Title of Project: A Patient-centered, System-based Approach to Improve Informed Dialysis Choice and Outcomes in Veterans with CKD (IIR 19-202)

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1. **Purpose of the Study:** The purpose of this research study is to see if information/education can improve the care of Veterans' who have kidney disease.
   The study plans to invite and enroll 544 Veterans who have kidney disease. Half will randomly receive our locally made "comprehensive patient education" or "CPE" and the other half will receive information from the freely available online kidney disease education materials. We will assess the benefits or effects of these by surveys and following the electronic health records (EHR).

2. **Procedures to be followed:** Your involvement in the study depends on study group assignment. In brief, if you agree to participate in this study we will randomly, like flipping a coin, assign you to receive Kidney Disease education by one of two methods. Half of the participants will receive CPE for a maximum of 3 sessions, either in person or through VA established telemedicine methods, while the other half of the participants will receive recommended kidney disease education material from freely available online resources. Both education methods will be offered in addition to your routine kidney care. Before and after education, some research data will be collected from you through surveys or telephone interviews. After these initial interactions, we will follow up with you , twice a year, to see if you started dialysis or not. If you do start dialysis, we will collect additional surveys at 90 days after you begin dialysis.

   If you agree to be part of this study, in addition to your routine care, we will collect the following information from you in a survey format. You will have the option to complete the survey in paper, telephone, or through VA approved electronic format online such as myhealthevet. We will invite a total of 45 participants for a telephone interview to inquire about their opinion of our education program and their preferences. We will also invite 15 participants that receive a dialysis type different then their original choice, to understand the reasons for change. The telephone interviews will be optional. We will digitally record the interviews on an encrypted recorder issued by VA IT and the audio interview files will be downloaded to a secure file stored on VA secured servers and to be accessed only by team members who are on the study protocol. We will erase recordings from the handheld recorder as soon as it is transferred over to the server.

   - socio-demographics: age, race/ethnicity, education level, household composition, and annual family income
   - health literacy test
   - medical conditions
   - health-related quality of life assessment
   - Kidney disease knowledge test
   - Confidence in dialysis selection
   - Type of dialysis selection

After this, you will be randomized to one of the two study groups: CPE group or enhanced usual care (EUC) group.
If you are in the CPE Group:

- You choose either face-to-face (F2F-CPE) CPE or tele-CPE (Tele-CPE)
- F2F-CPE group receive in class CPE at Gainesville VA Hospital
- Tele-CPE group receive CPE at a nearby VA facility over the VA tele-health system
- Both groups receive individual counseling following F2F CPE at Gainesville VA Hospital; or following the Tele-CPE at the VA facility

For the EUC group:

- You will not receive the CPE, but be sent a package of self-learning CKD resources that are freely available online.

For both groups, we collect the following information:
After education:

- Kidney disease knowledge test
- Confidence in dialysis selection
- Type of Dialysis selection

90 days after-starting dialysis:

- Type of Dialysis you choose to use
- Health-related quality of life assessment
- Satisfaction with your dialysis
- Number of hospitalizations (between your CPE and 90-day after- starting dialysis)
- Number of outpatient visits (between your CPE and 90-day after- starting dialysis)
- The following clinical information:
  - Duration from participation to when you start dialysis
  - Kidney function or what we call 'eGFR' at the start of dialysis
  - Need for inpatient initiation of dialysis
  - Vascular access presence (if applicable)
  - Vascular access use (if applicable)

In addition, you may be selected for two face-to-face or phone interviews at two study time points: within two weeks of education, and 90 days after starting dialysis.
Once this research study is completed, any information that could identify you might be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative

3. **Duration:** You will be in the study from the day you agree to participate, to approximately 4 months after you begin dialysis therapy (if you undergo dialysis), until we collect the 90-day post-dialysis data, which can last up to a maximum of the study duration, up to 4 years. However, once you education is completed, your participation will remain as a semiannual follow up.
4. **Research Benefits:** You may benefit from the study by having access to more education about kidney disease and more information about dialysis options, which may enhance your knowledge of kidney disease, improve your confidence in making an informed selection of an appropriate dialysis modality, and improve your health services and clinical outcomes.
5. **Research Risks:** This is an education intervention study; the overall risk related to the study is minimal since it is based on receiving education. There is a risk that information received by these authorized persons or agencies could then be passed on to others beyond your authorization and not covered by HIPAA.

6. **Statement of Confidentiality:** Your participation in this research is confidential. The survey does not ask for any information that would identify who the responses belong to. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared because your name is in no way linked to your responses.
7. **Right to Ask Questions:** Please contact Kidney disease research team at (352)-548-6813 or (352) 548-6000 x106813with questions or concerns about this study.

   Payment for participation: You will be paid $100 for your initial study interactions, which will include enrollment, pre study surveys, participation in the CPE/EUC, and the completion of the post-study surveys as per the study protocol. We will make the payment after all surveys are returned. This will mean that those enrolled in EUC will need to return a fully completed post-EUC surveys and for those enrolled in CPE arm will need to go through the required CPE sessions (for a maximum of 3 sessions) and complete the and pre and post surveys. If you are selected and choose to participate, you will also receive $40 for each qualitative study interview (for a maximum of 2 interviews). The study will require telephone follow-up to collect some data twice per year. You will be paid $10 for each telephone survey completed. Finally, if you initiate dialysis you will be paid an additional $40 for completing your post-ESRD surveys. Thus, if you are enrolled in the study at the beginning and happen to be eligible for all the follow-up needs, you will receive a possible maximum of $280 ($100, $10x6, $40x2, and 40x1) reimbursement over the entire study period.
   Payments will be issued by electronic funds transfer and deposited into your bank account, at the end of the respective study visits, once all study related procedures have been concluded, at the time of making future appointment. Your compensation for participation in this research study will come from the VA Finance Office, who will issue payment to you by direct deposit to your bank account. The study team will provide you with additional information regarding electronic funds transfers. You may be responsible for paying income taxes on any payments provided by the study. Any payment made to you on a VA-funded study, regardless of amount, has to be reported to the Internal Revenue Service (IRS) because the payment system cannot distinguish payment from reimbursement for expenses. If you have any outstanding debts to the government (such as back taxes, child support arrears, or defaulted school loans), the government can garnish this payment to offset your outstanding debt.
8. **Privacy Authorization**: NF/SG VHS will be allowed to collect, use and/or give out your medical information, but only to:
   a. Other researchers whose research is approved by an Institutional Review Board (IRB).
   b. The sponsor of the study, which is the VA office of research and development, the Department of Health and Human Services, the Office of Human Research Protections or other Government agencies.

9. **Voluntary Participation:** Your decision to be in this research is voluntary. You can stop at any time. You do not have to answer any questions you do not want to answer. If you do not want to take part, you can call my office at any time to let me know (phone(352) 548-6813 or (352) 548-6000 x106813) or you can tell me when I can call you. If you choose not to take part, this will have no effect on your current or future health care at NF/SG VHS. If you have any questions about your rights as a research subject, you can phone the Institutional Review Board at 352-273-9600.

Completion and return of the survey implies that you have read the information in this form and consent to take part in the research. Please keep this form for your records or future reference.