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Official Protocol Title: Social Network Analysis and Renal Education to Promote Transplantation (SNARE Transplant)

Protocol for Social and Behavioral Protocol

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Abstract of the Study: Barriers to kidney transplantation exist among patients with ESRD on hemodialysis. The aim of this study is to use survey research to understand attitudes towards hemodialysis and kidney transplantation to identify barriers to living donor kidney transplantation among hemodialysis patients. The Dialysis Patient Transplant Questionnaire, or DPTQ, was designed to identify barriers to transplantation in a large urban, predominantly African American population of hemodialysis patients by surveying their perceptions of their health and quality of life, the availability of social and emotional support, and their experiences and attitudes regarding dialysis and kidney transplantation. Based on the preliminary results The major concerns were for the donor, asking for a kidney and their own health. These concerns are amenable to the COACH intervention. These studies focused on a poor and underserved black population, limiting their generalizability. Patients also rely on the hemodialysis clinic social networks for information regarding kidney transplantation. . We believe that hemodialysis social networks facilitate the spread of information and behaviors, and that using a targeted social network intervention will improve access to transplantation especially among women and minorities. Furthermore, patients subjective health will be correlated with objective measures obtained from patients medical record.

- 1) **Protocol Title:** Social Network Analysis and Renal Education to Promote Transplantation (SNARE Transplant) formerly: Survey of Dialysis Patients Regarding Their Views on Renal Transplantation
- 2) **Investigator:** Avrum Gillespie M.D.
- 3) **Objectives:** The aim of this study is to use survey research and the COACH (Communicating about Choices in Transplantation) to understand attitudes towards hemodialysis and kidney transplantation among hemodialysis patients and how the social networks do they form affect the diffusion of knowledge, attitudes, and behaviors towards transplantation. Lastly, patients subjective health will be correlated with objective measures obtained from patients medical record, to better understand patients health outcomes among hemodialysis patients.
- 4) **Rationale & Significance:** For patients with end stage renal disease, kidney transplant has been shown to have better outcomes than maintenance dialysis. A comparison of patients on the transplant waiting list those who eventually undergo transplantation have better long-term survival than those who do not get a transplant.^{1,2} In the United States African Americans have lower rates of renal transplant than whites,³ including living donor transplants. Previous studies have suggested that possible barriers to cadaveric donation include: denial of the need for transplantation, religion, fear of surgery, access to care, distrust of the medical system, less access to care, poor education, and racism.⁴⁻⁷ Barriers to living donation in African Americans have not been as well studied. The Dialysis Patient Transplant Questionnaire, or DPTQ, was designed to identify barriers to transplantation in a large urban, predominantly African American population of hemodialysis patients by surveying their perceptions of their health and quality of life, the availability of social and emotional support, and their experiences and

attitudes regarding dialysis and kidney transplantation. The questionnaire assesses three areas of interest; (1) demographic characteristics and the availability of social and emotional support; (2) self-reported health, quality of life, and the specific impact of kidney disease and its treatment; and (3) patient views of kidney transplantation, including self-reported listing status and perceived bias in transplantation allocation. (4) who patients talk to in the hemodialysis clinic, what they talk about and how often. Many of the items included in the DPTQ have been validated in hemodialysis and transplant populations⁸⁻¹⁵ including quality of life measures and independent predictors of mortality. Previous research has speculated that the social networks that patients form in the hemodialysis clinic may influence attitudes and behaviors towards transplant and may be amenable to social network interventions. Social network behavioral interventions in other fields¹⁶⁻²¹ have found that it may be better to target dense (clustered) networks than diffuse networks. As diffuse networks function as discussion networks and can be more effective in changing behavior than diffuse networks which function as advice networks and are better at spreading novel information through a central person¹⁹⁻²¹. Once patients social networks have been mapped, we will assign every HD clinic shift to one of the two targeting strategies based on social network attributes for the COACH intervention. We will measure the spread of information, attitudes, and behaviors by comparing the targeted patients to those that they refer, as well as the other patients on their shift. The COACH was specifically designed to educate patients on kidney disease and communication skills to approach other people about potential donation.

- 5) **Resources and Setting:** All participants collecting and entering data will be IRB and HIPAA trained. All data will be stored on a HIPPA secure, password/firewall protected computer in an office that is locked. Once the data has been collected it will be de-identified for analysis. The participating facilities are medical clinics with standard HIPPA policies. The following facilities are: DCI Philadelphia 3300 Henry Ave. Philadelphia, PA 19129 DCI North Brunswick 105 North Center Drive, North Brunswick, NJ 08902. Patients are no longer going to be enrolled at the following sites: Fresenius Dialysis/Temple Joint Venture 3401 Fox Street Philadelphia, PA 19129, Fresenius Dialysis/Temple Joint Venture Port Richmond, 2301 East Allegheny Avenue Philadelphia, PA 19134, Temple Abdominal Organ Transplant Clinic 3509 N. Broad Street Philadelphia, PA 19140, however data collection and analysis is ongoing.
- 6) **Prior Approvals:** Approval has been granted by the medical directors of all of the aforementioned facilities.
- 7) **Study Design:**
 - a. **Recruitment methods:** Convenience sample of English speaking patients greater than 18 years old while receiving hemodialysis for ESRD, who are able to give consent. This population is over 500 patients. Patients will be approached by a survey researcher while getting their hemodialysis

treatment. There will be a ten dollar gift card as compensation for participating in the survey. There will be no advertisement for the study.

- b. **Inclusion/Exclusion Criteria:** All patients over the age of 18 who are receiving hemodialysis for ESRD are eligible to participate in the initial survey. Patients will be excluded if they are under the age of 18, or unable to consent for other reasons (i.e. dementia). Only transplant eligible patients may participate in the COACH intervention. Patients who have not been referred for kidney transplantation will be evaluated for transplant eligibility via chart review by a study transplant nephrologist for transplant candidacy. If the patient is eligible for transplant but not referred, the transplant nephrologist will discuss with the primary nephrologist if the participant is an appropriate candidate and reasons they have not been referred. We will defer the transplant referral to the attending nephrologist. Our major exclusion criteria are nursing home resident, >79 years of age, active or recent malignancy, inoperable coronary artery disease, or comorbid illness that will make it unlikely that the patient will survive >3 years after transplant.
- c. **Study Timelines:** The proposed research combines both a longitudinal observational cohort study to examine the structure of HD clinic social networks and a targeted transplant education intervention (COACH) trial to test the role of the network in the dissemination of knowledge, attitude, and behaviors with the overall goal of improving access to kidney transplantation. Data will be analyzed yearly and modifications and interventions will be made accordingly.
- d. **Study Procedure and Data Analysis:**
 - i. After consent has been obtained the patient will be given a baseline survey. This survey will then be repeated annually for the next 2 years. Three surveys in total. If the patient is chosen for the COACH intervention (see sections d.iii-v), they will also receive an additional survey post-intervention. The patient has the option of completing the survey themselves or completing it with a trained survey researcher. Clinic staff will also participate in a modified version of the survey to assess their attitudes towards HD and kidney transplantation.
 - ii. In addition to surveys, the clinic staff will be trained to observe which patients talk with whom, as well as, the frequency and approximate duration of the conversation. The staff will be instructed to continue to assign seating based on clinical necessity and patient preference. Research staff, while they are performing the surveys or the COACH intervention, will also make and record observed patient interactions. Furthermore seating assignments

will also be collected. This data will be coded, patients will be de-identified for the analysis.

- iii. COACH is a behavioral communication intervention designed specifically for ESRD patients pursuing kidney transplantation. The COACH program (appendix) consists of four modules: 1) Kidney transplant options, 2) Discussing your transplant options, 3) Requesting living donation, and 4) Maintaining positive relationships. The content and teaching strategies were guided by the concepts of social cognitive theory as well as principles of adult learning and communication skills²²⁻²⁵. Another study coordinator will conduct the intervention in four, face to face, one hour sessions in the HD clinic. Patients will receive the accompanying handbook and video for the COACH intervention.
- iv. Using the data collected from the original survey and social network analysis, we will randomly select one transplant eligible patient (based on network attribute (most-clustered or most-central) per shift to participate in the COACH intervention.
- v. We propose a pre-post design to assess the impact of the COACH education on patients' transplant-related knowledge and behaviors. Before administering the COACH education, we will survey targeted patients to assess changes in knowledge and behaviors towards transplant from the baseline survey. As another measure of the impact of the COACH intervention, patients not receiving the intervention will serve as controls and will be surveyed along with those receiving the intervention; we will then assess within and between group differences in transplant-related knowledge and behaviors. To assess the dissemination of information contained in the COACH intervention, all patients will be surveyed at 3-months post-intervention. The follow-up surveys will determine the sources of these changes (eg. self-reading after the survey, the COACH intervention, or discussing with other patients). Finally, during Year 4, one year post-intervention, a final survey will be administered to all the patients in both clinics to assess retention of information and change in attitudes and behaviors of those who participated in COACH and the spread of information and behaviors to the patients who were not targeted.
- vi. The medical information collected is age, insurance status, ESRD diagnosis, vascular access. Medical comorbidities: congestive heart failure, peripheral vascular disease, malignancy. Mental Health, Substance Abuse, and HIV information is not collected. If the patient has ESRD from HIV the diagnosis is coded as glomerulonephritis a common and non-specific cause of ESRD.

Phosphate binding medication, Vitamin-D, and Calcimetic prescribing information is collected. Laboratory data includes basic metabolic panel, phosphorus, cbc, iron studies, hepatic function, cholesterol. Data collected will be analyzed to better understand barriers to transplantation and compare self-reported (survey) health data to laboratory data. All data is entered in an Excel spreadsheet and analyzed in SPSS 17.0, using descriptive statistics, chi-square test of association and t-tests. Time series analysis will be done in MathWorks MATLAB software. A p-value of less than 0.05 will be deemed significant.

- e. **Withdrawal of Subjects:** Patients may withdraw at anytime, this will be as a result of the patient transferring out of the clinic. Once, the patient withdraws they can contact the survey researcher or the PI and data will stop being collected.
 - f. **Privacy & Confidentiality:** All documents and information pertaining to this research study will be kept confidential in accordance with applicable, federal, state, and local laws and regulations. If any data is published the patient will not be identified by name. All participants collecting and entering data will be IRB and HIPAA trained. All data will be stored on a HIPAA secure, password/firewall protected computer in an office that is locked. Paper records will be kept in a locked file cabinet in a locked office. Once the data has been collected it will be de-identified for analysis. The participating facilities are medical clinics with standard HIPAA policies. The survey is anonymous, and the patients' individual response will not be shared with the treating physician or staff. Patients will also sign a HIPAA secure discussing protected health information. Personal health information will be deleted 5 years after the completion of the study.
- 8) **Risks to Subjects:** There are no invasive procedures involved with this study, however, patients are given 24 hour contact information for the study coordinator as well as the study director if they feel they have experienced any adverse events or have any further questions. The COACH intervention was specifically designed to minimize the stress associated with asking for a living donor kidney transplant. The patients' individual response will not be shared with the treating physician or staff. As we are performing a social network study we will not disclose to other patients whether they have been identified in another patients social network, nor other patients transplant eligibility. Furthermore, the subjects' surveys are identified by study ID number and not by name. All data is kept on firewall protected HIPAA compliant computer in an office that is locked when not in use.

9) **Potential Benefits:** There are no immediate benefits, however, the benefit of this study is to better identify barriers to kidney transplantation and help create an intervention to decrease the disparities in kidney transplantation.

10) **Costs to Subjects:** None

11) **Informed Consent:** Consent will be obtained while the patients are receiving hemodialysis treatments in the clinic. Before patients are consented, they are clearly told both verbally and in writing that consent is voluntary and would not affect their treatment. Patients have up to an hour to decide whether to participate at which time they can discuss any questions regarding the study. Before patients sign the consent form they would be asked to repeat back the consent. Patients will be given a copy of the consent and are free to ask questions in person or via phone. For Spanish speaking patients, the consent and survey will be administered via Spanish interpreter or language line.

12) **Vulnerable Populations:** Vulnerable populations will be excluded from the study.

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