Title: Electronic Patient-Reported Outcomes in Clinical Kidney Practice (ePRO Kidney)

NCT #: NCT03149328

Date: August 12, 2019

STUDY PROTOCOL AND STATISTICAL ANALYSIS OVERVIEW

Provide a full description of your research proposal outlining the following:

- **Purpose**
- **Hypothesis**
- **Justification**
- **Objectives**
- **Research Method/Procedures**
- **Plan for Data Analysis**

Background

Internationally, the Institute for Healthcare Improvement urges health organizations to focus on what matters to patients. They found that patients report better outcomes and experiences of care when clinicians are curious about and act on patients' health priorities and concerns. Nationally, Canadian Institute for Health Information (CIHI) asserts that *patients' perspectives are essential* to a person-centred approach to care. CIHI has prioritized the need for coordinated programs, including kidney care, to routinely collect patient reported outcomes (PROs) as a means of improving health outcomes and person-centred care. In turn, CIHI and the Canadian Organ Replacement Register have created a *PRO Renal Care Group* to harmonise PRO collection and reporting in renal care across Canada. Dr, Klarenbach, Principal Knowledge User (KU), and Ms. Wu, KU from CIHI, co-chair this Group.

Four million Canadians living with end-stage kidney disease (ESKD) need dialysis to stay alive. Embedding PRO feedback in kidney care is essential because of the poor QOL and declining health outcomes that patients experience. QOL is recognized as an outcome that trumps other previously used metrics to measure outcomes, including survival. Use of PROs offers a means to address the **#1 research priority of Canadian dialysis patients**: communication of their QOL to their clinicians. PROs are a simple tool that offer *significant potential* to mitigate concerns that matter to ESKD patients from their point of view.

We have a large body of research spanning 4 decades, including systematic reviews and randomized controlled trials, providing evidence that use of PROs augments person-centred care in various clinical populations (i.e., improved communication with clinicians, enhanced care planning, and heightened recognition of patients' concerns that are otherwise not identified). Yet, PROs are *not* being used routinely, day-to-day at the point of care for people with ESKD because we do not know *how* they can or should be used.

While clinicians and policy developers endorse PRO incorporation in kidney practice, the processes and person-centred outcomes of doing so are unknown. There is a need for knowledge about the *process* of supporting clinicians to use PRO information at the point of care. In collaboration with government/industry/ clinician/patient stakeholders, we will address these gaps. Our aim is to understand how to best support clinicians and administrators in routinely integrating PRO information to enhance person-centred care in a kidney context.

We will use process evaluation to explore *how* integration of ePROs may provide the best care and health possible to kidney patients. Technology used at the point of care with ePROs facilitates immediate data access, potential linkage with electronic medical records (Nephrology Information System - NIS), storage of longitudinal data and cost-savings of time and resources.

This research will contribute much-needed knowledge, including guidance on the routine use of PROs and supportive educational materials, to ensure successful uptake of ePROs and utilization of PRO information by clinicians and administrators to enhance person-centred healthcare services for Canadians living with kidney disease. Further, this research will provide previously unexamined empirical evidence on the differences in person-centred outcomes when PRO information is used routinely in kidney care. Findings may also provide transferable lessons for policy makers and multidisciplinary clinicians caring for patients with other chronic conditions.

Goal and Objectives

It is fundamentally important that health services address what matters to patients from their point of view. **Our goal is to understand how to best support clinicians and administrators in routinely utilizing electronic patient-reported outcomes and experiences (ePROs) to enhance person-centred care.**

Internationally, the Institute for Healthcare Improvement champions organizations where clinicians value, routinely measure and act on what matters to patients. In turn, patients report better outcomes and experiences with care. Nationally, CIHI highlights PROs as *essential* to understanding whether health services make a difference to patients' health and quality of life (QOL). PROs are standardized tools for patients to answer questions about their health and QOL, including symptoms and physical, psychological and social wellbeing. PROs offer patients an avenue to report on the impact of an illness and its treatment on their lives. One of the health service sectors CIHI is targeting for PRO implementation is renal care. In spite of mounting support for PROs to enhance person-centred care, collection and reporting of PROs is *not* routinely integrated into kidney care anywhere in Canada. The problem is that we don't know *how* to integrate PROs into care. There is pressing need for knowledge about how to best support clinicians in utilizing PROs as the basis for enhancing person-centred care.

We will address this gap with the following **objectives**:

1. Understand the process of supporting clinicians to utilize PROs in multidisciplinary, home dialysis practice.
2. Examine to what extent utilization of PRO information is associated with differences in person-centred outcomes (including satisfaction with care [primary outcome], utilization of health services, symptoms and QOL [secondary outcomes]).

This research builds on two previous studies that were conducted on nurses' use of ePROs in two home dialysis locations. Greater understanding about how to best support clinicians in multidisciplinary teams to routinely integrate ePROs is foundational to ensuring that the care they provide addresses patients' priorities.

Methods and Procedures

To achieve these goals, we will use the mixed methods design of **process evaluation** and compare 2 groups: Northern and Southern Alberta Renal Programs, NARP (Edmonton) and SARP (Calgary). In Edmonton (Intervention group), patients and clinicians will be invited to participate in the study; only patients will be invited to take part in the study in Calgary (Comparison group).

The research study will be undertaken collaboratively with a Patient Advisory Committee (Edmonton-based), and knowledge users including NARP and SARP home dialysis and kidney medical directors, NARP home dialysis manager, CIHI, co-chairs of CIHI's *PRO Renal Care Group*, PRO experts, government administrator and patient-centred measurement expert and industry partners.

Patient advisory members will have the option of deciding for themselves whether they want to be study participants. Study co-investigators / collaborators who are NARP clinicians will be invited and may choose to participate in the study in Edmonton.

Setting

This research will be conducted among patients receiving home dialysis across Alberta Kidney Care, an integrated provincial dialysis program, from its 2 units: Aberhart Clinic in the Northern Alberta Renal Program (NARP) and Sheldon M. Chumir Health Centre in the Southern Alberta Renal Program (SARP). NARP and SARP have 305 and 350 home dialysis patients respectively. These 655 patients constitute the largest provincial population of home dialysis patients in Canada. Patients live in both urban and rural/remote areas, travelling to Edmonton (NARP) or Calgary (SARP) for scheduled appointments every 3 months.

Study Design (See Figure 1)

The mixed methods design of **process evaluation**, will orient the pragmatic nature of this study in which we seek to learn *how* to best support **clinicians and administrators** in routinely utilizing electronic PROs or ePROs. Process evaluation will allow us to focus on how person-centred outcomes are integrated and utilized, not only on the outcomes themselves. Findings will provide decision-makers with information to guide integration of PROs in renal settings in a way that *works.* Attending to process, formative and outcome evaluation will be threaded throughout the project, drawing on focus groups, interviews and PRO data. Informed by Santana and Feeny's conceptual framework of PRO use in routine clinical care of chronically ill patients, our study design follows the International Society of Quality of Life guidelines for integrating PROs in clinical practice which *requires* both ePRO feedback and education on use of PRO information in daily practice.

Obj. 1.

- Provide in NARP (intervention group):

  1) an *electronic tool (ePRO)* for patients that facilitates real time PRO data collection and feedback in clinical practice, and

  2) *educational support* to multidisciplinary home dialysis clinicians about how to use PROs routinely in their practice

- In SARP (comparator group) clinicians will not receive the intervention
- Formative evaluation: process of supporting clinicians to utilize PROs (employing usability testing, and patient and clinician interviews/focus groups)

Obj. 2.

- Formative evaluation: process of supporting clinicians to utilize PROs (patient and clinician interviews/focus groups, and clinician feedback on education sessions)
- Prospectively compare person-centred outcomes in NARP and SARP cohorts
- Outcome evaluation: symptoms and person-centered care (primary outcomes) as well as satisfaction with care, utilization of health services, mental health and QOL (secondary outcomes) (defined below)

The objectives will be achieved in 2 phases over 2 years (see Figure 1).

Participants

All NARP and SARP home dialysis patients will be invited to participate if they are ≥18 years old, able to read and speak English and provide written informed consent. Patients who are visually impaired, or cannot read or speak English will be excluded. Participants will be ethnically diverse (including First Nations, Inuit and Metis peoples), and include a range of ages (although people with ESKD are typically older adults), gender, work status and educational background.

Clerical staff currently call patients to confirm appointment times. When they make this call, they will read a short, 2-sentence script to let patients know about the study and invite them to come 10-15 minutes early if they are interested in participating. When NARP and SARP patients attend their outpatient clinics, clerical/clinical staff will invite them to take part in the study and obtain verbal consent for researchers to speak with patients. Clerical/clinical staff will also give the Patient Recruitment Poster to patients who are interested in the study. Clerical/clinical staff will then tell those patients who are interested in the study to approach the research assistant who is in the waiting room. Additionally a large, free standing study banner will be placed in the PD clinic waiting room. The research assistant will provide the patient with information about the study and, if he/she is willing to participate, will assist the patient with the consent process and ePRO survey completion.

In Phase 1 and 2, patients will be invited to complete ePRO surveys online using tablets in the clinics or using their own devices, on paper, over-the-phone, or to mail surveys in. They will also be invited to take part in focus groups and interviews. Consent to participate in the study will be authenticated when patients check the relevant boxes and sign the consent form. For NARP and SARP patients who consent, we will also contact the SPOR Platform to obtain administrative health data. We will collect the personal health care numbers (PHNs) of the patients in order to link to Discharge Abstract Database (DAD, for hospitalization data) and National Ambulatory Care Reporting System (NACRS, for ER data) and Registry (for all-cause mortality data, but not cause of death). We will collaborate with AB SPOR SUPPORT Unit for this administrative linkage.

If a patient joins the study while on home dialysis, but then moves to in-centre dialysis or has a transplant, we will continue to track the patient and involve him/her in the study, however research team members will not travel to the new dialysis clinic.

In addition to patients, all clinicians from the NARP home dialysis program will be invited to participate in focus groups (Phase 1) and attend education sessions/complete surveys and take part in interviews (Phase 2). The Nurse Manager requested that a 1-page study summary be provided so that both she and the research team members can give it to NARP clinicians to inform them of the study. NARP clinicians who have not participated in any study activities prior to the Phase 2 interviews, will be invited to participate by completing a sign-up sheet, which will be distributed during an allied health home dialysis staff meeting, by the nursing unit manager. A recruitment poster for the Phase 2 interviews will also be emailed to home dialysis nephrologists and posted in the home dialysis units of the Aberhart Building. NARP home dialysis follows a multidisciplinary team model that includes nephrologists, nurses, social workers, dieticians, and technicians. Study co-investigators / collaborators who are NARP clinicians/administrators may choose to participate in data collection activities or the education sessions, they will not be involved in data analysis; they will only see the data at an aggregate level. SARP clinicians will not be involved as participants, but will be informed about the study and provided with clinician education sessions if requested after data collection is complete.

In the Whiteboard study extension, those clinicians that participated in Phase 1 & 2 of the study and those patients that participated in an interview or focus group during Phase 1 or Phase 2 of the study, will be invited to take part in online Zoom workshops. Patients will be invited to these workshops either through email or over the phone, using their preferred mode of contact, while all clinicians will be invited through email. For the first patient workshop, patients will be asked to choose from two potential dates and the date that is chosen by the majority of patients will be the scheduled date for that workshop. For the first clinician workshop, the site champions and site administrator will be invited to provide feedback on the

date of the workshop. The date(s) of the second round of workshops will be determined by the study team.

Phase 1, Year 1: Usability Testing (See Figure 2) The 1st year will involve usability testing and formative evaluation, establishing baseline data and stable estimates of trends over time for the person-centred primary and secondary outcomes. Usability testing is an essential first step in ePRO feedback and use in clinical practice.

In NARP (Intervention Group), when patients first take part in the study they will meet face-to-face with a research team member in the renal clinic waiting room. Before the clinic visit, each patient will be invited to use a tablet to complete a consent form and demographic survey online or on paper. Then they will be invited to complete the Supportive Care Survey tool. Current practice is for patients to complete the Supportive Care Survey tool, which is given to clinicians to inform patient care during a clinic visit. One version of this tool is completed by Peritoneal Dialysis (PD) patients, and one version is completed by Home Hemo Dialysis (HHD) patients. The Supportive Care Survey tool includes the Edmonton Symptom Assessment Scale revised for renal patients (ESAS). To streamline research/clinic processes, the research assistant will invite patients, who consent to participate in the study, to complete the Supportive Care Survey. With the patient's consent, this survey will be given to clerical staff to inform patient care during the clinic visit. Patients who do not wish to take part in the study will follow the usual clinic practice.

The clerical staff will manually transcribe the Supportive Care Survey results on their electronic chart (via NIS), and the paper copy goes on patients' paper chart, which clinicians will see. (Note that all NARP patients already provide this information on paper, to clerical staff for the electronic and paper chart as a part of their standard care.) Clinicians will not use the tablets to see ePRO survey results; they will only see paper copies. Survey data will be printed in color because in our pilot study nurses emphasized that color helped them efficiently use results. During follow-up appointments, previous ePRO survey data will also be displayed for comparison by the clinician. If the patient shows up late, and is not able to complete the ePRO surveys prior to the clinic visit, he/she will be asked to complete them after the clinic visit.

Patients will complete the survey tools using a web-based ePRO system hosted by Cambian Business Services Inc. Cambian, will provide online services for collecting, analyzing, and managing patient-reported data. For follow-up appointments, patients will complete the surveys in the clinic on paper or on-line using a tablet, over-the-phone with a research team member, on-line using their own devices, or they can mail it in. The researchers will be able to communicate via email with patients using Cambian's online secure services. Cambian's services meet stringent requirements for privacy and security of medical records including guaranteed data sovereignty in Canada.

Before leaving the clinic and just after the first clinic visit as a study participant, NARP patients will complete the Kidney Disease Quality of Life (KDQOL-36), and the Patient Assessment of Care for Chronic Conditions (PACIC 20), a validated patient-reported experience measure on satisfaction with care. They will also complete the EQ-5D-5L, a generic, validated PRO. These 3 outcome evaluation measures will *not* be included in patient charts, made available on NIS, or be used by clinicians at point of care, so that patients may provide feedback without fear of it impacting the care they receive. If patients cannot stay to complete these surveys after the clinic visit they will be given the following options: over-the-phone with a research team member, or on-line using their own devices, or put in the mail. For 3-month follow-up visits patients may complete ePRO surveys in the clinic with a research team member or they may be given the options described above.

Patients will enter a username and password to create their own account on Cambian services so that they can log into the Cambian site at any time to view their own data, enter data, or print out copies. If a patient decides to later complete surveys on paper or on the phone, they will be invited to provide consent for researchers to use their password to access their account and enter their data into Cambian on their

behalf. Patients will be provided with paper copies of their surveys if they would like to have them either in-person, via Cambian services, or via the mail.

Usability testing and formative evaluation with NARP patients will also include 5 focus groups and 10 interviews during Year 1 (before intervention) to discuss how they would like their PRO information to be used by clinicians. The attached scripts for the focus groups and interviews provide sample questions; more questions will emerge during the discussions. NARP patient focus groups will take place in the Aberhart Renal Clinic or at the University of Alberta. NARP patient interviews will take place at the University of Alberta, in the patient's home, or over the telephone. Additionally, if a patient participant requests that a caregiver sit in on an interview or focus group, the caregiver will be asked to sign a Caregiver Consent Form and complete a demographic form. Any data provided by the caregiver can then be incorporated into the study data and used for analysis and dissemination. Refreshments will be provided at focus groups.

In SARP, the comparator group, patients meeting inclusion criteria will be invited to complete the consent form, demographic survey, Edmonton Symptom Assessment Scale revised for renal patients (ESAS), the Kidney Disease Quality of Life (KDQOL-36), the PACIC 20, and the EQ-5D-5L. (Current practice in SARP clinics is that patients do not complete any survey tools during clinic visits.) If a patient decides to later complete surveys on paper or on the phone, they will be invited to provide consent for researchers to use their password to access their account and enter their data into Cambian on their behalf. The ePRO surveys will not be shared with SARP clerical staff, entered into NIS, included in patient charts, or shared with clinicians. The survey data for the comparator group will only be available to the researchers. SARP patients will not be invited to participate in focus groups or interviews, but they will be provided with clinician education sessions if requested after data collection is complete.

In Phase 1, NARP and SARP patients will provide ePRO survey data 3-4 times (depending on intake), providing a robust baseline dataset.

Usability testing and formative evaluation with NARP multidisciplinary clinicians will include a series of focus groups (3-4) during Year 1 (before intervention) to discuss the ideal process for ePROs surveys to be integrated into existing practices and work structures. Phase 1 NARP clinician focus groups will take place at the renal clinic or at the University of Alberta. Refreshments will be provided at focus groups. Findings from these focus groups will be used to refine the targeted education sessions provided as an intervention in Year 2; interviews with NARP clinicians will also take place in Year 2. SARP clinicians will not participate in the study, but they will be provided with clinician education sessions if requested after data collection is complete.

Study participation from start to completion will be tracked using REDCap. Participants will only be identified in REDCap through their study IDs.

Phase 2, Year 2: Evaluation (See Figure 2)

Using a prospective design, the educational sessions (intervention) will occur in NARP where clinicians will receive ePRO survey feedback as well as targeted education about how to use PRO information. The comparator group will be in SARP and clinicians will not receive this information. The patient cohorts are very similar in size (SARP n=350; NARP n=305) and demographics (rural/urban). Both patient cohorts attend clinics every 3 months and receive multidisciplinary care.

Randomization of patients and clinicians is not feasible due to the organization of the clinical environment involving shared responsibilities among clinicians for the same patients. Intervention allocation will be based on geographic isolation of units, NARP and SARP. Drawing on Rubin's potential-outcomes perspective, the causal effect will be defined as the difference between symptoms and person-centered care (primary outcome) between units given 2 different treatments (comparator group vs PRO information

and education) in very similar contexts (NARP and SARP home dialysis clinics) while controlling for baseline and other potential confounding variables.

In NARP, the patient cohort will be followed over 1 year to determine outcomes on symptoms and person-centered care, satisfaction with care, utilization of health services, mental health, QOL, and changes in clinicians' decision-making. Patients will continue to complete the Supportive Care Survey tool just prior or at each clinic visit**. If other PRO measures are requested by clinicians in Phase 1, these will be added to Phase 2 data collection and an ethics amendment sought.** The Supportive Care Survey results will be made available electronically (via the NIS) and as printed reports in patients' charts. Clinicians will be asked to tick a box on the Supportive Care Survey printouts for patients to indicate if they reviewed the PRO information and changed their decision-making based on the PRO information.

After each clinic visit, NARP home dialysis patients will complete the KDQOL-36, EQ-5D-5L, and PACIC 20 for outcome evaluation. These 3 outcome evaluation measures will *not* be used by clinicians at point of care, included in patient charts, or made available on the NIS. If patients cannot stay to complete these surveys after the clinic visit they will be given the following options: over-the-phone with a research team member, or on-line using their own devices, or put in the mail. For 3-month follow-up visits patients may complete ePRO surveys in the clinic with a research team member or they may be given the options described above.

Patients will enter a username and password to create their own account on Cambian services so that they can log into the Cambian site at any time to view their own data, enter data, or print out copies. If a patient decides to later complete surveys on paper or on the phone, they will be invited to provide consent for researchers to use their password to access their account and enter their data into Cambian on their behalf. Patients will be provided with paper copies of their surveys if they would like to have them, either in-person, via Cambian services, or through the mail.

NARP patient participants in Phase 2 (intervention) will also be invited to engage in either a focus group (n=5) or an interview (n=10) to discuss how they see clinicians following up on their PRO information. The attached scripts for patient focus groups and interviews provide sample questions; more questions will emerge during the discussions. NARP patient focus groups will take place in the Aberhart Renal Clinic or at the University of Alberta. NARP patient interviews will take place at the University of Alberta, in the patient's home or over the telephone. Additionally, if a patient participant requests that a caregiver sit in on an interview or focus group, the caregiver will be asked to sign the Caregiver Consent Form and complete a demographic form. Any data the caregiver provides will then be incorporated into the study data and used for analysis and dissemination. Refreshments will be provided at focus groups.

The intervention (clinician workshops) (see Figure 2) is based on established guidelines for integration of PROs in clinical practice, as well as findings from our feasibility study. The NARP multidisciplinary clinician team will be invited to complete a consent form and demographic survey, and participate in workshops, refined with feedback from the team. In these sessions, reviewing and prioritizing ePRO findings with a patient will be discussed, critiqued and role played. Workshops will be offered every 1.5-months over a 6 month intervention period (Year 2). Evaluation survey feedback will be sought at the end of each workshop to tailor information to clinicians' needs. Clinicians will also be invited to complete a pre and post test. Test responses will be analyzed using descriptive methods to track changes in knowledge, skills and attitudes towards ePRO use from the start to the end of the workshop attendance. Clinicians will be given the option to complete both tests either online, through the REDCap data collection site, or on paper. In order to encourage attendance to the clinician workshops, each workshop will include a draw for a door prize. All door prizes are provided by study sponsors (businesses and non-for-profit organizations), who were approached by members of the study team.

All NARP clinicians who participated in the clinician workshops will also be invited to participate in 1 interview, that will be up to 60 minutes in length. During this interview, they will be asked to share examples of how they have used PRO information in their practice, and the challenges, benefits and facilitators of integrating ePROs in practice. They will also be asked to provide feedback on their

experience of the workshops. The attached script for interviews provides sample questions; more questions will emerge during the interviews.

Phase 2 NARP clinician workshops and interviews will take part at the renal clinic or at the University of Alberta.

All NARP clinicians will also be invited to complete a ticky-box form every two weeks. The purpose of this form is to assess whether a clinician reviewed and used a patient's ePRO in their care planning, over the last two weeks. Although completion of the ticky-box form is voluntary, completion of each form allows the clinician to enter a draw for a gift basket. Items for the gift basket will be provided by study sponsors (business and non-for-profit organizations), who were approached by members of the study team.

In SARP, the Comparison cohort, using the same protocol as that described above in Year 1, all patients meeting inclusion criteria will be invited to complete the consent form, demographic survey, Edmonton Symptom Assessment Scale revised for renal patients (ESAS), the Kidney Disease Quality of Life (KDQOL-36), the PACIC 20, and the EQ-5D-5L. If a patient decides to later complete surveys on paper or on the phone, they will be invited to provide consent for researchers to use their password to access their account and enter their data into Cambian on their behalf. In the SARP clinic the ePRO surveys will not be shared with clerical staff, entered into NIS, included in patient charts, or shared with clinicians. The survey data for the comparator group will only be available to the researchers. SARP clinicians do not receive survey information in current practice. SARP clinicians and patients will not be invited to participate in focus groups or interviews. However, clinicians will be provided with clinician workshops after data collection is complete if requested.

To attend to attrition as a threat to internal validity, NARP/SARP patients will repeatedly be invited to participate, even if they had not done so previously. This sampling retention procedure is in anticipation of attrition due to death or change in dialysis modality (i.e., from home to hospital dialysis). In our feasibility study, response rates were high, and the participation burden was low. The response rate was 68% in the pilot phase, and 79% in the longitudinal phase. We anticipate similar response.

Whiteboard Development-Phase 1 & 2-The objective of this phase of the study is to develop two whiteboards, or short, animated videos, intended for both kidney patients and home dialysis clinicians. These whiteboards will be used as a dissemination tools, based on findings from the ePRO Kidney study, to improve quality of life and person-centered care.

Phase 1: A professional whiteboard company will be hired to produce an initial script for both whiteboards, using findings from phase 1 & 2 of the ePRO Kidney study. Clinicians and patients who have previously participated in ePRO Kidney will be invited, by email or phone, to participate in separate workshops, which will take place through Zoom video conferencing, where they will be asked to review and provide feedback on a draft of a whiteboard script that is aimed at their peer group (i.e. clinicians, patients). Each participant will be asked to provide verbal consent prior to the workshop and and a member of the research team will sign a Whiteboards consent form, on the participants behalf. Each workshop will be audio and video recorded and detailed notes will be taken.

Phase 2: Feedback from phase 1 workshops will be shared with the production company and used to produce separate patient and clinician focused whiteboards. Clinicians and patients who have previously participated in ePRO Kidney study will then be invited to participate together, in 1-2 workshops, taking place through Zoom video conferencing. During each workshop, participants will watch each whiteboard and then will be asked to share their feedback. Any participants who did not attend the phase 1 workshop will be asked to provide verbal consent and a member of the research team will sign a

Whiteboards consent form, on their behalf. Each workshop will be audio recorded and detailed notes will be taken. Feedback from these workshops will be used to revise and finalize both whiteboards.

Both whiteboards will be made freely available for kidney home dialysis patients and staff provincially, nationally and internationally and will be one of the knowledge translation activities for this study.

Quantitative Evaluation

Outcome measurement.

The primary outcomes, symptoms and person-centered care, will be assessed using the symptoms/problems domain of the KDQOL-36 and the PACIC 20. Secondary outcomes will include use of health services (i.e., hospital admissions, trips to emergency room, death) determined through the SPOR Platform and AHS electronic health records, satisfaction with care (one item is added to the end of the PACIC-20 related to care received; this item is from the NHS Outpatient Survey [2011]), mental health (using the SF-12 mental component summary [MCS] subscale in the KDQOL-36) and quality of life (EQ-5D-5L).

Statistical methods.

We will use descriptive methods and statistical tests to examine the trajectories of outcome measures for patients in the comparator and intervention groups. The area under the curve (AUC) will be calculated for each trajectory during the period that the patient is participating to create a summary score. This robust approach is recommended when the number of measurement periods are not the same for each individual. Analysis of covariance (ANCOVA) will be used as the method of analysis to compare AUC scores of outcomes of both groups while controlling for within- and between-group differences, such as comorbidities, gender, age and dialysis type. ANCOVA is necessary to control for baseline and potential confounders.

Power.

Based on a power analysis for an ANCOVA comparing 2 groups using the area under the curve approach, a total sample 459 (655 x 70% response rate) will provide 80% power to detect effect sizes (f^2) of moderate magnitude at a statistical significance level of 0.05 (e.g., f^2 ranging from 0.15 for 1 covariate to 0.19 for 10 covariates).

Qualitative Evaluation

Qualitative data from focus groups and interviews will be recorded, transcribed verbatim and analyzed using the methodology of interpretive description. We will use well-established methods to ensure trustworthiness and rigor, including credibility (iterative cycles of engagement with both administrators and clinicians), confirmability (audit trails) and transferability (reporting on the kidney care context). NVIVO, a qualitative software system, will be used to create a filing system and coding database. The first focus group/interview transcript in each phase will be read and re-read to generate an initial codebook. The codebooks will be iteratively refined throughout the analysis. Codes will be categorized and analyzed thematically. Patient and clinician data will be analyzed separately. We will also look at differences pre- and post-implementation in NARP.

Navigation of Pitfalls

The comparator site, SARP, does not currently collect PROs. SARP medical directors collaborating on this research have agreed that PROs will not be used throughout the study duration.

To ensure secure protocols of data collection and storage, we will use the Cambian Patient-Reported Data Service. This ensures that we meet Data Sovereignty requirements with data collected, analyzed, and managed in Canada. Data will be transferred to the Health Research Data Repository (HRDR), a secure online repository, housed in the Nursing Faculty at the University of Alberta. Privacy impact and ethics approval ensure that all security requirements are maintained. Bringing electronic equipment into any healthcare environment can be challenging. We will work with Cambian and the Information Technology or Human Research Ethics departments in AB Health Services to ensure that all levels of security are in place. We have past experience navigating ethics and security requirements during the feasibility study, as well as in research led by Dr. Sawatzky.

Integrated KT (iKT)

Engaging knowledge users (KUs).

The research is intended to be relevant to clinicians and policy-makers, and is led *in partnership* with KUs. We will bring preliminary findings to national KUs on the CIHI PRO Renal Group for their input and feedback. Following a process evaluation design, multidisciplinary clinicians will be consulted throughout the project to ensure that results are meaningful at the point of care.

Engaging patients.

Patient engagement is integral to enacting patient-oriented research that is responsive to the needs of those living with the illness. We will have a Patient Advisory Committee who will be consulted on preliminary findings and iKT products. Patient involvement will enhance the quality, relevance and application of findings.

Committee members will be invited to act as advisors by attending committee meetings, where notes will be taken, observations and audio recordings made, which will not be transcribed. These patients will not be considered research participants; notes observations and recordings are not considered "data." This information is for the purpose of advising the research team throughout the research process. However, patient advisory members will have the option of deciding for themselves whether they want to be study participants by taking part in surveys, focus groups and/or interviews.

Patient orientation modules will be completed by Advisory members through the Alberta SPOR SUPPORT Unit Patient Engagement Platform. The principal applicants will also complete these modules to ensure understanding of the principles of patient engagement. Committee members will meet twice a year over 2 years, either in person (at the University of Alberta or in renal clinics), with Skype™, or on the phone. Refreshments will be provided and parking costs reimbursed for committee members.

iKT products include:

1. Education materials to support clinicians routinely using PRO information in kidney practice (i.e., a webinar, handbook, or “how to” publication with practical advice). These products will be developed in collaboration with NARP clinicians.
2. Recommendations on utilizing PROs in kidney programs and for policy development

iKT products will be disseminated to KU groups such as the CIHI PRO Renal Group, Canadian Associations of Nephrology Nurses and Technologists and Nephrology Social Workers, Canadian Society

of Nephrology, etc. These products will also be disseminated widely through the research teams' areas of influence, as well through publications and conference presentations.

Figures 1 and 2 are provided in the attachments at the end of the ethics application.