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Best Case/Worst Case: protocol for a multisite randomised clinical trial of a scenario planning intervention for patients with kidney failure

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ABSTRACT

Introduction Given the burdens of treatment and poor prognosis, older adults with kidney failure would benefit from improved decision making and palliative care to clarify goals, address symptoms, and reduce unwanted procedures. Best Case/Worst Case (BC/WC) is a communication tool that uses scenario planning to support patients’ decision making. This article describes the protocol for a multisite, cluster randomised trial to test the effect of training nephrologists to use the BC/WC communication tool on patient receipt of palliative care, and quality of life and communication.

Methods and analysis We are enrolling attending nephrologists, at 10 study sites in the USA, who see outpatients with advanced chronic kidney disease considering dialysis. We aim to enrol 320 patients with an estimated glomerular filtration rate of ≤24mL/min/1.73m² who are age 60 and older and have a predicted survival of 18 months or less. Nephrologists will be randomised in a 1:1 ratio to receive training to use the communication tool (intervention) at study initiation or after study completion (wait-list control). Patients in the intervention group will receive care from a nephrologist trained to use the BC/WC communication tool. Patients in the control group will receive usual care. Using chart review and surveys of patients and caregivers, we will test the efficacy of the BC/WC intervention with receipt of palliative care as the primary outcome. Secondary outcomes include intensity of treatment at the end of life, the effect of the intervention on quality of communication (QOC) between nephrologists and patients (using the QOC scale), the change in quality of life (using the Functional Assessment of Chronic Illness Therapy-Palliative Care scale) and receipt of dialysis.

Ethics and dissemination Approvals have been granted by the Institutional Review Board at the University of Wisconsin (ID: 2022-0193), with each study site ceding review to the primary IRB. All nephrologists will be consented and given a copy of the consent form. No patients or caregivers will be recruited or consented until their nephrology provider has chosen to participate in the study. Results will be disseminated via submission for publication in a peer-reviewed journal and at national meetings.

Trial registration number NCT04466865.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The communication intervention under study uses a graphic aid that is not only useful for patients, but also functions to measure adherence to the intervention.
⇒ There is a diversity of study sites and utilisation of complementary data from chart review, patient self-report and caregiver report.
⇒ There has been difficulty enrolling seriously ill older adults during the COVID-19 pandemic.
⇒ Nephrologists will need to use the tool during a busy in-person or virtual clinic visit.
⇒ Each patient’s overall health trajectory and time to death will vary, making study of end-of-life outcomes complex.

INTRODUCTION

Older adults with advanced kidney disease, particularly those with comorbidities and/or frailty, have life-limiting illness, which will lead to major changes in quality of life and functional status over time. As their kidney function declines, most will consider dialysis. Yet older adults often initiate dialysis without understanding their prognosis, the investment of time needed for receipt of dialysis and the life-sustaining nature of this treatment. Although some will gain a survival advantage, patients with multiple comorbidities will often fail to achieve this goal. For example, median survival after starting dialysis is 15.6 months for patients age 80–85, and 20% will die within 3 months of dialysis.
initiation. Patients who do achieve prolonged survival with dialysis will nonetheless experience treatment burdens and distressing symptoms. These include time spent in dialysis; repeat hospitalisations; vascular access complications; and symptoms of pain, sleep disturbance, depression, itching, oedema, constipation, nausea and loss of appetite. When patients choose to forgo dialysis, they experience fewer treatment burdens, but their symptoms are similarly formidable.

Clinicians, focused on disease management, describe dialysis options but struggle to concurrently communicate the severity of disease, the hardship of treatment and overall prognosis. As such, patients are often unaware of how sick they truly are. Because dialysis is described as ‘kidney replacement’, it is regarded as a straightforward solution. Describing dialysis as a ‘fix’ for kidney failure does little to reveal how a patient might experience dialysis, or expected downstream outcomes, such as predictable changes in functional status or long-term prognosis. In one study, investigators found that for roughly 90% of patients, nephrologists did not disclose prognosis. Studies have found that between 20% and 60% of older adults regretted their decision to start dialysis.

Given these concerns, nephrologists might benefit from a stronger framework to discuss dialysis initiation with older adults who have limited survival. This would support discussion of treatment options while describing the experiences and outcomes of treatment within the context of the patient’s overall health trajectory. Because kidney failure is life-limiting, the framework should also provide an entrée to concurrent palliative care, regardless of the patient’s choice about dialysis. Palliative care, with or without dialysis, is recommended for all patients with advanced kidney disease and limited survival to support advance care planning, symptom management and, when needed, high quality end-of-life care.

To address this problem, we developed a communication tool called Best Case/Worst Case (BC/WC) to help nephrologists better describe a treatment choice between life with or without dialysis. The tool uses a strategy called scenario planning and a graphic aid to help patients and their caregivers anticipate and prepare for a future with kidney failure. By using scenario planning—narrative description about plausible futures—nephrologists can translate evidence about the patient’s prognosis within stories to demonstrate a range of plausible futures. We theorise that training nephrologists to use this tool to support shared decision making about dialysis will increase receipt of guideline-recommended concurrent palliative care for older adults with life-limiting kidney failure.

We designed a multisite, cluster randomised clinical trial to test the effect of training nephrologists to use the BC/WC tool on receipt of palliative care, quality of life and quality of communication for older adults with kidney failure and limited life expectancy. First, we discuss the theoretical foundations of the intervention and study design. We then describe the research protocol including participant characteristics, data collection, outcomes and analysis plan.

Scenario planning

The BC/WC communication tool uses an approach called ‘scenario planning’ to facilitate decision making in the setting of uncertainty. Scenario planning was originally developed in the 1950s for military planning. It was then popularised for broader use by Pierre Wack, an economist, to translate vast probabilistic information into narrative description to facilitate strategic decisions. Rather than emphasising precise isolated risks, this technique generates multiple plausible futures, prompting decision-makers to visualise what might happen under different sets of assumptions. Scenario planning is distinct from standard medical practice that uses risk prediction and statistics to describe prognosis. Scenario planning enables clinicians to say, “I cannot see the future, but if all goes well, this is what’s likely to follow, and if things go poorly, this is what we can expect.” By highlighting the interaction between forces that drive change and providing an organised way to consider alternative futures, scenario planning promotes insight. Although it has been successfully applied to a wide range of decisions in business and government, scenario planning is not broadly used clinically.

We adapted scenario planning for healthcare decision making in the BC/WC communication tool. This tool is distinct from decision aids that demonstrate event rates and probabilities, represent outcomes numerically, or pictorially, and function by activating patients for decision making before meeting with a clinician (ie, with brochures, educational videos, web programmes and decision tables). In contrast, nephrologists use the BC/WC tool directly with patients to illustrate treatment options, convey a clear message about prognosis and acknowledge uncertainty using language such as, ‘this is what we are hoping for’ or ‘this is what we are worried about.’ By using scenario planning to translate evidence about the patient’s overall health within narratives that show the range of plausible futures, nephrologists can elicit patients’ opinions about specific health states and recommend goal-concordant treatment. Use of this tool can encourage patients to comprehend a new, previously unimaginable reality and prepare for major shifts in a way that simple prognostication (forecasting) cannot. Moreover, scenario planning allows patients to anticipate unwanted events, such as recurrent hospitalisations, which can facilitate use of palliative care consultation to alleviate symptoms and clarify care goals regardless of the patient’s dialysis initiation decision.

How the BC/WC tool works

The clinician verbally describes the ‘BC,’ ‘WC’ and ‘most likely’ stories about the experience of each treatment option while using a graphic aid to help patients follow along and have a record of the conversation (figure 1). Vertical bars represent each treatment option; their
length shows the range of outcomes and the magnitude of the difference between the ‘best case’ (star) the ‘worst case’ (square) and a ‘most likely case’ (oval). The clinician also writes notes about each option on the diagram. A copy of the graphic aid is stored in the patient’s chart. Patients also retain a copy to discuss options with family and to support future conversations with their nephrologist and other clinicians. This approach—using personalised information and a graphic aid—supports best practices to improve understanding of complex health information, especially for people with low health literacy.23 24

Study design
This study is designed to test the effect of a decision-making intervention on the quality of care received, based on evidence that patients with life-limiting illness benefit greatly from concurrent palliative care.25 26 We hypothesise that improving conversations about dialysis will help patients receive palliative care consultation and support subsequent treatment decisions that align with personal goals.

Patients who are more informed about the experience of dialysis and their overall health trajectory might take advantage of palliative care earlier in their course of illness. As compared with patients with terminal cancer and heart failure, patients with kidney failure are more than twice as likely to be admitted to the ICU and less than half as likely to be admitted to hospice in the final month of life.27–29 Fewer than 6% of patients on dialysis have had the opportunity to discuss end-of-life wishes.30 Palliative care for patients with poor prognosis is supported by the American Society of Nephrology,14 15 however, barriers to palliative care include (1) patient lack of awareness about the life-limiting nature of kidney failure and (2) an illness trajectory typified by a slow overall decline with interval catastrophic events and partial recovery, not a sharp and obvious deterioration.31 These barriers cannot be overcome by simply referring patients to palliative care.

Outcomes
As there is no ‘best treatment choice’ for these patients as a group, dialysis initiation is not the primary outcome. Measuring change in the rate of dialysis initiation does not reflect whether patients have received care in accordance with their goals. Moreover, there are unyielding challenges in attempting to measure receipt of goal-concordant care. One would first need to assess a patient’s goals and values, and then determine whether the treatment received was consistent with these values. Because clinicians do not typically elicit patients’ goals and values, measurement of this variable could change the outcome of interest.

We also considered assessing decisional conflict and regret but found this measurement to be unsatisfactory. Ascertaining of decisional conflict is hampered by the framing of the clinical question.32 For example, if a nephrologist says, “You need dialysis or you will die,” patients will report little decisional conflict or regret on starting dialysis, yet this outcome does not capture whether patients are well-informed or if they have
received goal-concordant care. Aiming to reduce decisional conflict suggests conflict around uncertainty is inherently undesirable, whereas conflict during deliberation might be necessary to make a decision that best reflects a patient’s values.

We theorise that patients whose nephrologists communicate better will receive better care. Therefore, we will measure receipt of palliative care as the primary outcome. Teaching nephrologists to use the BC/WC communication tool will lead to increased receipt of palliative care via multiple pathways: first, via direct provision of information about prognosis and health trajectory, second, through improving the QOC about options and outcomes, and third, via improving decision making about dialysis initiation.

**METHODS AND ANALYSIS**

**Design and setting**

To test the efficacy of the BC/WC intervention, we will use parallel randomisation with a wait-list control, randomising nephrologists within each site to receive intervention training at study initiation or on study completion. Patients in the control group will receive usual care; patients in the intervention group will receive care from a nephrologist trained to use the BC/WC communication tool. We anticipate 2 years will be needed to enrol a full cohort of 320 patients. The estimated total number of study participants is 680 which includes 320 patients, up to 320 caregivers and 40 nephrologists. We will follow patients and their caregivers for 2 years via survey administration and chart review. We are conducting the study in outpatient nephrology clinics at ten academic medical centres across the USA (table 1).

The study is coordinated by the University of Wisconsin study team with technical support provided by the Palliative Care Research Cooperative Group (PCRC).

**Screening and enrolment**

**Nephrologists**

We will enrol nephrologists, including doctors and advanced practice providers, who care for older patients with advanced chronic kidney disease considering chronic dialysis. We will exclude trainees and nephrologists whose practices are focused on other aspects of clinical nephrology. Qualifying nephrologists will be offered US$250 for completing training.

**Patients**

We plan to enrol 320 (160 per arm) patients with an estimated glomerular filtration rate (eGFR) of less than or equal to 24 mL/min/1.73 m² who are age 60 years and older. We will enrol patients who have an estimated survival of 18 months or less (with or without dialysis) based on meeting at least one of the three criteria defined by Robins: age greater than 80, evidence from the medical record that the patient has comorbid illness such that the modified Charlson score is 4 or greater, or a ‘no’ response to the ‘surprise Question’ (‘Would you be surprised if this patient died in the next year?’) from the patient’s nephrologist. We will exclude patients who (1) are currently treated with dialysis, (2) lack decision-making capacity or (3) do not speak English.

**Caregivers**

We will invite one family member or informally designated ‘like family’ caregiver per patient to participate. Patients can participate without caregivers; however, caregivers cannot participate without a corresponding patient. Caregivers must be at least 18 years old. We will exclude caregivers who don’t speak English, and those who do not have decision-making capacity. Including caregivers will help reduce missing data by providing a proxy measurement when study participants with life-limiting illness are too sick to respond.

**Recruitment and enrolment**

Patients who meet inclusion criteria will be contacted prior to their visit to obtain consent. Patients will receive US$20 at enrolment and US$10 for each follow-up survey. Caregivers will receive US$15 at enrolment and US$5 for each follow-up survey. Study enrolment commenced on 1 January 2021 with an original estimated primary completion date of January 2025 (2 years of enrolment, 2 years of follow-up).

**Randomisation and blinding**

Nephrologists will be clustered by site and are randomised to the control or intervention group in a ratio of 1:1. A block randomisation scheme will be used with blended block size. Nephrologists will not be blinded to study group and will be informed of the goals of this study. To maintain blinding of local research staff performing data collection, the Wisconsin-based education team will coordinate individual training with nephrologists.

To reduce the possibility of study staff exposure to the nephrologist’s randomisation assignment, we will provide regular reminders to nephrologists that they should not reveal their treatment group to study staff. To decrease ascertainment bias, study staff will adhere to a study script during interactions with nephrologists and during

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**Table 1**  Trial study sites and their locations

<table>
<thead>
<tr>
<th>Study site</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Columbia University</td>
<td>New York City, NY</td>
</tr>
<tr>
<td>University of Colorado</td>
<td>Aurora, CO</td>
</tr>
<tr>
<td>Johns Hopkins University</td>
<td>Baltimore, MD</td>
</tr>
<tr>
<td>Medical College of Wisconsin</td>
<td>Milwaukee, WI</td>
</tr>
<tr>
<td>Mount Sinai Health System</td>
<td>New York City, NY</td>
</tr>
<tr>
<td>Northwestern Memorial Hospital</td>
<td>Chicago, IL</td>
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<tr>
<td>University of Pittsburgh</td>
<td>Pittsburgh, PA</td>
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<tr>
<td>University of Vermont</td>
<td>Burlington, VT</td>
</tr>
<tr>
<td>West Virginia University</td>
<td>Morgantown, WV</td>
</tr>
<tr>
<td>University of Washington</td>
<td>Seattle, WA</td>
</tr>
</tbody>
</table>

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the survey administration with patients and caregivers. Patients and caregivers will be blinded to the measured outcomes of this study.

**Intervention**

The original version of the intervention was developed with input from older adults via focus groups conducted at senior centres in Wisconsin.37 The intervention was then modified to specifically fit dialysis decision making with support from patients and their caregivers. In interviews, they expressed enthusiasm for content about prognosis and decision making and ease of use within their clinic visit with the nephrologist.

The intervention comprises a 2-hour one-on-one training session, three additional 20min coaching sessions, debriefs every 2 months during the first year and quarterly debriefs in the second year. The 2-hour training session includes a 10min introduction, coach demonstration, individual preparation and practice with standardised patients, and expert feedback, that is, coaching. The primary skill targeted is translation of clinical knowledge and prognostic information into the BC/WC format, using scenario planning and the graphic aid. Nephrologists will receive specific instruction on how to refer patients to palliative care, including scripted language: for example, “I’d like you to see our palliative care team. They can help you feel as well as you can for as long as you can.”

The training programme culminates in an assessment of nephrologists’ use of the tool with a standardised patient. Instructors will assess the fidelity of the nephrologist’s use of the BC/WC tool using a 19-item checklist of adherence criteria (figure 2). Nephrologists who do not achieve minimal competence (<14/19) will receive additional training until they achieve competence.

Following the initial training, instructors will contact nephrologists for three additional 20min coaching sessions. This will occur every 2 weeks for 6 weeks after training when nephrologists have had the opportunity to use this tool clinically. These sessions will focus on troubleshooting in-the-moment issues with additional support.

**Figure 2** Best Case/Worst Case skills checklist and observation form. Instructors evaluate 19 criteria to assess nephrologists’ performance after they have completed training. Competence is defined as achieving a score of at least 14/19.
for integrating the tool within a busy nephrology clinic. Due to the COVID-19 pandemic, in-person training, standardised patient scenarios and coaching were adapted for virtual education on the Zoom platform.²⁸

To ensure intervention adherence throughout the study, study staff will remind nephrologists to follow the assigned communication condition prior to an enrolled patient’s clinic visit. Study staff will notify all nephrologists each time one of their patients has enrolled in the study. Specifically, study staff will say, ‘This patient is enrolled in the study, if you are in the intervention group, please use the communication tool during this visit.’ To document use of the tool, study staff will provide a folder including a triPLICATE carbon copy of the graphic aid template (one study copy, one copy for the patient and one copy for the patient’s chart), a written reminder to use the BC/WC tool (as appropriate), and blank carbon copy paper for notes written by study-enrolled nephrologists. Nephrologists in the waitlist control group may use any of the forms as they wish or disregard them. We anticipate minimal contamination between nephrologists as our experience indicates training and support is required to use the tool. Nephrologists will return the folder and its contents sealed in a preaddressed envelope directly to the Wisconsin education team.

To maintain use of the tool over time, the education team will conduct debriefings with nephrologists every 2 months during year one and quarterly debriefings in year two. Instructors will review the submitted graphic aids, provide feedback on fidelity to nephrologists, and take field notes to evaluate training and implementation of the tool.

Data collection
Patient and caregiver surveys
Prior to the patient’s visit with the nephrologist, study staff will administer the Functional Assessment of Chronic Illness Therapy-Palliative Care (FACT-Pal V.4) survey.³⁶ We obtain this prior to the patient’s first visit on study as patients who receive new information about their prognosis may rate their quality of life lower as a result. Simultaneously, caregivers will complete a single-item literacy screener and the Cambridge Palliative Audit Schedule (CAMPAS-R), which allows us to assess the patient’s quality of life (QOL) as reported by caregivers.

Within 48 hours after the patient’s visit with the nephrologist, study staff will administer the QOC questionnaire via telephone. Unlike other measurements of physician communication that have high ceiling effects and limited ability to measure change, the QOC includes seven items specific to end-of-life communication, which, if not performed by the clinician, are scored as zero. This will allow us to discriminate between QOC attributable to patient satisfaction vs content.

We will repeat the quality-of-life measurement every 3 months for 2 years after enrolment or until patient death. We will administer the Quality of Death and Dying (QODD) survey to enrolled caregivers between 30 days and 3 months after patient death for patients who die while on study.

Chart review
We will use monthly chart review to record treatments received, including palliative care consultation, ICU admissions, hospitalisations, emergency room visits, dialysis initiation and termination, life supporting treatments including intubation and CPR, days in hospice and death. These data will be collected and managed using REDCap electronic data capture tools hosted at the University of Wisconsin.⁴¹ ⁴² We will ensure data quality through an independent review of all data entry for one patient every 10 patients.

Outcomes
Palliative care
To assess receipt of palliative care, we will use chart review and patient and caregiver report to determine patient receipt of any inpatient or outpatient palliative care consultation within 12 months of enrolment. Palliative care consultation must be clearly marked and provided by a clinician with palliative care training (MD, DO, PA, NP, MSW, RN or Chaplain). The visit must have documented discussion of at least one of the following: advance care planning, symptom management or end-of-life care.

Intensity of treatment
To measure intensity of treatment received at the end of life we will ascertain whether patients have had an ICU admission within 30 days of death and ICU admission, emergency room (ER) visit, or hospital admission within 30 days of death as a composite outcome.

Secondary outcomes
Additional secondary outcome measures include health-related quality of life, QOC, dialysis initiation, death on study, caregiver bereavement and quality of life and QOC as assessed by caregivers (table 2).

Planned analysis
Sample size calculation
The sample size estimate, 320 patients (160/group), is based on the primary hypothesis that patients in the intervention arm will be more likely to receive palliative care. This study is powered to detect a 10%–15% absolute difference in the care patients receive, consistent with other interventions designed to effectively increase access to palliative care.⁴³–⁴⁶ Smaller differences are unlikely to be considered meaningful to clinicians, patients or researchers.⁴⁶ We desire a two-sided type I error rate of 0.05 for each aim and estimate that the between-physician variance is around 10%. We plan to use fixed effects to account for clustering by site because it is faithful to our study design and controls for confounding related to imperfect randomisation due to site imbalances better than a random effects model.
Primary outcomes analysis

Our primary analysis will compare the efficacy of the BC/WC training programme relative to usual care in regard to receipt of palliative care consult within 12 months of study enrolment. We will use summary statistics to describe, by group, patient and nephrologist characteristics. As patient comorbidity and baseline functional status are highly predictive of outcomes, we will adjust for these covariates to avoid spurious results, and to increase power by reducing residual error in the response. We will use an intention-to-treat analysis and compare outcomes between the two arms using a proportional odds cumulative incidence model, where death is incorporated as a competing risk. The intervention will be a binary predictor and the treating physician will be a random effect to account for the correlation within the physician. Site will be included as a fixed effect.

Secondary outcomes analysis

We will conduct secondary analyses with intervention as the main predictor while adjusting for demographic and clinical factors. All analytical methods used will account for the cluster effect of the treating physician by incorporating a random-intercept for physician. We will analyse the cumulative receipt of palliative care throughout the length of follow-up using a proportional odds cumulative incidence model.47 Death will be treated as a competing risk. Regarding quality of life, we will conduct a linear mixed effects regression on the difference in FACIT-Pal scale between baseline and death or at 2 years after enrolment, whichever occurs first. We will use a linear mixed-effects model with the QOC scale as the outcome.

We will perform additional analyses to test and quantify receipt of dialysis, and caregiver outcomes. We will analyse receipt of dialysis using the proportional odds cumulative-incidence model for competing risks with death as a competing risk. We will analyse the time from enrolment to death using a mixed-effects Cox regression. We will use linear mixed-effects model to analyse caregiver outcomes: QODD (for caregivers of decedents only), CAMPAS-R and QOC (family member version). We will use qualitative content analysis to analyse field notes from nephrologist training and follow-up sessions.

### Table 2 Primary and secondary outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Specific measure</th>
<th>Type; range</th>
<th>Source</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receipt of palliative care</td>
<td>Any palliative care consult within 12 months of enrolment (primary outcome)</td>
<td>Binary; 0/1</td>
<td>Chart review, patient or surrogate report</td>
<td>Enrolment, every 3 months up to 12 months on study</td>
</tr>
<tr>
<td></td>
<td>Any palliative care received</td>
<td>Binary; 0/1</td>
<td>Chart review, patient or surrogate report</td>
<td>Enrolment, every 3 months up to 2 years on study</td>
</tr>
<tr>
<td></td>
<td>New documentation of advance care planning</td>
<td>Binary; 0/1</td>
<td>Chart review</td>
<td>Enrolment to 2 years on study</td>
</tr>
<tr>
<td></td>
<td>Hospice enrolment</td>
<td>Binary; 0/1</td>
<td>Chart review</td>
<td>Enrolment to 2 years on study</td>
</tr>
<tr>
<td>Intensity of treatment</td>
<td>ICU admission within 30 days of death</td>
<td>Binary; 0/1</td>
<td>Chart review, surrogate report</td>
<td>Date of death minus 30 days</td>
</tr>
<tr>
<td></td>
<td>ER visit, ICU or hospitalisation within 30 days of death; surgical procedures within 30 days of death; Intubation; CPR; days in hospice</td>
<td>Binary composite; 0/1 count</td>
<td>Chart review, surrogate report</td>
<td>Date of death minus 30 days</td>
</tr>
<tr>
<td>Health-related quality of life</td>
<td>Functional Assessment of Chronic Illness Therapy-Palliative Care Version 4</td>
<td>Continuous; 0–184</td>
<td>Patient</td>
<td>Enrolment, every 3 months up to 2 years</td>
</tr>
<tr>
<td>Quality of communication (QOC)</td>
<td>QOC</td>
<td>Continuous; 0–10</td>
<td>Patient</td>
<td>Within 48 hours after enrolment</td>
</tr>
<tr>
<td>Dialysis</td>
<td>Initiation of dialysis; withdrawal of dialysis</td>
<td>Binary; 0/1</td>
<td>Chart review, patient or surrogate report</td>
<td>Enrolment to 2 years on study</td>
</tr>
<tr>
<td>Death</td>
<td>Patient death</td>
<td>Time to event</td>
<td>Chart review, surrogate report</td>
<td>Date of death</td>
</tr>
<tr>
<td>Bereavement</td>
<td>Quality of Dying and Death (QODD) survey</td>
<td>Continuous; 0–100</td>
<td>Caregiver</td>
<td>30 days to 3 months after patient death</td>
</tr>
<tr>
<td>Health-related quality of life</td>
<td>Cambridge Palliative Audit Schedule (Caregiver impression of QOL)</td>
<td>Continuous; 0–100</td>
<td>Caregiver</td>
<td>Enrolment and every 3 months up to 2 years</td>
</tr>
<tr>
<td>QOC</td>
<td>QOC Questionnaire (Family member version)</td>
<td>Continuous; 0–10</td>
<td>Caregiver</td>
<td>Within 48 hours after enrolment</td>
</tr>
</tbody>
</table>

QOL, quality of life.
Missing data
Study participants are subject to attrition due to death (ADD), attrition due to illness (ADI) and attrition at random. ADD and ADI can lead to non-ignorable missing data because the missing mechanism is related to the patient’s health status, which is potentially an effect of the intervention. We expect that missing outcomes will be minimal for receipt of palliative care, intensity of treatment and QOC because they are measured at early stages (within 12 months) or 30 days retrospectively from death. The QOL measure, however, is likely to suffer from both ADD and ADI. We plan to compare the difference between QOL at baseline and death or 2 years after enrolment (whichever comes first) to handle the fact that patients will have a different number of observations. Similar strategies have been used by other studies of palliative care interventions reflecting a quality of life/length of life trade-off. Receipt of palliative care and dialysis are subject to ADD. Death will be incorporated as a competing risk to account for different lengths of follow-up in our secondary analysis. Because death is not likely to be independent of the outcomes, we will conduct analyses using inverse probability censoring weighting adjusting for confounders such as patient QOL measures as sensitivity analysis.

Protocol modifications
Few patients died during the first 12 months of data collection, which was inconsistent with their estimated survival based on risk prediction. This observation led us to believe that it would be unlikely to have enough observed death on study to evaluate the effect of the intervention on care received at the end of life. With permission from the funder and the data and safety monitoring board (DSMB), we reclassified the outcome ‘intensity of treatment at the end of life’ from a coprimary outcome to a secondary outcome. In addition, to address the COVID-19-pandemic-related decrease in enrolment we modified the approved proposal to expand enrolment criteria to include patients with eGFR of 24 or less and two additional study sites (as reported herein). These modifications were approved by the funder and the DSMB.

Patient and public involvement
None.

ETHICS AND DISSEMINATION

Ethical review
The aims of the study meet criteria for minimal risk. All participants will provide informed consent and may withdraw from the study at any time without affecting the medical care they receive. Consent forms for patients, caregivers and nephrologists are provided as online supplemental files 1–3, respectively. For nephrologists, study participation will not affect their professional standing. Institutional review board (IRB) approval has been granted at UW (ID: 2022-0193) with study sites ceding review to the primary IRB. We will follow accepted adverse event monitoring procedures including review every 6 months by the data monitoring committee.

Relevance and dissemination
There is currently no level one data supporting the use of scenario planning for patients with life-limiting illness. Study results will be published in peer-reviewed journals and intervention training materials, including the graphic aid, instructional videos and learner manual, are available free of charge at https://patientpreferences.org/bcwc-nephrology/. Durable improvements in serious illness communication will require training in scenario planning, which could be disseminated by stakeholder groups including the American Society of Nephrology and the National Kidney Foundation. Empirical evidence of efficacy would support incentives from payors by rewarding nephrologists for use of the tool. We will distribute final study results to patient, caregiver and nephrologist participants via a study website, reminding them of the website at the time of final data collection. In addition, we will remind participants that study results are publicly available at ClinicalTrials.gov.

By conducting this study in a patient population with one specific decision about initiation of life-sustaining treatment, we can consider how scenario planning might be effective in other settings where treatment decisions vary widely, for example, acute surgical interventions or cancer care. If effective, the BC/WC intervention is easily scalable. This communication tool can be rapidly adapted for other clinicians in order to provide better care for older adults with life-limiting illnesses.

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7Division of Nephrology, University of Vermont, Burlington, Vermont, USA
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10Division of Nephrology, Mount Sinai Health System, New York, New York, USA
11Division of Nephrology, University of Washington, Seattle, Washington, USA
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Contributors MS is the principal investigator for this study. She developed the original study design and protocol together with KKL, PR, BMH, LS, TCC, RJ who provided input on study design, and the site principal investigators ADB, KC, DC, RF, HK, DL, AM, MR, DFW and JY. CB and RK provided study design and technical support. AB is the study manager and has the primary responsibility of coordinating development of all study materials. KH drafted this manuscript and along with A2 helped with development of educational materials. All authors reviewed and approved this manuscript.

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REFERENCES


45 McCarrol CM. Increasing access to palliative care services in the intensive care unit. Dimens Crit Care Nurs 2018;37:180–92.
[SITE NAME]
Research Participant Information and Consent Form

Title of the Study: Best Case/Worst Case: A Multisite Randomized Clinical Trial of Scenario Planning for Patients with Kidney Disease

Principal Investigator: [SITE PI NAME, PHONE NUMBER AND EMAIL ADDRESS]

Mailing Address: [SITE ADDRESS]

DESCRIPTION OF THE RESEARCH

You are invited to participate in a research study about communication between nephrologists and patients making significant treatment decisions. The purpose of the research is to improve communication between nephrologists and patients so that patients can make treatment decisions that are the best for them. We are studying a communication tool that uses a specific way to describe treatment options and a diagram to assist patients in their decision making.

You have been asked to participate because you are a nephrologist at [SITE NAME]. This study will enroll patients who are facing a choice about dialysis as well as their caregiver. This study will enroll up to 80 nephrology providers and 340 patients at sites across the United States.

This study is being overseen by The University of Wisconsin-Madison and The Palliative Care Research Cooperative Group (PCRC). The PCRC is the only US research cooperative focused specifically on the science of palliative and end-of-life research, and will be providing oversight on the conduct of this research study. By participating in a PCRC study, you will be part of a large group of study participants across the nation, and the findings from the research will be distributed quickly and widely. The Principal Investigator of this study is [SITE PI NAME] from [SITE NAME]. A grant from the National Institute on Aging is funding this study.

WHAT WILL MY PARTICIPATION INVOLVE?

If you decide to participate in this research study, you will be randomly assigned to participate in a training session, to learn how to use the communication tool, either at the start of end of the study. This 2-hour small group session will teach you how to use the “Best Case/Worst Case” communication tool to describe dialysis choices to patients. The training will include practice sessions with standardized patients and will be scheduled at a time convenient for you. Training will include a test of competence. After training we will contact you via phone or skype for three additional 20-minute coaching sessions. These will occur every two weeks for six weeks after the original training. Additionally, for those who are trained at the start of the study, in the first year we will debrief you every 2 months to evaluate your use of the communication tool. In the second year, we will debrief you every 3 months. These debriefings will last about 15 to 20 minutes.
Additionally, if you agree to participate in this study, your patients (and their caregivers, if they choose to enroll) will complete a short survey every 3 months for up to 2 years. These surveys will be given outside of their clinic visits.

You will be asked to complete two surveys:

- A brief demographic survey immediately after you agree to participate. This can be completed as a paper or web survey and will take 5 minutes to complete
- Once patient enrollment is complete, a short survey on your impressions of the communication tool. This can be completed as a paper or web survey and will take 10 minutes to complete

Your participation will require a maximum of about 6 hours in total.

**ARE THERE ANY RISKS TO ME?**

There is a risk that your survey information could become known to someone who is not involved in performing or monitoring this study. Additionally, there is a risk of lost time when learning to use the new communication tool. When you use the tool with patients, it is possible it may take you a bit longer than your usual conversation with patients.

A risk for your patients and their caregivers may be anxiety, or asking additional clinical questions as a result of participating in the study surveys.

If there are any patients you feel should not participate in the study, you will have the opportunity to request study staff exclude them. We will not approach these patients regarding study participation.

**ARE THERE ANY BENEFITS TO ME?**

You may benefit from participating in this study. It is possible you will learn new communication skills during the training session, which may subsequently improve the care of patients and families. This may impact your patient satisfaction scores positively and/or improve job satisfaction with the knowledge that you have helped patients to make a decision aligned with their preferences and goals. You will also have an opportunity to discuss the challenges of helping patients make these difficult treatment decisions with colleagues and study staff.

Your participation in this research study may benefit other people in the future by helping us learn more about how to help patients choose treatments that are the best for them.

**WILL I BE COMPENSATED FOR MY PARTICIPATION?**

You will receive compensation equal to $249 for participating in the training session.

**HOW WILL MY CONFIDENTIALITY BE PROTECTED?**

SITE NAME, Nephrologist Consent, 11/11/21

IRB Approval Date: 12/1/2021
University of Wisconsin – Madison
While there will likely be publications as a result of this study, your name will not be used. Only group characteristics will be published.

Data collected from you will be coded with a unique study number, and the link between your name and your study code number will be stored in a separate, secured file. Once all the data has been collected for this study, the link will be destroyed. Any hard copies of files will be stored in a locked cabinet in a locked office and all electronic data will be entered onto a password protected computer.

The information collected from you during this study will be used by the researchers and research staff of the UW-Madison and its affiliates for this study. It may also be shared with others at the UW-Madison and outside the UW-Madison.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

This study has a Certificate of Confidentiality from the National Institute on Aging. A Certificate of Confidentiality prohibits researchers from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent.

WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

You may ask any questions about the research at any time. If you have questions about the research after you leave today you should contact the Principal Investigator [SITE PI NAME AND PHONE NUMBER]

If you have any questions about your rights as a research subject or complaints about the research study that you could not resolve with the study team, contact the [SITE PATIENT RELATIONS DEPARTMENT AND CONTACT INFORMATION].

Your participation is completely voluntary. If you decide not to participate or to withdraw from the study it will have no effect on any services or treatment you are currently receiving or giving or your employment with [SITE NAME].
AGREEMENT TO PARTICIPATE IN THIS STUDY

Your signature indicates that you have read this consent form, had an opportunity to ask any questions about your participation in this research and voluntarily consent to participate. You will receive a copy of this form for your records.

Name of Participant (please print): ________________________________

____________________________________  ______________
Signature                                      Date

Signature of person obtaining consent and authorization:

____________________________________  ______________
Signature                                      Date
CONSENT to Participate in Research and AUTHORIZATION to Use and/or Disclose Identifiable Health information for Research

Title of the Study: Effective Communication between Kidney Specialists and Their Patients

Lead Researcher: [SITE PI NAME, PHONE NUMBER AND EMAIL ADDRESS]

Mailing Address: [SITE ADDRESS]

Funder: National Institute on Aging

Research Project Lead At UW-Madison: Margaret Schwarze, MD
UW–Madison, School of Medicine and Public Health
Department of Vascular Surgery
Invitation
We invite you to participate in a research study on communication between kidney specialists and patients. Your kidney specialist has identified you as a possible research participant because you are an older adult with treatment options for kidney disease. Up to 340 patients will participate in this study at sites across the United States.

The purpose of this consent form is to give you the information you need to decide whether to participate in the study. It also explains how your health information will be used for this study and requests your permission to use your health information. As we go through this consent, please ask questions about anything that seems unclear or confusing. I’m here to answer any questions you have. Your participation in this research study is voluntary. If you decide not to participate, the health care provided to you by the [SITE NAME] will not be affected in any way.

Why are researchers doing this study?
The purpose of this study is to evaluate a new training program to support communication between kidney specialists and their patients. The goal of our research is to help patients get the information they need to make treatment decisions that are right for them.

What will happen in this study?
If you decide to participate in this research study, we will ask you to:

- Complete a brief survey today, including questions on your physical health and well-being and how much help you may or may not need when reading materials from your doctor or pharmacy. You may skip any questions you do not wish to answer.
- Complete a survey 1-2 days after today’s appointment. We will call you to complete this survey by phone and it takes just 10-15 minutes. The survey will include questions on how well you think your kidney doctor/clinician communicates with you. We will also ask you a few questions about yourself, such as your race and level of education. You may skip any questions you do not wish to answer.
- Complete a follow up survey every 3 months, for up to 2 years. You can do these surveys in the way best for you: on the phone, on your computer, or on a paper copy mailed to you. These surveys take 10-15 minutes each. The surveys will include questions about your physical health and well-being. You may skip any questions you do not wish to answer.
- Allow study staff to review your medical chart for up to 2 years after you enroll in the study. We are doing this to collect:
  - Information about you such as age, gender and race
  - Information related to the evaluation, treatment and outcomes of your kidney disease and general health
- Pick a family member or loved one to participate in the study with you. This is someone who knows you well and is involved in your care with the kidney doctor/clinician you are seeing today. They will also complete brief surveys. However, this is optional and you are not required to have anyone participate in the study with you.
How is being in this study different from my regular health care?
This study is not part of your health care. Your kidney doctor/clinician and his/her team will know that you are participating in this research, but they will not be able to see any individual results from this study.

Will being in this study help me in any way?
There are no direct benefits to you. However, since the purpose of the study is to improve communication, you may benefit from having better conversations with your kidney specialist. Your participation can make a difference in the future by helping to improve care for others with kidney disease.

Will I be paid for my participation?
You will be paid for participating in this study. If you complete all of the surveys over two years, you will receive a total of $100. If your loved one chooses to participate with you, they will receive up to $55 over two years.

<table>
<thead>
<tr>
<th>STUDY ACTIVITY</th>
<th>TODAY</th>
<th>IN A FEW DAYS</th>
<th>YEAR 1 (EVERY THREE MONTHS)</th>
<th>YEAR 2 (EVERY THREE MONTHS)</th>
<th>TOTAL</th>
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<tr>
<td>You</td>
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<td>Payment:</td>
<td>$20</td>
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<td>A loved one (Optional)</td>
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<tr>
<td>take a short survey</td>
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<td>$55</td>
</tr>
</tbody>
</table>
What are the risks?
Participating in this study involves few risks for you. The risks include:

- You may feel confused or conflicted about the kidney treatment options presented to you
- You may feel some distress when answering the survey questions about your health and kidney treatment decisions
- There is a very small chance that study information could become known to someone who is not involved in the study

We don’t expect any of these things to happen. We will explain how we protect the confidentiality of your information in the next section.

How will researchers keep my research information confidential?
Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Things you tell the researchers about your health
- Information currently in your medical records as well as information added to your medical records during the course of this study
- This information could include information related to the evaluation and treatment of your kidney health and other related medical conditions

We have strict rules to protect your personal information and PHI. Only trained study staff will access your medical chart for study purposes. We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. This study has a Certificate of Confidentiality from the National Institute on Aging. A Certificate of Confidentiality prohibits researchers from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent. Researchers might use information from this study in scientific journal articles or in presentations. None of this information will identify you personally.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials (including the National Institute on Aging) responsible for monitoring the safety of this study.

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.
Who at [SITE NAME] can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research

Who outside the [SITE NAME] may receive my information?

- U.S. Office for Human Research Protections
- The study sponsor, the National Institute on Aging
- Collaborating researchers outside [SITE NAME], specifically researchers at University of Wisconsin-Madison who are coordinating this study
- The Palliative Care Research Cooperative Group (PCRC) will use or share your de-identified protected health information (PHI) in compliance with the PCRC Data Sharing Policy. Data from this study also will be transferred and stored on a server maintained by the PCRC at the University of Colorado. This data will not contain information which could identify you and will be carefully protected. This data will be stored for at least 10 years after the study is completed. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

Will information from this study go in my medical record?

None of the information we collect for this study will go in your medical record. The researchers are not required to release health information to you if it is not part of your medical record.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Do I have to be in the study? What if I say “yes” now and change my mind later?

No, you do not have to be in this study. Your permission is voluntary. You do not have to sign this form and you may refuse to do so. If you do not sign this form, however, you cannot take part in this research study. You may completely withdraw from the study at any time. You also may choose to skip any questions that you do not feel comfortable answering. Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at [SITE NAME], or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.
Patient Consent

Your authorization for researchers to use your protected health information (PHI) collected for this study does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, [NAME], at [FULL MAILING ADDRESS].

Who should I contact if I have questions?

If you have any questions about this study at any time, contact the Principal Investigator [SITE PI NAME, PHONE NUMBER].

If you have any questions about your rights as a research subject or complaints about the research study that you could not resolve with the study team, contact the [SITE PATIENT RELATIONS DEPARTMENT AND CONTACT INFORMATION].
AGREEMENT TO PARTICIPATE IN THIS STUDY AND
PERMISSION TO USE AND/OR DISCLOSE MY HEALTH INFORMATION

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Name of Participant (please print): ________________________________

_________________________  __________
Signature of Participant     Date

YOU WILL RECEIVE A COPY OF THIS FORM AFTER SIGNING IT.

Signature of person obtaining consent and authorization:

_________________________  __________
Signature                 Date

FUTURE RESEARCH

In the future, other researchers may find it valuable to use the survey data and health information obtained from this study. We would like your permission to let other researchers use this data for future research studies, and to house your de-identified study information in the Palliative Care Research Cooperative Group (PCRC) Data Repository. These researchers would not have any information about who you are or access to your medical records. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed and all data will be de-identified.

I give my permission for the use of the de-identified data for future research:

_____ YES

_____ NO
CONSENT TO CONTACT

In order to contact you and to mail you your compensation throughout the research study, study staff would like your preferred U.S. mailing address and phone number(s). The information you provide on this form will not be used for any other purposes. It will be kept in a locked and secure location, which only study staff can access and use. This information will not be shared with anyone outside of the research team at [SITE NAME] and will be destroyed at the end of the study.

By signing this form and providing your contact information, you agree that study staff can contact you for the uses described above.

Your name (please print): _______________________________________________________

Mailing Address: ________________________________________________________________

Home phone number: ___________________________________________________________

Mobile phone number (if applicable): _____________________________________________

What’s the best time of day to call you? _____________________________________________

Email address (if applicable): _____________________________________________________

Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact [Name, Title, Phone Number for appropriate contact person, such as the lead investigator or physician on call]. You do not have to provide your email address to participate in this study.

What’s the best way to reach you? _________________________________________________

______________________________________________________________

Signature of Participant........................................................................Date
Research Participant Information Sheet

Title of the Study: Effective Communication between Kidney Specialists and Their Patients

Lead Researcher: [SITE PI NAME, PHONE NUMBER AND EMAIL ADDRESS]

Mailing Address: [SITE ADDRESS]

Funder: National Institute on Aging

Research Project Lead
At UW-Madison: Margaret Schwarze, MD
UW–Madison, School of Medicine and Public Health
Department of Vascular Surgery
Invitation

We invite you to participate in a research study on communication between kidney specialists and patients. You are invited to take part because you were recommended as a possible study participant by a friend or loved one you care for who is seeing a kidney doctor/clinician to discuss their treatment options. Up to 340 patients will participate in this study at sites across the United States.

The purpose of this consent form is to give you the information you need to decide whether to participate in the study. As we go through this consent, please ask questions about anything that seems unclear or confusing. I'm here to answer any questions you have.

Your participation in this research study is voluntary. If you decide not to participate, the health care provided by the [SITE NAME] to you and the patient who recommended you as a study participant will not be affected in any way.

Why are researchers doing this study?

The purpose of this study is to evaluate a new training program to support communication between kidney specialists and their patients. The goal of our research is to help patients get the information they need to make treatment decisions that are right for them.

What will happen in this study?

If you decide to participate in this research study, we will ask you to:

- Complete a brief survey today. This survey takes 10-15 minutes and includes questions about the physical health and well-being of the patient who recommended you as a study participant. You will also be asked to answer one question about how much help you may or may not need when reading materials from your doctor or pharmacy. You may skip any questions you do not wish to answer.
- Complete a survey 1-2 days after today’s appointment. We will call you to complete this survey by phone and it takes just 10-15 minutes. The survey will include questions on how well you think the kidney doctor/clinician communicates with you and the patient who recommended you as a study participant. We will also ask you a few questions about yourself, such as your age and race. You may skip any questions you do not wish to answer.
- Complete a follow up survey every 3 months, for up to 2 years. You can do these surveys on the phone, on your computer or on a paper copy mailed to you; you decide what option is best for you. These surveys take 10-15 minutes each. The surveys will include questions about the physical health and well-being of the patient who recommended you as a study participant, as well as your mental health. Depending on your loved one’s...
health, we may ask you questions about the medical care they received recently. You may skip any questions you do not wish to answer.

The kidney doctor/clinician and his/her team know that you are participating in this research, but will not be able to see any results from this study.

**Will being in this study help me in any way?**

There are no direct benefits to you. However, since the purpose of the study is to improve communication, you may benefit from having better conversations with your loved one’s kidney specialist. Your participation can make a difference in the future by helping to improve care for others with kidney disease.

**Will I be paid for my participation?**

You will receive $15 after enrolling in this study. In addition, you will receive $5 for every follow-up survey you complete. If you complete all of the surveys over two years, you will receive a total of $55.

**What are the risks?**

Participating in this study involves few risks for you. The risks include:

- You may feel confused or conflicted about the kidney treatment options presented to your loved one
- You may feel some distress when answering the survey questions about your loved one’s health and kidney treatment decisions
- There is a very small chance that study information could become known to someone who is not involved in the study

We don’t expect any of these things to happen. We will explain how we protect the confidentiality of your information in the next section.

**How will researchers keep my research information confidential?**

The kidney doctor/clinician and his/her team know that you are participating in this research, but they will not be able to see your survey answers.

We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. This study has a Certificate of Confidentiality from the National Institute on Aging. A Certificate of Confidentiality prohibits researchers from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent. Researchers might use information from this study in scientific journal articles or in presentations. None of this information will identify you personally.
However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials (including the National Institute on Aging) responsible for monitoring the safety of this study.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

This study has a Certificate of Confidentiality from the National Institute on Aging. A Certificate of Confidentiality prohibits researchers from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent.

**Do I have to be in the study? What if I say “yes” now and change my mind later?**

No, you do not have to be in this study. Your permission is voluntary. You do not have to sign this form and you may refuse to do so. If you do not sign this form, however, you cannot take part in this research study.

You may completely withdraw from the study at any time. You also may choose to skip any questions that you do not feel comfortable answering. Let the researchers know if you choose to leave the study.

**IF YOU DECIDE NOT TO PARTICIPATE IN THIS STUDY OR IF YOU STOP WHILE THE STUDY IS UNDERWAY, THE HEALTH CARE YOU OR YOUR LOVED ONE RECEIVE FROM THE [SITE NAME] WILL NOT BE AFFECTED IN ANY WAY.**

**Who should I contact if I have questions?**

If you have any questions about this study at any time, contact the Principal Investigator [SITE PI NAME, PHONE NUMBER].

If you have any questions about your rights as a research subject or complaints about the research study that you could not resolve with the study team, contact the [SITE PATIENT RELATIONS DEPARTMENT AND CONTACT INFORMATION].
AGREEMENT TO PARTICIPATE IN THIS STUDY AND
PERMISSION TO USE AND/OR DISCLOSE MY HEALTH INFORMATION

If you sign the line below, it means that:

● You have read this consent form.
● You have had a chance to ask questions about the research study, and the researchers have answered your questions.
● You want to be in this study.

Name of Participant (please print):
________________________________

Signature of Participant ____________________________

Date ______________

YOU WILL RECEIVE A COPY OF THIS FORM AFTER SIGNING IT.

Signature of person obtaining consent and authorization:
________________________________

Signature ____________________________

Date ______________

FUTURE RESEARCH

In the future, other researchers may find it valuable to use the survey data obtained from this study. We would like your permission to let other researchers use this data for future research studies, and to house your de-identified study information in the Palliative Care Research Cooperative Group (PCRC) Data Repository. These researchers would not have any information about who you are. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed and all data will be de-identified.

I give my permission for the use of the de-identified data for future research:

_____YES

_____NO
CONSENT TO CONTACT

In order to contact you and to mail you your compensation throughout the research study, study staff would like your preferred U.S. mailing address and phone number(s). The information you provide on this form will not be used for any other purposes. It will be kept in a locked and secure location, which only study staff can access and use. This information will not be shared with anyone outside of the research team at [SITE NAME] and will be destroyed at the end of the study.

By signing this form and providing your contact information, you agree that study staff can contact you for the uses described above.

Your name (please print): ___________________________________________________

Mailing Address: ____________________________________________________________

Home phone number: _________________________________________________________

Mobile phone number (if applicable): __________________________________________

What’s the best time of day to call you? ________________________________________

Email address (if applicable): _________________________________________________

Email is generally not a secure way to communicate as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact [Name, Title, Phone Number for appropriate contact person, such as the lead investigator or physician on call]. You do not have to provide your email address to participate in this study.

What’s the best way to reach you? _____________________________________________

_________________________________________  ____________________________
Signature of Participant                     Date