**Name of Project:**
Primary Care eHealth Intervention for Improved Outcomes in Chronic Kidney Disease—Pilot RCT

**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 and/or cardiovascular morbidity and mortality (e.g., albuminuria, poorly-controlled hypertension), new medications prescribed, and intervention feasibility measures.

**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 disproportionately 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 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 or angiotensin receptor blocker, 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.

**Inclusion criteria**
Adult patients with stage 3b chronic kidney disease (defined as eGFR 30-44): The rationale for including patients with stage 3b CKD (defined by eGFR 30-44) but not stage 3a (eGFR 45-59) is to reduce the possibility of misclassification of those with higher eGFRs (who have little or no underlying kidney dysfunction) and to respond to evidence that patients with stage 3b CKD have much higher rates of progression to kidney failure than those with stage 3a. We chose the following inclusion criteria to optimize the balance between generalizability, participant safety, treatment adherence, and retention.

1. **Patients**
   - Age (as of date of enrollment):
     - Lower age limit: 18 years;
     - Upper age limit: NONE (only exclude for cause, as detailed below);
   - Gender: Men and women;
   - Ethnicity and race: All ethnic and racial backgrounds welcome;
   - Having a primary care provider (PCP) at UCSF, defined as an identified individual provider or provider group from whom the participant receives ongoing medical care, if needed;
   - Able and willing to enroll and provide written informed consent.

**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;
- 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 interfere with ours in some way;
- Investigator discretion for clinical safety or protocol adherence reasons.
- Severe hypertriglyceridemia (TG>500 mg/dl)
- Hyperkalemia (K>5.0 meq/L)
- Serious illness likely to preclude study completion
- Contraindications to or intolerance of all of the medications/medication classes being promoted
- Medication management for CKD (i.e., with all of the medications/medication classes targeted for promotion by the eHealth intervention) has already been optimized
- Has never used MyChart
- Having no access to a computer or smartphone;

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)
September 1st 2016 to January 1st 2017

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