Name of Project: PERsonal Contextual prEcision health (PERCEPT)

Investigator(s):

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Research question(s):
We propose to assess the feasibility of designing and implementing a mobile health application to integrate patient-reported and clinical data during periods of disease and medication transition, and assess participant adherence to these technologies.

Brief Background/Significance:
The exponential growth of physiological, behavioral and environmental data generated through consumer mobile health (mHealth) devices and Internet of Things (IoT) technology provide unprecedented sources of personalized and contextual health information. If linked to clinical health data from the Electronic Health Record (EHR), these data can provide dynamic and individualized views of patient health states and trajectories that can greatly inform clinical care and health-related research. We propose to advance precision health through the development and evaluation of a mobile application and data platform that collects, harmonizes and integrates mHealth and environmental data from patients' daily lives with their clinical histories and electronic health record data.

We propose a participatory design approach to implement and evaluate a precision health platform through the study and modeling of hypertension (HTN) and depression in patient communities of UC Davis (UCD) and UC San Francisco (UCSF). These chronic diseases have high prevalence across geography, socioeconomic status, and race/ethnicity, and have significant economic, societal and personal costs. They are considerably challenging to manage due to difficulties in acquiring high-quality and consistent data from patients outside of their clinical care appointments that is so needed for a full view of the patient's disease state. Despite a broad array of self-monitoring devices and consumer applications, mHealth data are not getting into the clinical care process, and patients do not regularly monitor their own health states, particularly during periods of medication change, when frequent assessments are especially important.

Inclusion criteria:
1. Primary care patient at UCD or UCSF.
2. Able to speak and read English
3. Male or female 18-80 years of age at Telephone screening.
4. Documentation of a diagnosis of hypertension (defined as SBP >= 140 mmHg or DBP >= 90 mmHg on anti-hypertensive medication including beta-blockers, ACE-I, ARB, alpha-blockers, calcium-channel blockers) **OR** depression (PHQ-8 over 10) on an antidepressant medication
5. Written informed consent (and assent when applicable) obtained from subject or subject's legal representative and ability for subject to comply with the requirements of the study.
6. Have an Android or Apple iOS smartphone
7. Willing to install the PERCEPT, iHealth (for hypertension cohort) and Moves mobile applications

8. Willing to self-report blood pressure (for those with hypertension and with provided iHealth and/or standard blood pressure cuff) or mood data (for those with depression) at specified frequency
9. Willing to be have your location and activity tracked.
10. Have downloaded a mobile application from the appropriate mobile app store (App store for iPhones or Google Play for Android) within the past 1 year.
11. Have home Wifi access.

Exclusion criteria:
1. High blood pressure or depression being managed by a physician outside of UCD or UCSF
2. Current participation in any other mobile app-based clinical study
3. A diagnosis of both hypertension and depression
4. A diagnosis of depression with psychosis (ICD-9: 296.24, 296.34) bipolar disorder (ICD-9: 296.0, 296.1, 296.4, 296.5, 296.6, 296.7, 296.8, 296.9) schizophrenia (ICD-9: 295.x), schizoaffective disorder (ICD-9 295.70)
5. Planning to relocate from area within the study duration
6. Impaired vision that could limit the use of the mobile apps (participant-reported)
7. Primary care patient of the Investigator, Dr. Meghana Gadgil

Method of contact/recruitment
Opt-out postal mailing to all eligible patients from DGIM PCPs.
Follow-up telephone recruitment to determine interest and obtain verbal consent.

Benefits/burden for participants (clearly identify potential for harm)
Minimal risk. Although the information participants provide through mobile phones or with study surveys is confidential, some participants may feel embarrassed at having to answer questions, especially those related to depression symptoms. There will be slight inconvenience in time and effort to complete web-based self report of BP and depressive symptoms and questionnaires.

Any benefits or burden to DGIM practitioners?
No direct benefits or burdens. Participants may bring in virtual blood pressure or mood measurements to augment their clinical care of hypertension or depression.

Timeline for recruitment (projected start and stop dates)
Recruitment will begin approximately September 5, 2017.
Project to conclude in August 2018.

Funding source
CIAPM (California Initiative to Advance Precision Medicine); State of California

Potential for DGIM collaborators? None at this time.

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

Date form completed: 8/18/17