Pathways Project Collaborative Phase II:
Implementation of Kidney Supportive Care in Practice
GW IRB # **180679**
GW IRB Application version 1.10
Revision Approved by GW IRB 1/20/22

Redacted for ClinicalTrials.gov to remove names of participating clinical sites

NCT # NCT04125537

Document date: November 15, 2022

GW IRB Application (Version 1.10)

1.0 General Information

***Please enter the full title of your study:**

Pathways Project Collaborative Phase II: Implementation of Kidney Supportive Care in Practice

***Study Short Title:**

Pathways Project
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

Is this a multi-site study in which GW will be the lead site and will enter into a reliance agreement (IAA) with other collaborating institutions who will rely on our review?

Yes

2.0 Add Department(s)

2.1 List departments associated with this study:

Primary Dept?	Department Name
◆	**GW** - SCHOOL OF NURSING RESEARCH

3.0 Assign key study personnel (KSP) access to the study

3.1 *Please add a Principal Investigator for the study (Students are not eligible to be Principal Investigators)

Lupu, Dale Ellen, PhD, MPH

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

B) Research Support Staff

Aldous, Annette Marie
Research Staff
Dowling, N. Maritza, PhD
Research Staff
Nicklas, Amanda C.
Research Staff
Sliwa, Sharon
Research Staff
Smith, Payton

Research Staff

3.3 *Please add a Study Contact:

Lupu, Dale Ellen, PhD, MPH
Sliwa, Sharon

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves). Anyone **not** added here will NOT receive email or correspondence from the system for this study

3.4 Please select the Designated Department Approval(s):

Malliarakis, Kathleen Driscoll
Department Chair

Add the name of the individual authorized to approve and sign off on this protocol from your Department (e.g. the Department Chair or Dean). **All new submissions MUST be signed off by a Department Chair before the IRB will review a submission.**
For ALL MFA Studies: In addition to having your Department Chair sign off (for Dept of Medicine, please add Dr. William Borden as Department Chair), all studies need to be signed off by **Radwa Aly and Mardi Gomberg-Maitland**. Please add them **here** or during final routing of signatures after your application has been completed.

4.0 Research Team Personnel

4.1 Provide the following information below for each research team member:

Click "add another entry" to respond to this item.

Entry 1

Research team member name:	Lupu, Dale Ellen, PhD, MPH
Degree:	PhD, MPH
Status:	Faculty
Email address:	dlupu@gwu.edu
Phone number:	[REDACTED],
GWID:	
Research duties:	List all that apply: ☑ Primary contact person ☑ Consent Designee ☑ Study procedures ☑ Data entry ☑ Chart reviews and data extraction ☐ Laboratory analysis ☐ Regulatory activities (IRB) ☑ Data analysis ☑ Evaluates Inclusion/Exclusion Criteria ☑ Interprets medical reports and laboratory results

	☐ Completes Case Report Forms (CRFs) ☐ Dispenses study drug ☐ Adverse Event documenting and reporting ☑ PI ☐ Sub-investigator
Affiliation:	**Note:** Non-GW team members should only be included on this list if they are not listed on an IRB approved protocol at their own institution or organization. An Institutional Authorization Agreement or Independent Investigator Agreement will be needed for these individuals.
Conflict of Interest - Do you have any outside interests related to this research (ex: personal stock in the company sponsoring the research, receipt of income, including royalties and entitlement to royalties, from the sponsor of this research for purposes other than this research, etc.) that could possibly be perceived as introducing bias into the research or as a conflict of interest?	○ Yes ◉ No
Date added to research team:	11/01/2018
Date removed from research team:	

Entry 2

Research team member name:	Sliwa, Sharon
Degree:	MA
Status:	Staff
Email address:	sonsas@gwu.edu
Phone number:	[REDACTED]
GWID:	[REDACTED],
Research duties:	List all that apply: ☐ Primary contact person ☑ Consent Designee ☑ Study procedures ☐ Data entry ☐ Chart reviews and data extraction ☐ Laboratory analysis ☐ Regulatory activities (IRB) ☑ Data analysis ☐ Evaluates Inclusion/Exclusion Criteria ☐ Interprets medical reports and laboratory results ☐ Completes Case Report Forms (CRFs) ☐ Dispenses study drug

	☐ Adverse Event documenting and reporting ☐ PI ☐ Sub-investigator
Affiliation:	**Note:** Non-GW team members should only be included on this list if they are not listed on an IRB approved protocol at their own institution or organization. An Institutional Authorization Agreement or Independent Investigator Agreement will be needed for these individuals.
Conflict of Interest - Do you have any outside interests related to this research (ex: personal stock in the company sponsoring the research, receipt of income, including royalties and entitlement to royalties, from the sponsor of this research for purposes other than this research, etc.) that could possibly be perceived as introducing bias into the research or as a conflict of interest?	○ Yes ◉ No
Date added to research team:	01/25/2019
Date removed from research team:	

5.0 Review Determination

5.1 Are you applying for an Exempt study?

○ Yes ◉ No

5.2 Please indicate which of the categories below describe this study:

◉ Minimal Risk
○ Greater than Minimal Risk

6.0 GW's Role

6.1 Select GW's Role in the Project:

○ Sole Site (GW is the only IRB involved in this study)
◉ GW is the Lead Site
○ GW is a Participating Site (and will rely on another IRB for review)
○ GW is a Participating site (and each site is doing their own review)

6.2 Is GW acting as a data coordinating site?

◉ Yes ○ No

7.0 Funding

7.1 Is this study externally funded?

◉ Yes ○ No

7.2 Provide the following information for each individual funding source:

- **Note:** attach a copy of each grant, sub-award, contract, etc. in the Initial Review Submission Packet so the IRB can compare the aims outlined in the funding document scope of work with the research protocol. *(If your funding source documents are over 200 pages, include only the cover page and the applicable sections of the funding source documents as they relate to this new IRB application or existing IRB file.)*

View Details	Sponsor Name	Sponsor Type	Contract Type:	Project Number	Award Number
⊟	Gordon and Betty Moore Foundation	Nonprofit	Contract		

Sponsor Name:	Gordon and Betty Moore Foundation
Sponsor Type:	Nonprofit
Sponsor Role:	Funding
Grant/Contract Number:	
Project Period:	From:11/01/2018 to:10/31/2018
Is Institution the Primary Grant Holder:	No
Contract Type:	Contract
Project Number:	
Award Number:	
Grant Title:	
PI Name: (If PI is not the same as identified on the study.)	
Significant Discrepancy:	

8.0 Objectives and Justifications

8.1 Summary of the study using lay language (200 words or less):

The Pathways Collaborative is the first attempt to implement supportive (palliative) kidney care at multiple sites in the United States. While supportive kidney care is growing in other countries, notably Canada, Australia, and Great Britain, it is not yet known how to integrate it into the unique nephrology environment in the United States. In Phase 1 of Pathways (completed), we developed an evidence-based change packet of 14 best practices for integrating supportive care practices into the continuum of care for patients with end stage renal disease (ESRD). In Phase 2 (described in this application), we will conduct a learning collaborative to help up to 15 dialysis centers and associated CKD practices implement these best practices. The learning collaborative is based on the IHI Collaborative Model for Achieving Breakthrough Improvement. This model is a tested systematic approach to quality improvement designed to help organizations close the gap between current and future practice based on evidence-based best practices.**[i] [ii]**

The Pathways Project faculty will work with up to 15 change teams at dialysis centers and associated CKD practices to create a system to identify seriously ill patients with kidney disease; conduct conversations with them so that their values, preferences, and goals for current and future medical treatment are known and respected; assess and address patients' physical, psychological and spiritual needs; and coordinate care throughout the healthcare system so patients receive only the care they want in settings in which they wish to be.

[i] Nadeem E, Olin SS, Hill LC, Hoagwood KE, Horwitz SM. Understanding the components of quality improvement collaboratives: A systematic literature review. *Milbank Q*. 2013;91(2):354-394. doi:http://dx.doi.org/10.1111/milq.12016.

[ii] Wells S, Tamir O, Gray J, et al. Are quality improvement collaboratives effective? A systematic review. *BMJ Quality and Safety*. 21 October 2017. doi. 10.1136/bmjqs-2017-006926

8.2 Objective(s) and justification of the study including the purpose, research question(s), hypothesis and relevant background information:

Aim 1: Hold Breakthrough Collaborative for integrating supportive care into kidney care
To achieve an overall improvement in aligning treatment with patient values and preferences, satisfaction with care, quality of life, and symptom and pain management, Pathways Project Collaborative teams will embark on an 18-month Collaborative beginning spring 2019. The Collaborative will be preceded by a 4-month observation period to obtain baseline measurements of current dialysis center and associated CKD practices supportive care practices. Through the application of the Pathways Project change package, project teams will enhance the delivery of supportive care processes for patients with kidney disease, specifically through the testing and implementation of shared decision-making and advance care planning; systematically identifying seriously ill patients; and providing palliative dialysis to seriously ill patients with advanced CKD whose goals are not compatible with standard dialysis schedules.

Aim 2: Revise Pathways change package and resources in preparation for dissemination
In summer 2020, the Pathways Project Advisory Committee, including patient subject matter experts, will revise and strengthen the change package, resources and tools based on the knowledge gained through the Collaborative. The revisions will incorporate the dialysis center/CKD teams' experience during the collaborative along with the preliminary evaluation results.

Aim 3: Develop strategy for dissemination
In fall 2020, the Pathways Project Advisory Committee will develop a strategy to disseminate the revised change package and results of the Collaborative. The dissemination strategy will include outreach to three audiences based on the outcomes of the Pathways Project: 1) the professional and scientific community through presentations at national meetings and articles in peer-reviewed journals; 2) the large dialysis organizations and those who oversee quality of dialysis care including the Forum of ESRD Networks, the individual networks, and the American Health Quality Association; and 3) policy makers including members of Congress and CMS to advocate for changes to improve patient-centered care for patients with kidney disease.

To achieve these aims we will employ three primary tactics:
1) The IHI Breakthrough Collaborative Model - The Collaborative Model is the primary intervention for this project. It has been used to foster successful change adoption in numerous settings with a variety of health problems.
2) Integrated payment models. Integrated payment models realign financial incentives to create a fertile field for uptake of innovations in patient- and family-centered care in the kidney care continuum. Several of the sites participate in the ESCO Model (ESRD Seamless Care Organizations) which is a pilot program being conducted by CMS to test value-based payment models for dialysis care. At least four of the participating dialysis centers are part of the ESCO demonstration. Three centers (at [REDACTED],) are part of a similar private initiative to provide an integrated care model for ESRD patients. The site within the Veterans Administration also works within the financial system of the VA, which is a budget based model, rather than service reimbursement model.
3) The Pathways Change Package - Provides an evidence-based set of changes and tools collated from the research literature and experiences and efforts of exemplars and organizations that have already successfully adopted supportive care best practices and shown positive outcomes.

Justification for the study: ESRD patients have significant unmet palliative care needs and arguably are the chronic disease patient population who receive the worst end-of-life care because of high intensity care (intensive care unit admission with frequent cardiopulmonary resuscitation, mechanical ventilation and feeding tube use compared to patients with cancer and other chronic diseases) at the end of life with very low referral to hospice. They have a high symptom burden, multiple comorbid illnesses, and a shortened life expectancy.

Hypothesis**:** A collaborative quality improvement approach with training of independent dialysis centers and associated CKD practices in supportive care best practices will lead to improvements in patient and staff-reported outcomes in patient care.

Research Question: Will a collaborative quality improvement approach to spreading supportive care best practices at dialysis centers and affiliated clinics measurably increase the provision of supportive care best practices leading to more effective goal-concordant care?

Relevant background information:
The absence in the United States of a comprehensive medical management without dialysis pathway which is available and selected by about 15% of advanced chronic kidney disease (CKD) patients in other countries is a major deficit in U.S. kidney care. In other ways as well, the current care of patients with advanced CKD in the U.S. is not patient-centered, nor does it utilize supportive care[1] approaches to optimize patients' quality of life. The Pathways Project is seeking to address these deficits through the implementation of a Collaborative.

In a 2013 survey of dialysis center staff, only 4.5% of 487 respondents believed they were presently providing high-quality supportive care including at the end-of-life. When asked what one change could most improve supportive care in their dialysis center, the top choice was "guidelines to help with decision-making in seriously ill patients." The second most frequently selected choice was the availability of supportive care consultation to patients. With the exception of a few innovative practices, specialty supportive care consultations are not generally available to patients on dialysis. In those places where supportive care consultation is an option for seriously ill patients on dialysis, nephrologists and their teams typically have not been trained in eliciting shared decision-making, communication, and symptom management skills that would help them deliver primary supportive care.

Shared decision-making is a necessary component to informed consent for patients with advanced CKD. The American Society of Nephrology (ASN) has recommended shared decision-making prior to the initiation of dialysis. Despite ASN's recommendation, shared decision-making—the process in which patients and their family collaborate with healthcare providers to develop a care plan and make decisions about treatments based on patient preferences and values as well as the clinical risks and advantages—is poorly integrated into the care of patients with kidney disease. Most nephrologists express lack of comfort in discussing end-of-life issues. Consequently, most patients with CKD and those on dialysis have little awareness of their prognosis.

Patients older than 75 years are the fastest growing segment of the dialysis population, but these patients, especially if they are frail or have comorbidities, may not experience a survival benefit from dialysis treatment. The current default is to start elderly patients with advanced kidney disease and multiple comorbid conditions on dialysis irrespective of their prognosis or likelihood of benefit. The symptom burden for patients with advanced CKD is comparable to that for patients on dialysis, and symptoms are under-recognized and undertreated because of lack of nephrology clinician expertise in supportive care.

The symptom burden of patients on dialysis rivals that of those with cancer, and their five-year survival rate is worse. This tremendous suffering leads to staggering rates of voluntary dialysis withdrawal as high as 35% in the oldest groups, yet hospice and supportive care are underutilized. As a result, patients on dialysis are subjected to more aggressive treatment at the end-of-life than patients with other serious illnesses. Most patients die in the hospital and often after intensive procedures including mechanical ventilation, feeding tube placement, and cardiopulmonary resuscitation. Families of deceased dialysis patients rate the quality of their loved ones' end-of-life care worse than families of those with cancer and other chronic conditions.

There is an urgent need to improve the care of patients with advanced and end stage renal disease (ESRD). The current situation offers the opportunity to intervene with multiple evidence-based supportive care best practices to transform the care of these seriously ill patients by improving the delivery of supportive care throughout the continuum of kidney disease and making available to seriously ill patients who wish to withdraw from dialysis, delay dialysis, or avoid dialysis, a pathway that offers medical management without dialysis.

[1] In surveys of patients and physicians, they prefer the term supportive care over palliative care. The term palliative care will be used to refer to the specialist title of physicians with board certification in hospice and palliative medicine along with specialist palliative care teams and to the practice of "palliative dialysis" which has a particular definition in the literature. Primary supportive care includes basic communication and symptom management skills provided by other than specialty-trained clinicians.

8.3 Describe how the research results will be used and will contribute to generalizable knowledge:

The overall aim of supportive kidney care is to improve the patient and family experience by shaping care to meet patient-defined goals and preferences, especially toward the end-of-life. This is expressed in the short-hand term "goal-concordant care." This short phrase is an umbrella for a complex array of actions including patients having insight into their values, preferences, and goals; clinicians eliciting and listening to those preferences; the healthcare system offering choices that assist patients in achieving their goals;

and all parties flexibly responding as healthcare needs and corresponding patient preferences evolve. This Collaborative phase of the Moore Foundation grant will provide knowledge on how best to implement comprehensive kidney supportive care delivery in the United States. The following bullet points describe the overall, immediate, and long-term projected impact of this knowledge.

Addressing the absence of comprehensive kidney supportive care delivery in the U.S. would lead to goal-concordant care, and thus improved quality of care, reflected in the following ways:

- Patients' preferences for future care would be more systematically elicited through shared decision-making and advance care planning;
- Patients' high symptom burden would be addressed through the routinization of pain and symptom assessment and management using validated tools and best practice recommendations;
- Patients' quality of life, experience of care, and satisfaction with care would improve as their treatment becomes more aligned with their preferences;
- The high intensity of care at the end-of-life would decrease and more patients would die outside the hospital and at home with hospice, which is what most patients say they prefer; and
- The high cost of end-of-life care for patients with kidney disease would decrease.

The immediate impact of the Collaborative's uptake of the change package will result in:

- Nephrology clinicians trained in communication skills for shared decision-making and advance care planning;
- Nephrology clinicians trained in pain and symptom assessment and management;
- Nephrology practices developing a medical management without dialysis pathway;
- Dialysis centers including a palliative dialysis option for patients near the end-of-life;
  and Nephrology practices and dialysis centers engaging in collaborative efforts with palliative care and hospice programs for seriously ill patients with CKD and ESRD.

The potential longer-term impact could result in:

- More patients reporting end-of-life care discussions with their nephrologist and other clinicians;
- More patients with advanced CKD choosing medical management without dialysis (literature from other countries suggests there could be a five-fold increase);
- More patients choosing palliative dialysis;
- More patients referred to palliative care and hospice; and
- Patients reporting a higher quality of life because of better pain and symptom assessment and management.

8.4 How will the data be analyzed to answer the research question? Briefly describe the data analysis procedures (e.g., statistical tests, thematic analysis, factors to be compared):

Briefly describe statistical tests, thematic analysis, and the factors to be compared.

Univariate and bivariate statistics will be used to analyze outcomes. Differences between categorical variables will be analyzed with the chi-square test and between continuous variables with the t-test. Trends over time in utilization measures will be analyzed with ANOVA.

To improve the efficiency of the design, given existing limitations, the "post" intervention sample will be matched to the pre-sample in term of cluster size and pre-treatment variables that affect the outcomes of importance.

The effect of the intervention will be measured as the difference between matched clusters (post intervention minus pre-intervention) in outcome changes over the 18-month study period from pre-intervention to post-intervention. Negative differences will indicate lower outcomes post-intervention, adjusted for baseline measures. A one-sample two sided t test with corresponding confidence interval will be used to determine whether the mean difference as calculated over all matched pairs is statistically different from zero. A nonparametric permutation test will also be used with an exact p-value. We will follow the same approach for secondary outcomes on which we have appropriate pre-intervention data. To adjust the mean rate difference in (the primary outcome) between groups for variables that show some residual imbalance after the post-intervention cluster pair-matching, a multiple linear regression model will be used, with the difference between matched clusters within dialysis centers as the dependent variable and variables with pre-intervention differences between matched clusters as the independent variables. Adjusted inferences for the effect of the intervention will be estimated by calculating the intercept of the resulting regression equation and comparing it to its estimated standard error.

Donner A, Klar N: Design and Analysis of Cluster Randomization Trials in Health Research. New York: Wiley; 2000. Section 6.3.3.

8.5 Are you performing a social or behavioral study?

(•) Yes ( ) No

8.6 Are you performing a biomedical study?

( ) Yes (•) No

8.7 Are you performing a clinical trial?

( ) Yes (•) No

8.8 Are you conducting a chart review only?

( ) Yes (•) No

9.0 Study Details

9.1 Provide a step-by-step description of the research procedures, study schedule, and interactions with human subjects:

- Submit all data collection tools that will be used in the study in the Initial Review Submission Packet.

There are three separate study populations for this study, with procedures and instruments specific to each population.
1) The first population is seriously ill patients served by the participating dialysis centers and CKD practices. (Instruments A, E, and F)
2) The second population is staff of the dialysis center and associated nephrology practices and associated palliative care programs. (Instrument B)
3) The third population is a subset of clinical staff who are actively participating with the change team. (Instrument C)

A. Patient-reported outcomes (telephone survey)
Summative evaluation - before and after the learning collaborative.
To measure whether the intervention of the learning collaborative has impacted patient reported outcomes, we will interview seriously ill patients at the participating dialysis centers. We have developed a questionnaire based on several standardized measures relating to shared decision making, advance care planning, and end of life discussions. The survey will be administered by telephone and takes about 20 minutes. We will survey patients selected from the dialysis center patient population in a baseline period prior to the start of learning collaborative activities. We will then survey another cohort of patients at the completion of the 18 months of collaborative activities.

B. Staff perception of organizational competence in delivering supportive kidney care - Kidney Supportive Care Implementation Quotient (KSC-IQ on-line survey)
Summative evaluation - before and after the learning collaborative.
We have designed an on-line survey that assesses staff perception of how well their organization delivers supportive kidney care. Survey questions are tied to the best practices in the evidence-based change package. The survey link will be distributed to all local staff associated with the dialysis center, associated nephrology offices, and palliative care or hospice organizations cooperating with the dialysis center. The survey will be conducted at baseline prior to inception of the collaborative. Survey results will be shared with the participating organizations to use as a needs assessment. The survey will be conducted again after the close of the collaborative.

C. Clinical staff and change team perception of integration of new practices - NOMAD survey (online)
Both formative and summative evaluation.
We will administer the NOMAD survey to measure staff perception (all dialysis center clinical staff) about the extent to which Pathways best practices have become part of normal work flow. Based on

Normalization Process Theory. All dialysis center clinical staff will be invited to complete the survey after the first and third learning periods. Change team participants will be especially encouraged to complete the survey as part of their participation on the change team.

D.Facility monthly report of utilization statistics
Formative evaluation - monthly reports during 18 months of the collaborative.
To assess interim progress of sites in implementing changes, each change team will submit a monthly report providing aggregate monthly information on utilization indicators such as the number of patients assessed as seriously ill, number of patients with completed advance directive, number of patients using hospice. (See attached in study documents).

E. Baseline and follow-up patient demographic and utilization data
During the 4 month baseline and 4 month follow-up periods, we will collect de-identified patient-level data for patients identified as seriously ill. The data to be collected is similar to the utilization statistics collected in (D) above, supplemented with demographic and health status data to allow a comparison between patients who participate in the patient survey (A above) and those who are ineligible to participate. This data will allow us to assess generalizability of the patient survey results. These data will also be linked to the patient survey in order to link patient reported outcomes with health utilization outcomes.

F. Pathways MMWD CKD Intervention Tracker
For CKD sites only. The tools we created for use in dialysis centers (D, E) are not practical for CKD clinics. The clinics are unable to identify a patient group to serve as the background (denominator) population for the Seriously Ill/Medical Management Without Dialysis (SI/MMWD) patients, so in this simplified version, we track only de-identified patient data for the SI/MMWD patients, not overall clinic numbers. We have come to regard the CKD clinic piece as a pilot side project and may adapt the collection instrument - without collecting any unapproved data - in collaboration with clinics as we figure out what is feasible.

Procedures for each of these studies is further described:
A. Patient-reported outcomes (telephone survey)
The steps in the procedure for the subjects who are patients are as follows:

1. The subjects (ESRD patients), who are being treated at participating dialysis centers and CKD practices and are identified as "seriously ill" by clinic staff using the screening tool, will form the population from which patients will be selected. We plan to survey 360 patients across the 15 participating sites during the baseline period. We will select a separate cohort of another 360 patients to interview at the completion of the 18-month learning collaborative.
2. Identified subjects will be approached by a member of the dialysis organization or CKD practice. The nature of the study will be explained. If the patient agrees to be contacted to learn more about the study, their contact information will be shared with the WVU CTSI and a research coordinator from WVU CTSI will contact the patient to explain the study. If the patient is interested, the interviewer will provide information needed for informed consent and will obtain verbal consent to proceed. A copy of the information provided during verbal consent process will be mailed to patients who consent along with the incentive gift card.
3. The subjects who give verbal consent will be interviewed as described in the attached patient questionnaire.
4. A "thank you" incentive of a $25 gift card will be mailed to patients who complete the survey.

B. Staff perception of organizational competence in delivering supportive kidney care - Kidney Supportive Care Implementation Quotient (KSC-IQ on-line survey)
The steps in the procedure for the subjects who are dialysis center personnel or personnel with associated nephrology practices are as follows:
1. The dialysis center or nephrology practice will have the option of an on-line survey or a paper survey to distribute to staff. We have added the paper survey option because many of the dialysis center and nephrology practice staff have no or very limited access to internet at the worksite. For the on-line survey option, we will ask the dialysis center and/or nephrology practice to send a survey link to all of its staff. Some change teams may also be working closely with associated nephrology practices and/or palliative care teams or hospice teams. In the case where the change team has identified such partner organizations, those organizations will send a survey link to all of its staff.
2. The survey will start with a page which explains the purpose of the survey and describes risks and benefits of participating in the survey. The survey contains a question asking for electronic consent, as follows:

ELECTRONIC CONSENT: Please select your choice below. Clicking on the "Agree" button below indicates that:

* You have read the above information

* You voluntarily agree to participate

* You are at least 18 years of age

Agree

Disagree (this will end the survey)

3. Survey results will be anonymous. However, surveys will be traceable to a particular dialysis center.

C. Clinical staff and change team perception of integration of new practices - NOMAD survey (online)

1. The dialysis center will have the option of an on-line survey or a paper survey to distribute to staff. We have added the paper survey option because many of the dialysis center staff have no or very limited access to internet at the worksite.
2. For the online survey, the dialysis center or nephrology center will send an on-line survey link to all of its clinical staff.
3. The on-line survey will start with a page which explains the purpose of the survey and describes risks and benefits of participating in the survey. The survey contains a question asking for electronic consent, as follows:

ELECTRONIC CONSENT: Please select your choice below. Clicking on the "Agree" button below indicates that:

* You have read the above information

* You voluntarily agree to participate

* You are at least 18 years of age

Agree

Disagree (this will end the survey)

4. The paper survey will have the same informed consent text as the on-line survey. Presumably, staff who do not consent to participate will not submit the paper survey.
5. Members of the change team in particular will be strongly encouraged by the Pathways Project staff to complete the NOMAD survey at designated times through email reminders and reminders on regularly scheduled calls.

Change team selection and consent

1. The subjects who are part of the intervention team in each dialysis center or associated CKD practice will be identified by the dialysis or CKD clinic management.
2. The identified team members will be approached by the research coordinator who will describe the surveys to be completed as part of the study and the time when each survey will need to be completed. The surveys and their timing are listed on the attached measures spreadsheet. Copies of the surveys are also attached. The surveys are the Kidney Supportive Care Implementation Quotient, the NoMAD implementation tool, and the Institute for Healthcare Improvement single-item measure of the dialysis personnel's sense of the progress of the intervention in his/her dialysis center.
3. The dialysis or CKD clinic research coordinator will ask for verbal consent from the subject to participate.
4. The subjects who give verbal consent will be asked to complete the surveys at the intervals specified in the measures spreadsheet. The Kidney Supportive Nephrology Care Implementation Quotient and the NoMAD implementation tool only need to be completed twice. The Institute for Healthcare Improvement single-item measure needs to be completed monthly (but only by the head of the change team).

D. Facility-level monthly report of utilization statistics

The monthly report to be filed by each dialysis center or associated CKD practice provides aggregated data at the clinic level. To collect this data, a designated staff person will fill out a worksheet that collects the necessary information about all seriously ill patients served by the dialysis center or associated CDK clinic in that month. This worksheet will have a separate line for each seriously ill patient where the utilization statistic (such as whether hospitalized in the month, duration of hospitalization), can be entered. Alternatively, the staff person will query their database for the data on the utilization statistics (such as number of hospitalizations). The worksheet will then tally across the entire patient population for that month. The staff person will transfer the AGGREGATED TOTAL to the monthly reporting form, for submission via secure upload via REDCap. Alternatively, for sites that do not establish connection with REDCap, they securely email the form to a member of the Pathways research staff. The worksheet with

information for individual patients will NOT be transmitted to GW. The sites will be instructed to store those individual worksheets for the duration of the project, should there be a need to audit the aggregated monthly statistics.
In addition to the monthly report of utilization statistics, the dialysis center or associated CKD practice staff will provide short progress report on their activities in implementing the Pathways change package.

E. Patient-level demographic and utilization information
During 4 month baseline and 4 month follow-up period, the site will provide de-identified person level data ONLY for seriously ill patients. The reason for doing this is to allow comparison between seriously ill patients who consent to the survey vs. those who are not eligible or do not provide consent for the survey to determine the generalizability of the survey results. Optionally, sites may choose to provide deidentified patient-level data during the interim months. This instrument also includes a chart audit of advance care planning conducted once during the baseline period and once during the followup period. See attachment:(include patient level template and chart audit template).

Each subject will be identified by a study identifier assigned by the site. A code link between the study identifier and the patients name and/or dialysis/CKD center identifier will be maintained by the site in a locked file. The purpose of the site code link is to allow the site to pull the correct information from clinic records to record in the data collection form. A different code link for patients who agree to participate in the survey will be kept in REDCap, and will only be accessible by the WVU study coordinator. The purpose of this codelink is to determine which of the patients on the data submitted by the sites corresponds to which patient survey.

F. Pathways MMWD CKD Intervention Tracker
The CKD site will provide de-identified person level data ONLY for the Seriously Ill/Medical Management Without Dialysis (SI/MMWD) patients, not overall clinic numbers. The data we collect will be suitable only for descriptive analysis, but will provide information and experience towards future, more systematic efforts.
Each subject will be identified by a study identifier assigned by the site. A code link between the study identifier and the patients name and/or dialysis/CKD center identifier will be maintained by the site in a locked file. The purpose of the site code link is to allow the site to pull the correct information from clinic records to record in the data collection form.

9.2 Will subjects be audio-recorded, video-recorded, or photographed? Check any that apply.

- ☐ Audio-recorded
- ☐ Video-recorded
- ☐ Photographed

9.6 Describe alternatives to the study procedures (ex: not to participate, standard care):

A. Patient-reported outcomes (telephone survey)
If the patients choose not to participate in the telephone surveys they will receive standard care.
B. Staff perception of organizational competence in delivering supportive kidney care - Kidney Supportive Care Implementation Quotient (KSC-IQ on-line survey)
Staff participation in the survey is voluntary and no one will know who participated or not. If participation rates are low overall, management may exhort general increase in participation through posters, emails, discussions at staff meetings - but these will be general and not directed to an individual staff person.
C. Staff change team perception of integration of new practices - NOMAD survey (online)
Same as above for KSC IQ survey
D. Facility-level monthly report of utilization statistics and average patient Collaborate score.
Filing monthly reports is a requirement of participating in the collaborative. If a change team director repeatedly fails to provide monthly reports, the site may be asked to leave the collaborative.
E. Patient level demographic and utilization information
Patients who decline to release their utilization information will receive standard care.
F. Pathways MMWD CKD Intervention Tracker
Patients who decline to release their utilization information will receive standard care.

10.0 Subject Population

10.1 General description of the study population:

A. Patient-reported outcomes (telephone survey)

The study population of subjects will include 720 dialysis patients who were determined to be seriously ill according to the "surprise question" screening tool. (360 at baseline and 360 at the end of the study 18 months later. This includes about 20 patients for pre-testing the survey.)

B. Staff perception of organizational competence in delivering supportive kidney care - Kidney Supportive Care Implementation Quotient (KSC-IQ on-line survey)
All current employees of the participating dialysis center or associated CKD practices will be invited. The number of staff is not currently known, but it likely ranges from about 40-50 personnel per site. In some cases staff of associated offices will also be invited (for instance, staff of the clinics or offices operated by nephrologists associated with the site). This invite will be extended if the change team is implementing change practices in conjunction with the nephrology clinic or palliative care clinic. Total respondents anticipated: up to 750 staff members at baseline. 750 repeated at follow-up. Many of these may be the same staff person, but we will not be tracking that, so will count staff members each time they answer the survey.

C. Staff change team perception of integration of new practices - NOMAD survey (online)
All current employees of the participating dialysis center or associated CKD practice will be invited. The number of staff is not currently known, but it likely ranges from about 40-50 personnel per site. Staff members participating in the change team will be strongly encouraged to complete the survey through reminders associated with their activities with the collaborative. There are typically five staff members on a change team. Total respondents anticipated: approximately 10 per center X 15 centers = 150 at baseline, repeated at follow-up.

D. Facility-level monthly report of utilization statistics
One report per dialysis center or associated CKD practice will be obtained monthly. These reports cover all patients at the site, but data is only reported in aggregate.

E. Patient level demographic and utilization information
This is collected on all patients who are identified as seriously ill, using a validated screening process. At most centers, we expect about 20% of centers at the patient will be identified as seriously ill. We expect 300 patients to be identified at baseline (20% of the 1500 total patients) and another cohort of 300 patients to be identified at follow-up.

F. Pathways MMWD CKD Intervention Tracker
This is collected on all patients in CKD site who are identified as seriously ill, have chosen medical management without dialysis (MMWD), or are considering MMWD. This group is part of the 300 patients to be identified at baseline (20% of the 1500 total patients) and another cohort of 300 patients to be identified at follow-up.

10.2 Locations where subjects will participate in GW IRB supervised research activities:

Organization / Facility/ Location	Research Activities Performed (recruitment, consenting subject/researcher interaction or data retrieval):
[REDACTED], New York, NY (3 sites)	recruitment, data retrieval
[REDACTED], New York, NY (3 sites)	recruitment, data retrieval
[REDACTED, Denver, CO (3 sites); Dallas, TX (1 site)	recruitment, data retrieval
[REDACTED], Washington, DC (1 site)	recruitment, data retrieval
[REDACTED],, Dallas, TX (1 site)	recruitment, data retrieval

10.3 Do you have permission from the site to conduct the research?

(•) Yes ( ) No

Please upload documentation of permission in the Initial Review Submission Packet.

10.4 Maximum number of subjects to be enrolled:

- For a multi-center study, both local and total accrual numbers must be provided if GW is acting as the IRB of Record.
- If this study does not involve multiple sites or the number of subjects at other sites is unknown, complete only the "Locally" row.
- Subjects are considered to be enrolled and count towards your total number of subjects once they begin study procedures, which excludes screening procedures. A list of subjects who sign the informed consent document but did not meet inclusion criteria should be kept for your files.

Maximum Number of Subjects to be Enrolled

	Annually	Entire Study
Locally (by GW researchers)		
Study-wide (Multi-center)	1260	2520

10.5 Age range of subjects:

18 years old and older

10.6 Inclusion Criteria:

Order Number	Criteria
1	Patients at least 18 years old who are currently being treated by participating dialysis center.
2	Dialysis patients identified as "seriously ill" by screening with "surprise question"- a validated tool that identifies patients with elevated mortality risk. The treating nephrologist or nurse practitioner or dialysis nurse answers whether they would be surprised if the patient died in the next 6 months.
3	For staff surveys only: Dialysis personnel working in the participating dialysis centers or associated nephrology practice or associated palliative care practice.

10.7 Exclusion Criteria*:

These are the characteristics that a participant must NOT have in order to be eligible to participate in the study.

Order Number	Criteria
1	Patients with impaired congitive decision making processes as determined by a screening tool.

***If excluding a population or group that may benefit from the research, please provide justification:**

All patients will potentially receive the impact of changes in care processes implemented by the dialysis and CKD centers. However, only patients who are cognitively able and English or Spanish speaking will be surveyed by phone. We do not have the budget to translate the survey instruments nor hire survey administrators fluent in languages other than English and Spanish.

10.8 Special populations to be involved in the research:

- [x] Employees
- [ ] Students
- [ ] Educationally Disadvantaged
- [ ] Economically Disadvantaged
- [ ] Mentally Ill
- [ ] Decisionally-Impaired
- [ ] Illiterate
- [x] Non-English speaking
- [ ] Research conducted internationally
- [ ] Other

For any population listed above, please explain why the population is necessary and explain additional steps that will be taken to protect the subjects:

Dialysis center and/or CKD practice patients: patients are the only ones who can report on whether communication is effective from their point of view. Therefore a direct survey of patients is the only way to obtain patient assessment of whether communication practices have improved as a result of the project. When the survey is explained to them, they will be assured that their care will not change regardless of whether they participate in the survey or not. Also, when the survey administrator introduces the survey, the administrator will remind them that they can skip any questions or stop the survey at any time.

Non-English speaking: Spanish-speaking patients are a significant proportion of the patients served by the participating dialysis and CKD clinics. At some sites, they are a third or more of patients served. Excluding Spanish-speaking patients would make it more difficult to generalize to this population, and possibly limit their access to the care improvements developed by this project. To protect these patients we are hiring an interviewer who is fluent in Spanish to conduct the consent process and patient interview. The Spanish translation of the survey will be prepared by a professional translator for the portions that are not already available as Spanish translations of validated scales. We will also have an arrangement with a telephone interpreter service available to use if any participating patient has concerns and wants to talk with members of the research team.

Change team selection criteria and withdrawal mechanism: Change team members are selected by their management to participate in the project. All project participants will receive study information and a consent form. Consent will be given verbally. The participation agreement will state that answering the staff surveys is voluntary and not required. If a staff person wishes to withdraw from the entire project (from participation on the change team), the staff member will be directed to talk with their manager.

Spanish translation services by a certified and reputable company will be used to translate study documents. These documents include the patient flyer and letter, as well as the telephone questionnaire. A Spanish speaking interviewer will be used to interview these patients. The company used for translation of the documents, as well as the questionnaire is Language Scientific. Their process is outlined in their quote for services, which is included in addtional documention portion of this application.

10.9 Does the research involve prisoners?

- [ ] Prisoners

10.10 Does the research involve children?

- [ ] Children

10.11 Does the research target pregnant women, fetuses or Neonates?

- [ ] Pregnant women, fetuses or neonates

10.12 Does the study involve wards of the state or any other agency, institution, or entity?

- ( ) Yes
- (•) No

11.0 International/Non-English Speakers

11.1 If Non-English speakers will be targeted for enrollment, will the consent be translated into the local language(s)?

- ○ N/A (participants will all speak English)
- ◉ Yes
- ○ No

In the Initial Review Submission Packet, please submit translated document(s) in the non-English language. For greater than minimal risk studies, please also submit a back translation and a certification of verification of translation by someone who if fluent in the language and include their credentials.

11.2 International Research:

Please thoroughly describe the local laws and regulations the IRB should consider in its review of the study being conducted at a foreign site, as applicable:

Not international research.

Is this study also being reviewed by a local ethics committee familiar with the laws/ethical codes that might apply to the country?

- ☑ N/A (all research taking place is U.S.)
- ☐ No
- ☐ Yes

The IRB may request the name, contact information, and credentials of someone that is unaffiliated with your research but is familiar with the laws/ethical codes in the country so that the IRB can consult with them if there are questions or concerns about the risks to participants.

If you have already identified this person, please provide their information:

12.0 Subject Recruitment

12.1 Does any member of the research team have an existing relationship with any potential subjects?

◉ Yes ○ No

Please explain the relationship and describe steps that will be taken to minimize risks to subjects and reduce potential for bias. Address any conflict of role that this relationship poses:

Patients have ongoing relationships with treating health care providers in each of the dialysis or CKD clinics. They will be approached for the survey by a staff person designated by the dialysis or CKD center. That person will be provided with a script and trained to assure patients that participation is voluntary and their care will not be impacted in any way whether or not they agree to participate in the survey. An informational flyer to be given to patients by staff is attached.

12.2 Step-by-step recruitment process:

- How will potential subjects be found?
- Who will approach potential subjects to take part in the research study?
- Where subjects will be approached?
- How will potential subjects be asked to participate in the study?
- What will be done to protect individuals' privacy in this process?
- Describe all of the recruitment techniques that will be used, if any (e.g., email, flyers, other print media, social media, verbal announcements, snowball sampling).
- Explain if subjects will be recruited through the access of records, such as medical, student, employment, prisoner, health and human services, financial, etc.

1. Subjects are patients in participating dialysis or CKD centers who are determined to be seriously ill by their treating nephrologists.
2. Subjects will be approached in the dialysis center or CKD clinic.
3. Dialysis or CKD center staff will approach individually each eligible patient who has been identified as seriously ill who is at least 21 years old. Center staff will ONLY be asking patients if they are willing to be contacted by the study staff. If patients are willing to be contacted by study staff, they will give permission to the center staff to provide contact information to the study staff at WVU CTSI. Dialysis/CKD center staff will transfer contact information to the study staff at WVU CTSI.
4. A researcher from WVU CTSI will then contact the patient by several methods (email or mailed informational letter) followed by phone call. In this phone call, survey administrator will explain the study and obtain informed consent to proceed with interview.
5. Subjects will not be recruited by accessing records.
6. Recruitment methods will include flyers and posters in the dialysis center along with verbal announcements.

12.3 What steps will be taken to avoid coercion or undue influence in the recruitment of research subjects?

Patients: Only subjects who give voluntary informed consent to participate will be enrolled in the study. Subjects who do not agree to participate will continue to receive standard care.
Study staff will not provide final lists of who agreed to participate or not to the dialysis/CKD center staff. Therefore, unless the patient themselves mention it, the staff delivering patient care will not be aware of whether or not an individual patient participated.
Staff: Participation in change team as staff at a participating dialysis center is strictly voluntary. Participants are also free to leave the change team at any time. Their employment nor their relationship with participating dialysis center will not in any way be affected should they choose to not participate or if you withdraw their participation at any time.

12.4 Retrospective data analysis only: Provide the exact date range (MM/DD/YYYY- MM/DD/YYYY) from which data will be accessed. All data accessed for this research must be in existence at the time of the initial IRB submission in order to meet the definition of "retrospective.":

12/01/2018-04/10/19

13.0 Informed Consent Process

13.1 Consent method being requested for the study:

- ☐ Written Consent Document with Signature (obtaining subject or Legally Authorized Representative signature).
- ☑ Waiver of Documentation of Consent (electronic or verbal consent)
- ☑ Waiver of Consent process
- ☐ Waiver or Alteration of Some of the Required Elements of Consent

Study Population:

WOD: Staff perception survey; patient survey
WOC: Demographic and utilization statistics for seriously ill patient population
See table in 12.2 outlined by instrument

13.2 Describe the informed consent process, assent process, and parental permission process:

Instrument	A. Patient-reported outcomes (telephone survey)	B. Kidney Supportive Care Implementation Quotient (KSC-IQ) on-line survey with paper option	C. Clinical staff and change team perception of integration of new practices - NOMAD survey	D. Facility level monthly report of utilization statistics	E. Baseline and follow-up patient demographic and utilization data (including chart audit for advance

			on-line survey with paper option		care planning)
Population	"Seriously ill" patients at dialysis center	All staff of dialysis center, and associated nephrology practices and /or palliative care practices	Clinical staff of dialysis center or CKD practice	Patients served by dialysis center or ESRD Stage 4 & 5 patients of CKD practice	"Seriously ill" patients at dialysis center or CKD practice
Level of data collection	Individual	Individual	Individual	Aggregate (by center)	Individual
Consent	Waiver of documentation (already IRB approved)	Electronic consent for on-line. Check box consent (no name) for paper survey.	Electronic consent for on-line. Check box consent (no name) for paper survey.	N/A	Waiver of Consent
Consent type	verbal	Electronic or paper	Electronic or paper	N/A	N/A
Consent process	WVU interviewer reads consent script and asks for consent. (script already IRB approved). Copy of study information mailed to survey participants along with $25 incentive gift.	Self administered - Study information provided included in written form at beginning of questionnaire.	Self administered - Study information provided included in written form at beginning of questionnaire	N/A	N/A

Instrument: MMWD CKD Intervention Tracker
Population: "Seriously ill"/Medical Management without Dialysis patients at CKD practice
Level of data collection: individual
Consent: Waiver of consent
Consent type: N/A
Consent process: N/A

13.3 Where and how long signed consent documents will be securely maintained:

Note: Signed consent forms must be maintained for a minimum of 3 years following study closure per the federal regulations.

N/A

13.4 Are you performing research in an emergency setting?

○ Yes ◉ No

14.0 Waiver of Documentation of Consent

14.1 To request a waiver of documentation of informed consent (you will obtain informed consent but not have the participant sign), please select at least one of the following statements:

- **Note:** The IRB requires the investigator to provide subjects with an information sheet regarding the research. Submit the information sheet with your application in the Initial Review Submission Packet. Please be specific in explaining why either statement is true for your research.

Study population for which you are requesting:

Staff perception surveys; patients - telephone survey

☐ The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. If you answer this question and the IRB grants the waiver of written consent request, each participant must be asked whether the participant wants documentation linking the participant with the research and the subject' s wishes will govern.

☑ The research presents no more than a minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context. (e.g., asking individuals on the street about eating habits).

Please explain:

A. Patient-reported outcomes (telephone survey)
No PHI will be collected. The questions ask only the subjects' assessment of their inclusion in the decision-making process, the quality of the communication in their care, and their preferences for topics of discussion. All of the surveys will be conducted by phone and written consent would present undue burden on the patient if they were required to mail a form back or submit it via fax.

B. Staff perception of organizational competence in delivering supportive kidney care - Kidney Supportive Care Implementation Quotient (KSC-IQ on-line survey)
No PHI is collected. No identifying information is collected. However, because we will code surveys to link them to each change dialysis center, certain respondents may be identifiable if they are the only professional in their category at a dialysis center. For instance, most dialysis centers will only have one dietitian on staff. So in the professional category, a dietician would be theoretically identifiable. We will collapse professional categories so that there are at least two possible respondents at a center.

C. Staff change team perception of integration of new practices - NOMAD survey (online)
No PHI is collected. No identifying information is collected. However, because we will code surveys to link them to each change dialysis center, certain respondents may be identifiable if they are the only professional in their category at a dialysis center. For instance, most dialysis centers will only have one dietitian on staff. So in the professional category, a dietician would be theoretically identifiable. We will collapse professional categories so that there are at least two possible respondents at a center.

15.0 Waiver of Consent

15.1 In order to request to completely waive the informed consent process, please provide a response to the following questions as they apply to your research:

To qualify for IRB approval, **ALL** must be true and you must justify your response. Please be specific in explaining why each statement is applicable to your research. This type of request is typically only granted if you will not have any contact with participants.

Study population for which you are requesting:

Patient - utilization data from medical record

The research in its entirety involves no more than "minimal risk" to participants:

☑ True
☐ False

Please explain:

E. Seriously ill patients demographic and utilization statistics
Minimal risk. No sensitive information collected. We protect against loss of confidentiality by limiting access to codelink only to dialysis/CKD center staff who are performing the chart review or other data collection. The staff member who pulls the data from individual charts will already be trained in confidentiality and HIPAA procedures. The staff person to collect the data will be a staff member at the site who normally has access to the health information and/or is a member of the local research office of the site.

F. MMWD CKD Intervention Tracker

Minimal risk. No sensitive information collected. We protect against loss of confidentiality by limiting access to codelink only to dialysis/CKD center staff who are performing the chart review or other data collection. The staff member who pulls the data from individual charts will already be trained in confidentiality and HIPAA procedures. The staff person to collect the data will be a staff member at the site who normally has access to the health information and/or is a member of the local research office of the site.

The waiver will not adversely affect the rights and welfare of the participants:

☑ True
☐ False

Please explain:

There are no other benefits to which these patients will have been entitled.

The research could not be practicably carried out without the waiver:

☑ True
☐ False

Please explain:

Participants may be cognitively impaired or otherwise unable to provide consent. Due to varying state-wide laws regarding legally authorized representatives it is not practical to seek consent for this population.

Whenever appropriate, participants will be provided with additional pertinent information after participation:

☑ True
☐ False

Please explain:

Incidental findings or information obtained as a result of this study will be provided in the patient medical record.

16.0 Risks and Benefits

16.1 Risks to subjects:

Note: All research studies have some risk, such as possible loss of confidentiality. You may not answer this question "N/A" or "no risk". All must be included.

A. Patient-reported outcomes (telephone survey)
Minimal risk. It is possible that some patients would find questions about advance care planning or about their end of life preferences upsetting. Loss of confidentiality is highly unlikely since no code links or identifying information will be kept.

B. Staff perception of organizational competence in delivering supportive kidney care - Kidney Supportive Care Implementation Quotient (KSC-IQ on-line survey)
Minimal risk. Staff might be concerned that management would learn of critical answers they had provided about their organizations practices. Loss of confidentiality is highly unlikely since no identifying information is collected. However, it might theoretically be possible to identify certain professionals if they are the only one at their dialysis center (such as dietician.)

C. Staff change team perception of integration of new practices - NOMAD survey (online)
Minimal risk. Staff might be concerned that management would learn of critical answers they had provided about their organizations practices. Loss of confidentiality is highly unlikely since no identifying information is collected. However, it might theoretically be possible to identify certain professionals if they are the only one at their dialysis center (such as dietician.)

D. Facility level monthly report of utilization statistics
Aggregate data only being reported for this section. There are no risks to an individual patient from this data collection.Loss of confidentiality is highly unlikely since no identifying information is collected and centers only report aggregate data. The data will be collected either by the center producing an electronic report that pulls data from the EMR, or by a staff member who normally has access to EMR pulling data from individual charts. The staff member who pulls the data from individual charts will already be trained in confidentiality and HIPAA procedures.

E. Seriously ill patients demographic and utilization statistics
Minimal risk. We protect against loss of confidentiality by limiting access to codelink only to dialysis /CKD center staff who are performing the chart review or other data collection. The staff member who pulls the data from individual charts will already be trained in confidentiality and HIPAA procedures. The staff person to collect the data will be a staff member at the site who normally has access to the health information and/or is a member of the local research office of the site.

F. MMWD CKD Intervention Tracker
Minimal risk. We protect against loss of confidentiality by limiting access to codelink only to dialysis /CKD center staff who are performing the chart review or other data collection. The staff member who pulls the data from individual charts will already be trained in confidentiality and HIPAA procedures. The staff person to collect the data will be a staff member at the site who normally has access to the health information and/or is a member of the local research office of the site.

16.2 Steps taken to minimize risks and to protect subjects' welfare:

Steps to maintain privacy and confidentiality are addressed in section 16. Here we address only the other types of risks that could impact subjects welfare.
A. Patient-reported outcomes (telephone survey)
Patient will be informed that participation is voluntary and that they will not be penalized for their choice to participate or not participate, or for changing their choice. They will be informed that they will not lose medical care, any legal rights, or any benefits to which they are otherwise entitled. Staff who are administering surveys to patients will be trained to provide empathic responses if a patient becomes upset. With the patient's permission, the interviewer will request that the patient's care team call the patient promptly (within 24-48 hours) to assess their emotional well-being and provide additional reassurance or referral for further support or counseling. In addition,survey administrators will remind patients that they can skip any questions they don't want to answer or may terminate the survey at any point.

B. Staff perception of organizational competence in delivering supportive kidney care - Kidney Supportive Care Implementation Quotient (KSC-IQ on-line survey)
The written introduction to the survey provides information that participation is voluntary and that study team will protect confidentiality. If a staff member is highly concerned, they will likely not complete the questionnaire. No further follow-up by study team is anticipated.

C. Staff change team perception of integration of new practices - NOMAD survey (online)
The written introduction to the survey provides information that participations is voluntary and that study team will protect confidentiality. If a staff member is highly concerned, they will likely not complete the questionnaire.

D. Facility level monthly report of aggregate utilization statistics
No risks to patients or staff participants.

E. Seriously ill patients demographic and utilization statistics
No other risks to patient welfare.

F. MMWD CKD Intervention Tracker
No other risks to patient welfare.

16.3 Anticipated Benefits of research for individual subjects and/or each subject group:

Note:compensation is never a benefit.

A. Patient-reported outcomes (telephone survey)
Subjects will be asked for their input on the decision-making and communication processes at the dialysis center. The treatment they receive may be better tailored to their preferences. There is a possibility that their care may be better coordinated than prior to the study and that their wishes for care will be better respected. If as a result of the patient answering the PHQ-4 questions during the survey, the portion which asks two questions each about anxiety and depression, the patient is perceived to need immediate attention, the research coordinator conducting the phone survey will contact the patient care team at the dialysis center where the patient is treated.

B. Staff perception of organizational competence in delivering supportive kidney care - Kidney Supportive Care Implementation Quotient (KSC-IQ on-line survey)

Staff will be helping their organization improve supportive care. Participating in care improvement helps staff to feel valuable and valued by an organization It also MAY improve working conditions by reducing the emotional and ethical distress which some staff perceive when providing care that is misaligned with patient goals.

C. Staff change team perception of integration of new practices - NOMAD survey (online)
Staff will be helping their organization improve supportive care. This MAY improve working conditions by reducing the emotional and ethical distress which some staff perceive when providing care that is misaligned with patient goals.

D. Facility level monthly report of aggregate utilization statistics
By measuring improvement in quality indicators, dialysis center and CKD practice will see progress in better communication and better and more consistently delivery of supportive kidney care. This improvement in care will benefit patients. It may also reduce moral distress for staff who experience distress from delivering care that does not align with patient goals.

E. Seriously ill patients demographic and utilization statistics
No direct benefit to current patients. By measuring demographics and utilization characteristics of entire seriously ill group at baseline and follow-up to allow comparison between patients who are interviewed and those who are not, the validity of the research is strengthened. This makes it more likely that the final results will be interpretable, and that what is learned in the implementation of the project could in the future be used to improve care for similar seriously ill patients.

F. MMWD CKD Intervention Tracker
No direct benefit to current patients. The data we collect will be suitable only for descriptive analysis, but will provide information and experience towards future, more systematic efforts, and that what is learned in the implementation of the project could in the future be used to improve care for similar seriously ill patients.

16.4 Benefits of this research for society:

If the intervention to implement supportive care in dialysis centers is successful, it will provide a scalable approach to improve dialysis patient care throughout the country.

16.5 Is any deception or incomplete disclosure (withholding of complete information) required for the validity of this study?

○ Yes ◉ No

16.6 Is there a data and safety monitoring plan or board (DSMB) for this study?

○ Yes ◉ No

17.0 Privacy and Confidentiality

17.1 Which personal or demographic data will be collected?

Check all that apply:

- [x] Name
- [ ] SSN
- [ ] Medical Record # (MRN)
- [ ] DOB
- [x] Age
- [x] Phone #
- [x] Home Address
- [x] Email
- [ ] Date of medical procedures
- [x] Race / Ethnicity
- [x] Gender
- [x] Employer / School Name

- [ ] Department / Division
- [x] Disease Status
- [x] City
- [x] State / other
- [x] Zip Code
- [ ] Biological samples

Describe how the information selected in the previous question will be collected:

- Will any of it be obtained from the medical record or other existing record?
- Will it be obtained via self-report?

Instrument	A. Patient-reported outcomes (telephone survey)	B. Kidney Supportive Care Implementation Quotient (KSC-IQ) on-line survey with paper option	C. Clinical staff and change team perception of integration of new practices - NOMAD survey on-line survey with paper option	D. Facility level monthly report of utilization statistics	E. Baseline and follow-up patient demographic and utilization data
Mode of administration	Telephone survey	Self-administered on-line survey with paper option	Self-administered on-line survey with paper option	Aggregate data from quality improvement reports	Chart review or EMR report
Level of data collection	A. Individual Collecting: gender, ethnicity, race, age, and education NOTE: Name, phone, email and physical address are obtained only for purposes of contacting patient to enroll them in study and then for mailing incentive gift card and copy of information needed for consent. Name, phone, email, and physical address will not remain linked to survey data.	B. Individual Collecting: employer name	C. Individual No personal or demo data collected	D. Aggregate (by center)	E. Individual Non-identifiable data to be collected Demo include age group, sex, race, Medicaid status (proxy for economic status), ESCO status, primary language, vintage (years in dialysis treatment.

Instrument: F. MMWD CKD Intervention Tracker
Mode of administration: Chart review or EMR report
Level of data collection: Individual Non-identifiable data to be collected

17.2 Will you retain a link between study code numbers and direct identifiers?

- ( ) Yes
- (•) No

17.3 Protections that will be implemented to maintain the confidentiality of data, and specimens:

Instrument	A. Patient-reported outcomes (telephone survey)	B. Kidney Supportive Care Implementation Quotient (KSC-IQ) on-line survey with paper option	C. Clinical staff and change team perception of integration of new practices - NOMAD survey on-line survey with paper option	D. Facility level monthly report of utilization statistics	E. Baseline and follow-up patient demographic and utilization data
Codelink	Yes – maintained in separate REDCAP project at WVU	no	no	no	Yes – maintained at clinical site.
Access to code link	Site inputs code link. WVU interviewers can access to obtain contact information to call patients. Only WVU interviewers can access, not central GW research team.	N/A	N/A	N/A	Clinical site only
Share code link	no	N/A	N/A	N/A	no

Instrument: F. MMWD CKD Intervention Tracker
Codelink: Yes – maintained at clinical site.
Access to code link: Clinical site only
Share code link: no

Where and how will data and specimens be stored? How long will the data and specimens be stored?

Instrument	A. Patient-reported outcomes (telephone survey)	B. Kidney Supportive Care Implementation Quotient (KSC-IQ) on-line survey with paper option	C. Clinical staff and change team perception of integration of new practices - NOMAD survey on-line survey with paper option	D. Facility level monthly report of utilization statistics	E. Baseline and follow-up patient demographic and utilization data
Codelink	Yes – maintained in separate REDCAP project at WVU	no	no	no	Yes – maintained at clinical site.
Access to code link	Site inputs code link. WVU interviewers can access to obtain contact information to call patients. Only WVU interviewers can access, not central GW research team.	N/A	N/A	N/A	Clinical site only

Share code link	no	N/A	N/A	N/A	no
Destroy code link	WVU destroys at end of analysis.	N/A	N/A	N/A	Clinical site destroys at end of analysis.

Instrument: F. MMWD CKD Intervention Tracker
Codelink: Yes – maintained at clinical site.
Access to code link: Clinical site only
Share code link: no
Destroy code link: Clinical site destroys at end of analysis.

Who will have access to all study materials?

Only the WVU CTSI research coordinators, the GW data mananger, and a graduate assistant and a study assistant at GWU will be inputting data from the patient surveys pre-and post-intervention and the dialysis /CKD personnel responses to NOMAD, KSC-IQ and IHI single-item question respectively. Only the research team including co-PIs Drs. Lupu and Moss, the GW data manager, and the study statistician, N. Maritza Dowling, PhD, will have access to the data. Data analysis will take place at GW (Dowling). A de-identified data set will be securely emailed to the independent outside evaluators.

How will study materials be destroyed?

Instrument	A. Patient-reported outcomes (telephone survey)	B. Kidney Supportive Care Implementation Quotient (KSC-IQ) on-line survey with paper option	C. Clinical staff and change team perception of integration of new practices - NOMAD survey on-line survey with paper option	D. Facility level monthly report of utilization statistics	E. Baseline and follow-up patient demographic and utilization data
Destroy code link	WVU destroys at end of analysis. Note: Any worksheets listing patients who can be contacted will be deleted from the password-protected computer files.	N/A	N/A	N/A	Clinical site destroys at end of analysis.

Instrument: F. MMWD CKD Intervention Tracker
Destroy code link: Clinical site destroys at end of analysis.

How will data and specimens be transported and who is responsible for receipt or transmission of the data or specimens?

No specimens will be collected.
Data will be transmitted via secure messaging through REDcap or secure email from site's secure email to GW secure email.

Will data or specimens be used for future research?

No identifiable data will be used or shared for future research.

Where will data analysis take place and how will data security be maintained during analysis?

Data analysis will take place at WVU CTSI and GWU. Only the research team including co-PIs Drs. Lupu and Moss, the data manager, and the study statistician, N. Maritza Dowling, PhD, will have access to the data, stored securely in REDCap or on GW Box.

17.4 Data Reporting: Describe whether data will be aggregated/summarized in publications and presentations and/or individual results (e.g.,

de-identified quotes) will be communicated. If individual results are to be communicated, this should be clearly described to the subject in the consent document:

If individual results are to be communicated, this should be clearly described to the participant in the consent document, or the participant should have the option to opt out of having their individual results presented.

In general, the data will be aggregated and summarized. In qualitative analysis, we may include some transcribed comments or conversations, for purposes of illustration. In this case, no identifying information will be included. This is described in the consent document.

17.5 Will you retain identifying information for recruitment into future research?

○ Yes ◉ No

17.6 Is the study NIH funded?

○ Yes ◉ No

17.7 If the study will collect information that, if disclosed, could have significant negative consequences to the subjects such as damage to their financial standing, employability, insurability or reputation (e.g., HIV, AIDS, other STDs; use of alcohol, drugs, or other addictive products, illegal behaviors, etc.), will a Federal Certificate of Confidentiality (CoC) be obtained for this research?

◉ N/A (no sensitive information is being collected)
○ No
○ Yes

18.0 Use of Protected Health Information (PHI): HIPAA Requirements

18.1 If obtaining, viewing, or collecting records or data from medical or clinical settings to support subject selection, will any potential subjects currently be under treatment by a member of the research study team?

◉ Yes ○ No

18.2 Will this study involve access to, or use of, any subjects' 18 identifiable pieces of protected health information (PHI) defined under HIPAA (45 CFR 164.514(A)(2)) from a covered entity?

- Visit **https://www.hhs.gov/hipaa/** for more information about the Health Insurance Portability and Accountability Act (HIPAA).

◉ Yes
○ No

Select one or more options that apply:

☐ I will create a HIPAA Authorization to be included in the consent document.
☐ I am requesting a HIPAA Partial Waiver (for recruitment purposes only)
☑ I am requesting a HIPAA Full Waiver (to be used when viewing PHI or collecting PHI without consent)

Attach HRP-281 Form "HIPAA Partial Waiver Request" in the Initial Review Submission Packet.
This form can be found at: **https://humanresearch.gwu.edu/hipaa-forms-0**

19.0 Compensation and Cost

19.1 Will subjects be given payments/compensation, gift cards, travel expense reimbursement, gifts, incentives, or raffles?

◉ Yes ○ No

Describe the payment schedule, and what will happen if subjects withdraw from the study:
Note: that compensation is not considered a benefit of research.

A. Patient-reported outcomes (telephone survey): Participants will receive compensation $25 per telephone survey for their time and effort completing baseline and follow-up surveys. Gift cards are distributed to patients at the completion of each survey. Compensation will be distributed over the course of study participation. Our initial plan is to provide $25 following the baseline survey and $25 after the follow-up survey. If a patient is selected into the sample for both studies, this will result in total compensation of $50 for participants. However, the follow-up sample will be selected separately, so many people will only receive $25 for completing one survey. Gift cards will be sent via U.S. mail after the telephone survey is completed.

19.2 What components of the study are provided free of charge to the participant (e.g., drugs, procedures, etc.), and what components will be the participants responsibility?

No charge to participants.

19.3 Are there any costs to the subjects?

○ Yes ◉ No

19.4 Who will be financially responsible for research related injuries?

Please check all that apply and include this information in the Informed Consent document.

- ☐ Study Sponsor
- ☐ Research participant or participant's insurance / third party payer
- ☐ PI's compensation plan
- ☑ Minimal risk research with no risk for research related injuries
- ☐ Other

20.0 Medical, Therapeutic, or Other Diagnostic Studies

20.1 Does this study involve drugs or biologics?

○ Yes ◉ No

20.2 Does this study involve devices?

○ Yes ◉ No

21.0 Ancillary Reviews

21.1 Radiation Safety Committee Review: Will radioactive materials (e.g., nuclear medicine, radio-immune therapy) or an ionizing radiation producing machine (e.g., CT, X-ray, Accelerator, DEXA scanner) be used as part of the study and result in a study participant or a healthy volunteer receiving a radiation dose they would not otherwise receive as part of their standard clinical care?

○ Yes ◉ No

21.2 Institutional Biosafety Committee Review: Will this study involve the deliberate transfer/administration of recombinant DNA, DNA /RNA derived from recombinant DNA, or synthetic DNA into one or more study participants?

- **Note:** For multicenter studies where GW is the IRB of record for an external clinical trial site, please attach a copy of the clinical trial site's IBC review and approval in the Initial Review Submission Packet.

○ Yes ◉ No

21.3 Institutional Stem Cell Research Oversight: Does this study involve the use or destruction of embryonic stem cells?

○ Yes ◉ No

22.0 Application Questions Complete

22.1 Please click Save & Continue to proceed to the Initial Review Submission Packet.

The Initial Review Submission Packet is a short form filled out after the protocol application has been completed. This is an area to attach protocol-related documents, consent forms, and review the application.