A. Study Design or Approach

Overview of the study design:

We propose to test the effectiveness of mentoring by trained peers on CKD patients' QOL, caregiver burden and patient engagement. We will randomize CKD patients and caregivers into 3 groups: 1) face-to-face peer-mentoring; 2) online peer-mentoring; 3) information-only control. We will use the Patient and Family Partner Program (PFPP), described above, as the mentoring program for the intervention groups. Patients with CKD and their caregivers assigned to the face-to-face intervention groups will receive 6 months of peer-led mentoring through the face-to-face PFPP. Participants assigned to the online intervention group will also receive 6-months of peer-led mentoring through the online version of the PFPP. The information-only group will receive the informational textbook of the PFPP to review independently. At baseline, 12 months, and 18 months, the patients will complete QOL surveys and the Patient Activation Measure; the caregivers will complete the Zarit Burden Inventory. The proposed study design is shown in figure 3.

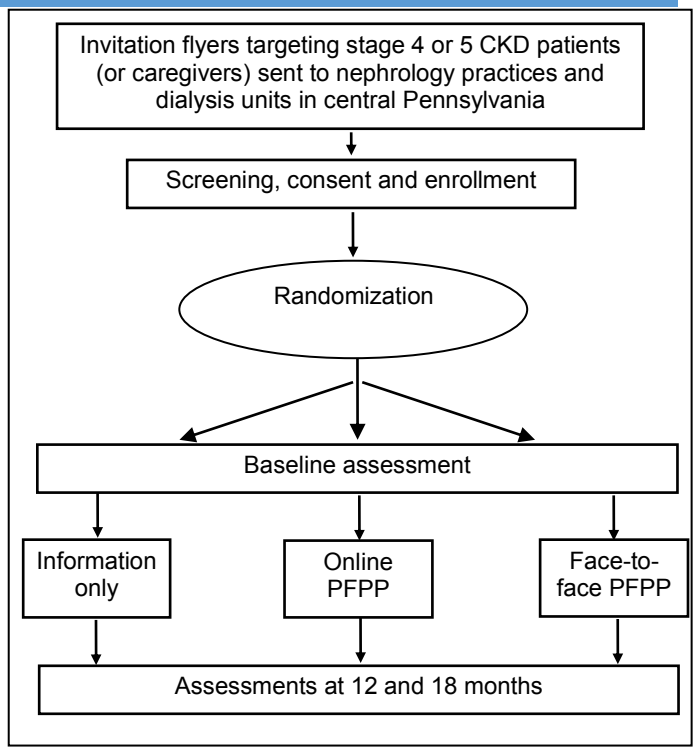

Figure 3. Proposed Study Design

Research Question: **Will a peer-led mentoring program (Patient and Family Partner Program: PFPP) lead to improvement in HRQOL among patients with CKD and caregivers of patients with CKD?**

Comparators: We will conduct a randomized controlled trial among CKD patients and their caregivers. The comparators are: 1) face-to-face PFPP; 2) online PFPP; 3) information-only control. The choice of comparators emerged following a review of mentor and mentee evaluations and a focus group discussion involving patients, renal social workers, director of the KFCP, PFPP program coordinator, and the PFPP medical director (PI). We have included an online intervention as a comparator based on evidence that Web-based peer-support is a potential alternative, particularly for populations with limited ability to travel, and for regions with limited resources. Such programs have enhanced the care of diabetes [65, 66]. Zrebiec evaluated a web-based educational and emotional resource for patients with diabetes and their family members at Joslin Diabetes Center. Over 74 months, a total of 74% of all respondents rated participation in the discussion board as having a positive effect on coping with diabetes, and 71% rated participation as helping them to feel more hopeful [67]. Improvements in the online group were similar to those achieved in the face-to-face groups [68]. *Despite the increasing awareness of the burden and adverse effects of CKD on caregivers, high-quality evidence is lacking about the effect of information or support interventions on the psychosocial well-being of caregivers [69].*To further investigate this, we have included caregiver burden as an outcome measure.

Participant recruitment, randomization and retention: Participants will include caregivers and patients. A significant number of the renal professionals, particularly renal social workers within the area served by KFCP, are familiar with the PFPP. The Program Coordinator (PC) will contact all the nephrology practices and dialysis units on a quarterly basis to provide them with information about the program. For the purpose of this study, the PC will travel to all of the dialysis units and will provide information about PFPP, as well as recruitment flyers to be distributed among patients and their caregivers. The flyers will provide brief information about PFPP and will ask patients who might be interested in exploring being matched with a certified partner (CP) to contact their social worker or the PC to initiate the process. The social worker will screen the volunteers and

will refer candidates who meet the inclusion criteria to the PC. *PFPP does not allow patients or caregivers to self-refer.*

Recruitment, randomization and retention. Mentees will be recruited from among patients with CKD stage 4 or 5, or caregivers of patients with CKD, 18 years or older, willing to participate. With assistance from renal professionals and the KFCP, we will recruit 132 patients with CKD and 84 caregivers, for a total sample of 216 potential mentees (please see sample size determination below). Recruitment for the purpose of this proposed study will occur continuously until the target sample size is achieved. The principal contact person in each practice will be the social worker. Information packets about the program are sent to dialysis units and nephrologist practices asking renal professionals to distribute them among patients. The packets include introduction to the program, and an application form. Prior to enrollment, the PC or the executive director of the KFCP interviews each applicant. Inclusion criteria: 1) at least 18 years of age; 2) diagnosed with stage 4 or 5 CKD by a physician or caregiver to a CKD patient; 3) not participated in previous peer-mentoring for CKD; 4) access to computer with internet and email capability. Following informed consent, mentee candidates will undergo permuted block randomization with 1:1:1 allocation into "face-to-face PFPP", "online PFPP", and "information-only control". To improve retention, we will compensate participants with $50 stipend for the baseline assessment and each of the follow-up assessments for a total of $150 per participant

Baseline Assessment. Following randomization, the participants will complete the baseline assessments which include demographic data and completion of the appropriate survey instrument. Patients will complete the QOL and patient activation instrument; caregivers will complete the burden inventory.

The interventions

The partnership: Once a candidate is referred, the PC collaborates with the referring professional to identify the most appropriate match, taking into consideration age, gender, treatment modality and preference for online or face-to-face mentoring. All participants will receive the PFPP textbook. Partnerships are maintained for 6 months.

- *For the face-to-face partnership*, the frequency of contact by a CP is weekly by phone and monthly face-to-face visit. The mentees have the choice of meeting their CP at a location preferred by them. If the pair decides on a lunch meeting, reimbursement is provided by the KFCP.
- *For the online partnership*, the frequency of contact by CP is weekly by online communication using the platform, and more frequently as initiated by the mentee. The coordinator maintains regular contact with the mentors and mentees and closely oversees the interactions. Each CP submits, to the coordinator, a confidential report of the communications with the respective mentee, highlighting points of discussion, mentee concerns and plan for next contact. The coordinator also maintains close communication with the mentee's care group, particularly the social worker.

Information-only control: The control group will receive copies of the PFPP textbook which contains detailed information, the outline of which is presented in table 1. The text targets 8th grade reading level.

Content of online peer-mentoring: We will develop the contents of the online mentoring program, according to themes that emerge from qualitative interviews and discussions with experienced peer mentors, patients, caregivers and healthcare professionals. We will administer an online version of the face-to-face PFPP via a secure internet site. The Online PFPP will consist of password-protected, interactive web-based instruction, web-based bulletin board discussion thread with the peer mentor. All communications between mentors and participants will be online. Following initial introductions, the trained mentor will initiate the discussion thread by presenting an overview of the program. The mentor and the participant will also review mutual goals and expectations at time of initial communication. The mentor will encourage the participant to become familiar with the textbook and to post any questions or concerns they might have. The mentor will send a weekly reminder email to each participant to log on to the website to review posted contents and to post a weekly action plan, as well as any problems they wish to discuss with their mentor. The PI will monitor the posts of all participants and mentors to ensure appropriate communication and to correct inaccurate information posted by participants.

Follow-up Assessments.

- 12 month and 18 month follow-up assessments will include demographic data and completion of the appropriate survey instrument. Patients will complete the QOL and patient activation instrument; caregivers will complete the burden inventory.

Variables: *The independent variable* will be group allocation to the face-to-face PFPP, online PFPP or information-only control group. Analyses will be intent-to-treat. *Covariates* will include demographic measures (age, gender, race/ethnicity, marital status, highest grade completed, primary language spoken at home, employment status, household income, rural vs. urban location, and mode of ESRD treatment).

Primary outcome variable 1 (Aim #1): Improvement in HRQOL

The primary outcome for specific aim 1 is health related QOL (HRQOL). At each assessment, the patients will complete the short form Kidney Disease QOL instrument from the Rand Corporation (KDQOL-SF) [72]. This instrument was developed as a self-report, health-related QOL tool designed specifically for patients with CKD [72]. The original 134-item instrument was later condensed into the 80-item Kidney Disease Quality of Life Instrument-Short Form (KDQOL-SF)[73]. The questionnaire consists of the generic SF-36 [74] as well as 11 multi-item scales focused on kidney-specific QOL domains. The subscales are scored on a 0 to 100 scale, higher numbers indicating better HRQOL. The Kidney Disease Component Summary (KDCS) is an average of the 11 kidney-specific subscales.This tool has been validated among patients with CKD with predictive value for several outcomes including survival [75-77]. The instrument adds a kidney disease component (44 items) to the SF-36 instrument and is the most widely used and validated measure of HRQOL in the nephrology literature [76, 78-83].

Primary outcome variable 2 (Aim #2): Decrease in Caregiver Burden

The primary outcome for specific aim 2 is caregivers burden. Caregiver burden will be assessed by the Zarit Burden Inventory (ZBI), a self-administered questionnaire of 22 items, which measures the impact of caregiving in psychological, physical and social domains. The items are ranked on a five-point Likert scale [84], and a total score is calculated from 0 to 88; the higher the score the heavier the burden [85]. ZBI has been used to measure caregiver burden among caregivers of dialysis patients [86].

Secondary outcome (Aim #3): Improvement in patient engagement

The secondary outcome is improvement in patient engagement. At each assessment, the patients will complete the Patient Activation Measure (PAM). Initially developed as a 22-item instrument, the 13-item short version of the PAM has been shown to have similar validity to the original version [87, 88]. The instrument is a participant-completed questionnaire which yields a continuous activation score ranging from 0 to 100, representing patients' positions along a multistage, hierarchical process of activation. PAM is a well-validated tool for assessing patient engagement and its impact on outcomes among individuals with various chronic diseases, such as inflammatory bowel disease [89], and multiple sclerosis [90]. It has also been validated as a measure of patient activation and adherence to physical therapy for individuals undergoing elective spine surgery as reflected in attendance and engagement [91]. The high reliability estimate of PAM (Cronbach′s alpha = 0.91) maintains precision across gender and age groups [92], and geographic locations [88, 93, 94]. Higher PAM scores are associated with better self-management health behaviors such as adherence to medication adherence and other health behaviors, higher satisfaction, QOL, and physical and mental functioning [92, 95, 96]**.**

Quantitative analytical methods. The outcome variables are continuous and will be measured at three time points (baseline, 12 months and 18 months). Descriptive statistics will be computed for all variables. Repeated measures analysis of variance (ANOVA) within the context of a linear mixed-effects model will be applied to estimate time-related changes in QOL. If overall differences are found via this model, then pair-wise comparisons of group means will be conducted using approximate t-tests from the model estimates. SAS, version 9.4 (SAS Institute Inc., Cary, NC) will be used for data analysis.

Avoidance of bias: To avoid bias in group allocation, a strict randomization procedure will be followed. We will test for even distribution of potentially confounding variables between the three groups. In the event of uneven distribution of confounding variables, we will control for those variables in the final analyses.

Sample size for patients

The primary outcome for specific aim 1 is improvement in KDQOL-36. A 10-point change in the components of KDQOL-36 has been associated with significant changes in clinically relevant outcomes. Considering a mean of 63 and a standard deviation of 13 [97] for the Kidney Disease Component Summary (KDCS), alpha of 0.05,

comparison of three means, a sample size of 39 per group will yield a statistical power of 0.8. Assuming dropout rate of 15%[68], a total of 132 patients will be recruited (44 for each of the three study groups).

Sample size for caregivers

The primary outcome for specific aim 2 is improvement in the Zarit Burden Inventory. The number of subjects needed is computed using data from a study assessing burden among caregivers of PD patients, in which the mean combined caregiver burden score was 12.5 ± 8.7 [86]. Assuming an effect size of one SD, an alpha of 0.05, comparison of three means, a sample size of 23 will yield a statistical power of 0.8. We will recruit a total of 84 caregivers (28 for each of the three study groups) to adjust for a dropout rate of 15%.

Potential limitations and strategies to minimize their impact:

1. Success of the program will depend on cooperation between renal professionals and the PFPP. Renal professionals may not consider the PFPP as a reliable resource. They might be concerned that the program will interfere with the patient-provider relationship. They will be reassured that the mentors are trained to avoid providing medical advice. A requirement of participation of mentors and mentees is referral by their renal professional. This establishes a collaborative bond between the professionals and the program. In addition, instructors recruited from various practices are likely to serve as advocates of the program.
2. Renal professionals might be concerned that trained mentors from different practices may try to attract mentees to their personal medical teams. To address this concern, PFPP is currently conducted as an intra-practice program; trained mentors are assigned only to patients and caregivers from the same medical practice. Exceptions will be made only with prior approval of the mentee's medical team.
3. Some social workers may view PFPP as additional work. They will be reassured that the PFPP will do much of the work involved in the training, providing informational and educational material and interviewing recruits. Social workers who have actively participated in the past have noted that they are pleased that the PFPP has helped their patients become more actively engaged. Social workers who serve as members of the curriculum committee, Advisory Board and as instructors will serve as ambassadors to their colleagues in various practices.
4. The study is limited to subjects with computer literacy and those with Internet access. On the other hand, this strategy allows for involvement of participants who cannot benefit from face-to-face mentoring due to distance and travel considerations. Furthermore, with increasing accessibility of computers and the Internet, web-based mentoring is expected to be available to a larger population.

B. Project Milestones

This Milestone Schedule assumes a start date of 08/01/2014.

Year 1: During the first 12-month period of the project, IRB approval will be obtained, the Website will be produced, at least 108 mentees will be recruited, randomized, will undergo baseline assessment and will start the intervention. During the first 12-month period, each of the Advisory Boards will have at least two meetings. Preliminary results of the interventions will be presented to the scientific community and the stakeholders.

Year 2: During the second 12-month period, mentee recruitment, randomization and all baseline assessments and interventions will be completed. The Patient and Caregiver Advisory Group will meet twice, the Provider Advisory Group once and the Community Advisory Board quarterly during Year 2. Results of the interventions will be presented to the scientific community and the stakeholders.

Year 3: During the third 12-month period, all assessments will be completed, data will be analyzed and final results will be presented to the stakeholders and the scientific community with input from the Advisory Groups and the Community Advisory Board.

C. Patient Population

The study population will be derived from dialysis units and nephrology practices in central Pennsylvania. Eligible participants will be female or male participants 18 years or older who are either patients diagnosed with CKD stage 4 or 5, or caregivers to patients with CKD 4 or 5. CKD is a prevalent condition that affects men and women of all ages, and all race/ethnic and socio-demographic categories. The recruitment area is wide and includes 28 counties, including urban and rural areas, all race/ethnic categories, and all socioeconomic levels.

No socio-demographic category will be excluded from the study. This will allow us to explore the relationship of the effect of the intervention and socio-demographic variables.

D. Research Engagement Plan

Patient and stakeholder engagement has been essential in the design of the proposed project.

IDENTIFICATION OF KEY STAKEHOLDERS

Patients are defined as individuals 18 years of age or older with stage 4 or stage 5 CKD residing in one of the 28 counties served by the Kidney Foundation of Central Pennsylvania. Other stakeholders include caregivers to patients with stage 4 or 5 CKD, the KFCP, and providers of care to patients with CKD.

Patient and Caregiver Advisory GroupPatients and caregivers have been involved in all phases of the development of the proposed research. The Patient and Family Partner Program was initially envisioned and designed by a patient with CKD; it has been subsequently refined according to periodic qualitative review by patients and caregivers. The success of the Program has depended on the commitment of patients and caregivers as Certified Partners. Patients have actively participated in the development of this proposal. A Patient and Caregiver Advisory Group of 12 members (minimum of 5 patients; minimum of 5 caregivers) will be convened to provide the patients' and caregivers' perspectives regarding the content of the interventions, strategies for recruitment of participants, interpretation and dissemination of findings.

Provider Advisory Group Providers have played an important role in the development of this proposal and are key stakeholders in the success of the proposal. We will invite nephrologists, primary care providers, transplant professionals, renal social workers, dialysis nurses and transplant coordinators to participate in a 12-member Provider Advisory Group. In order to maintain balance within the group, at least one member will be selected from each of the disciplines). The Provider Advisory Group will meet with the Research Team before participant recruitment and during the fourth quarter of each year to contribute the providers' perspective on the interpretation and dissemination of findings.

Board of Directors of the KFCP A 15-member volunteer Board of Directors of the KFCP guides the activities of the PFPP and has provided insight in the development of the proposed research. The membership of the Board of Directors includes patients, caregivers, nephrologists, a transplant surgeon, a senior medical director of a major healthcare network (Highmark) and primary care physician, dialysis social workers, members of the community, and an attorney. Some of the members of the Board have been trained as Certified Partners. For the purpose of this project, the Board of Directors will function as the Community Advisory Board. Dr. Ghahramani (PI) is a member of the Board of Directors and will present updates on the project at the quarterly meetings to seek input regarding recruitment, conduct of the study, interpretation and dissemination of findings.

Consultant *XXXX, MSW* is an experienced renal social worker and one of the original founders of the PFPP. She has had active involvement in the development of the proposed research. As a consultant, she will assist in the development of the content of the online intervention. She is well-known to the renal social work community of central Pennsylvania and will also assist in the description of the PFPP to potential participants and healthcare providers, in order to enhance recruitment. She will provide 50 hours of consultation per year for the 3 year period of the study.

Describe the protection of human subjects involved in your research.

The proposed study meets the definition of Scenario E: Human Subjects Research Involving a Clinical Trial

Risks to Human Subjects

Human Subjects Involvement, Characteristics, and Design

Following recruitment, consent and randomization, the participants will then complete their assigned intervention if applicable. The study population will be derived from dialysis units and nephrology practices in Central Pennsylvania. Eligible participants will be female or male participants 18 years or older who are either patients diagnosed with chronic kidney disease stage 4 or 5 or caregivers to patients with chronic kidney disease stage 4 or 5. It is anticipated that 252 individuals (mentors or mentees) will participate. There will be no special vulnerable populations in the study. This is a longitudinal population-based survey of human subjects. Human subjects participate by providing self-reported survey data in the form of written questionnaires. Each survey takes approximately 30 minutes to complete. This study will be approved by the Institutional Review Board of the Pennsylvania State University Hershey Medical Center.

Sources of Materials

Data for this study will include self-administered survey instruments. Each subject is assigned a unique study identification number that appears on all survey documents for that subject. Electronically coded data is transferred by the investigators into a secure database that is constantly password protected. There will be no linkage to any personal identifiers in this file. Once all analyses are complete, all data will be destroyed.

Potential Risks

The potential risk to the participants is minimal.

Adequacy of Protection Against Risks

- Recruitment and Informed Consent

Participants will be recruited by posting flyers in dialysis units and nephrologist offices. Participation will be totally voluntary and subjects will be compensated for their time and effort. The participants will be fully informed about the purpose and procedures of the study. The privacy and confidentiality policy and the voluntary nature of participation will be outlined. The PI will be available to each participant for any questions. Prior to participation, the subjects will provide informed consent.

- Protection Against Risk

Participants will be told they may decline to answer any questions that make them uncomfortable and that to ensure confidentiality, their names will not be included on any survey documents. To maintain privacy, the participants will not be asked to provide any identifying information. Participants will be oriented to contact the PI with any questions or concerns about possible breach in privacy or confidentiality. Participants will be informed that there is the potential risk of loss of privacy or confidentiality of data. They will be informed that the Research Team will attempt to minimize the risks by keeping all identifiable data in password locked electronic data files, that all data will be de-identified once data collection is completed, and that no participants will be identified in any analyses or reports.

Potential Benefits of the Proposed research to Human Subjects and Others

Potential benefits to subjects include gaining skills and knowledge regarding management of their disease and improved QOL. The benefits to be gained by society are substantial, as described in the next section.

Importance of the knowledge to be Gained

The information gained in the study will increase understanding of the impact of a peer-led mentoring program on QOL, and will aid in the development of interventions to expand the scope of such programs.

Inclusion of Women and Minorities

The study will include women and minorities. Specific outreach programs will be employed to recruit various race/ethnic groups. In order to ensure adequate representation of minority groups, African-American and Hispanic subjects will be over-sampled.

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