DGIM Project Summary

Name of Project: Tailored drug titration through artificial intelligence: an interventional study (ARTERY)

Investigator(s). (Include phone numbers and email address, indicate PI and primary contact)

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Research question(s):
To employ personalized treatment optimization to achieve a mean systolic blood pressure difference of 6mmHg between groups from baseline to 12 months, with the interventional group reaching lower blood pressure values than the control.

Brief Background/Significance:

The goal of the proposed research is to test a connected medication management platform technology to address medication optimization and non-adherence in HTN management. Poor medication adherence and mismatches in the treatment (due to patient's reported side effect, complexity of treatment, and suboptimal efficacy of a chosen pharmacological treatment) are a major reason of failure in the management of chronic disease. The platform tested in this award will evaluate a complex machine-learning algorithm in treatment optimization. The results of the proposed randomized clinical trial, if successful, will lead to a change in the treatment paradigm for chronic diseases.

Optima-for-Blood Pressure (O4BP) is a cloud-based artificial intelligence clinical decision support system (CDSS) that evaluates patient status updates in real-time to provide advanced decision recommendations for medication treatment changes, when needed, personalized to each patient. O4BP provides a multi- parameter (age, gender, ethnicity, current treatment, comorbidities, side-effects, laboratory values, compliance) overall score computation that ranks possible treatment changes in order of % improvement over current treatment. The goal of the study is to test if blood pressure management by using the O4BP CDSS is superior to standard of care (SOC) (i.e. blood pressure management during office visits)

Inclusion:

- Adults 21 - 80 years
- Two or more blood pressure readings of ≥ 150/90 mmHg during primary care office visits in the Department of General Medicine within the last 6 months
- Therapy with medications from at least 1 anti-hypertensive pharmacological agents at the time of the last office visit
- At least minimally "tech-savvy" defined as
    - Ownership of a compatible smartphone
- Ability to access the internet

Exclusion:

- Inability to operate a blood pressure cuff
- Incompatible smartphone device (Galaxy S5 Android 5.0)
- Less than minimally "tech-savvy" defined as
    - Inability to use the Internet
- Non-compliance with medical follow-up (frequent "no shows")

- Planned coronary revascularization in the next 12 months
- Myocardial infarction, coronary revascularization, stroke, cardiac or aortic surgery in the previous 90 days
- GFR < 30 (CKD stage IV/ V)
- Primary care provider rules out the patient due to comorbidities or other factors

Method of contact/recruitment (be specific)

- UCSF Department of General Internal Medicine (UCSF DGIM) will screen patient panels of DGIM PCPs for eligible patients. After screening, these providers will approve individuals from a list of potential participants to give a final list to the ARTERY study coordinator (CRC).
- Patients from the list will be further screened by the study staff using the EHR to confirm eligibility. Screened patients who meet the inclusion criteria of the study will be contacted by the study coordinator (CRC) via phone. The CRC will explain the study description, answer basic questions (regarding willingness to participate in the study, ownership of a smart phone, ability to access email and internet daily) and schedule an on-boarding appointment with each participant.

Benefits/burden for participants (clearly identify potential for harm)
Participants will be asked to monitor their blood pressures and comply with a patient portal. These virtual blood pressures will allow for virtual titration of blood pressure medications. The possibility of harm arises with the trial of new blood pressure medications, however all decisions for clinical care will be made by the PCP, and all participants will have normal access to their PCPs and emergency services if they have an adverse reaction to any blood pressure medications.

Any benefits or burden to DGIM practitioners?
Participating PCPs enrolled into the study intervention arm will be expected to receive and act on in-basket messages sent by Optima 4BP every two weeks to optimize blood pressure for their patients. This will be outside the scope of in-person visits. The benefits will be improved control of blood pressure for intervention participants, as well as data from virtual monitoring of blood pressure.

Timeline for recruitment (projected start and stop dates)

Recruitment will begin in April 2018, and will continue for 6 months.

Funding source: NHLBI SBIR 1R44HL132622-01A1

Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular)

There may be opportunities for secondary analyses after data collection is complete, for resident/fellow/junior faculty projects.

Do you agree to notify us when recruitment is completed?

Yes, we will notify you when recruitment is complete.

Date form completed: 2/19/18