaining subject consent will be required to complete all necessary training in the protection of human subjects and privacy through the Department of Veterans Affairs (VA) Learning University Talent Management System (TMS) and Collaborative Institutional Training Initiative (CITI) Program.

To safeguard against potential loss of confidentiality, all subjects will be given a unique study ID, and data collected for this study will be associated with study IDs only. A separate crosswalk file linking study IDs with personal identifiers will be kept in separate from data analysis files. Data analysis files will not contain personal identifiers. Data analysis will be conducted using only the de-identified data files.

Veteran, caregiver, and clinician interview and survey responses will also be kept confidential and not shared with each other or anyone outside the study team. Study data will be aggregated for presentations or publications related to the study in order to conceal the identities of subjects.

The Head of the Division of Nephrology will be notified of any adverse events or changes to the study protocol.

8.0 Information Security and Data Storage/Movement

All analysis will take place at VAPS. All study data will be stored on local secure servers at VAPS in a secure J-drive study folder.

The server is located at:
VA Puget Sound Health Care System
Office of Information and Technology
1660 S. Columbian Way
Building 1, Rm B70
Seattle, WA 98108

Digitally audio-recorded interviews and clinical encounters will be downloaded from recorders to secure study folders using a USB fire cable. After audio-recordings have been saved, audio files will be erased from audio-recorders. Audio files of interviews will be labeled with study IDs and date of the interview only and will be accessible to the transcriptionist through the secure study folder. Transcripts of audio files will be saved as Microsoft Word format directly to secure study folders. Study staff responsible for transcription of audio files will not be permitted to save copies of audio files or transcripts onto personal computers or devices.

Structured study data will be assembled using Microsoft Excel forms and saved in secure study folders. Medical record abstraction and field observation notes will be assembled using Microsoft Word documents and saved in secure study folders.

All research records, including the investigator's research records, must be retained until disposition instructions are approved by the National Archives and Records Administration (NARA) and are published in VHA's Records Control Schedule (RCS 10-1). (VHA Handbook 1200.05).

After all data are analyzed and manuscripts summarizing study findings are published (estimated 2029), all identifiable and crosswalk files will be destroyed.

9.0 References

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