Name of Project:
Primary Care eHealth Intervention for Improved Outcomes in Chronic Kidney Disease—Focus Group

Investigator(s). (Include phone numbers and email address, indicate PI and primary contact)
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Research question(s):
This project seeks to improve the health of patients with moderate chronic kidney disease (CKD) by developing and testing an electronic health intervention to promote patient use of effective medications that can help protect their kidneys and/or reduce their associated risk for cardiovascular morbidity and mortality. The electronic health intervention is comprised of electronic medication messages that combine images, words, and patient educational materials that are designed to prompt patient engagement and activation and a conversation with their primary care physicians about medications they are not yet taking but from which they may benefit. The outcome measures are control of risk factors for CKD progression/cardiovascular morbidity and mortality (e.g., albuminuria, poorly-controlled hypertension), new medications prescribed, and intervention feasibility measures. The information we collect on the electronic health intervention will guide future research, including a larger trial and other studies among related patient groups (e.g., racial minorities) and diseases (e.g., type 2 diabetes mellitus). The project has the potential to improve health outcomes for the millions of patients with CKD who are not yet receiving effective medications.

Brief Background/Significance:
Chronic Kidney Disease (CKD) affects over 20 million American adults. Effective medications for reducing progression remain vastly under-utilized due to well-known behavioral barriers, including the affective barriers of denial, inertia, and uncertainty. The health consequences of this poor level of medication adoption warrant development of new strategies to facilitate their use.

Moderate CKD as a Critical Juncture for Intervention: Rates of CKD are likely only to escalate as contributing conditions (e.g., type 2 diabetes, obesity) increase. With progression, patients experience costly but preventable renal and cardiovascular disease adverse outcomes (e.g., dialysis, myocardial infarction). CKD also imposes a disproportionally heavy burden on racial/ethnic minorities and those of lower socioeconomic status. There are an estimated 8 million U.S. adults with stage 3 or "moderate" CKD (defined by an estimated glomerular filtration rate (eGFR) of 30-59 mL/min/1.73m²) offering a sizeable target population for intervention. Patients with stage 3 CKD are often diagnosed at this stage of disease through routine laboratory tests performed by their primary care providers and at a time when disease progression can still be minimized.

Underutilization of Effective Medications for CKD Exposes a Quality Gap: These effective drugs remain vastly under-utilized despite their promotion through drug formularies, practice guidelines, and clinician and patient educational campaigns, including the landmark 2002 Kidney Disease Outcomes Quality Initiative and related undertakings. National ambulatory data indicate that even among patients with CKD who are diagnosed with cardiovascular disease (CVD), only 57% are on an angiotensin converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB), only 35% have achieved the target blood pressure control, and only 52% are taking a lipid-lowering agent, despite their clear benefits in high-risk populations. Those without a CVD diagnosis have comparable or even worse rates for these target measures.

Focus Group Inclusion Criteria
Patients with stage 3b CKD, those who have stage 3a CKD plus additional risk factors for progression (i.e., hypertension, diabetes, and/or obesity), or those who have stage 4 CKD

Medical exclusions:
- Diagnosis of cancer (other than non-melanoma skin cancer) that is active
- Other severe non-renal medical condition or medical comorbidities that require aggressive treatment: e.g., advanced liver failure
- Diagnosis of a terminal illness and/or in hospice care
- Poor vision or hearing

Other exclusions:
• Inability to speak, read or understand English at the 6th grade level or above due to concern about ability to actively participate in interventions
• Currently pregnant or lactating or planning to become pregnant
• Plan to move out of the area or discontinue primary care at UCSF during the study period
• Family/household member of another study participant or of a study staff member
• Already enrolled or planning to enroll in a research study that would limit full participation in this trial or confound interpretation of its results
• Investigator discretion for clinical safety or protocol adherence reasons.

Method of contact/recruitment (be specific)
We will send a recruitment letter signed by the PI with a pre-stamped return postcard, which will give the patient an option to opt out of the study. If patient sends back the postcard stating he or she is unwilling to participate, we will not contact them any further. The patient will also have the option to call or email the study coordinator and PI to opt out the study. If we do not receive a response within 3 weeks, we will telephone the patient to perform a phone screen to confirm eligibility and interest in participation.

Benefits/burden for participants (clearly identify potential for harm)
Subjects may experience the benefit of better health behavior including activation to discuss with their primary care clinicians potentially indicated medications for improved CKD management or reduction of their risk for cardiovascular morbidity or mortality. Given that this is a behavioral intervention designed to activate and educate patients about potentially useful medications and to prompt them to have a discussion about their CKD and medications with their primary care providers, we believe the risks are low to minimal. However, we cannot rule out the possibility that some of the eHealth messages may produce uncomfortable feelings or other discomfort.

Any benefits or burden to DGIM practitioners?
There is no guarantee or promise that DGIM practitioners will receive any personal benefits from this study; however this study may improve our scientific knowledge regarding the management of chronic kidney disease, and thereby inform the future development of tailored health messages and interventions for patients. It is also possible that participation may prompt more conversations between physicians and patients regarding chronic kidney disease.

Timeline for recruitment (projected start and stop dates)
June 1st 2016 to September 1st 2016.

Funding source
NIH—National Institutes of Diabetes & Digestive & Kidney Health (NCT02097550)

Potential for DGIM collaborators?
Leah Karliner is assisting with certain aspects of patient identification and is one of the data and safety monitoring personnel in case of adverse events.

Do you agree to notify us when recruitment is completed?
Yes.

Date form completed: 26 April 2016