BP Activate: Project Summary

The BP Activate Study is a randomized quality improvement trial. We will deliver one of two versions of a letter to established English-speaking primary care patients at Mt Zion with uncontrolled hypertension, defined by SBP>140 or DBP>90 in the past two years (identified via EHR). The letter will prompt patients to schedule a visit with their provider or team nurse practitioner to discuss their BP recommendations with their clinician. We will test 2 versions of the letter:

- 1) A "BP Activate Report" letter uses recommendations for medication changes from a computerized algorithm using the patient's medical records and recommends discussing these specific recommendations with their clinician; or
- 2) A "Control" letter suggesting they talk to their clinician about their BP without providing any specific medication recommendations.

We may have some patients randomly assigned to get no letter at all (depends on how many patients we identify). This goal of the study is to assess the effectiveness of the BP Activate Report letter compared with Control, and see if it shortens time to appointment, time to visit, time to medication change, and time to achievement of BP goal. Clinicians, with patient input, will still have full control of how BP is clinically managed. A small number of patients will be contacted by a research coordinator to hear what they thought when they received the letter, and why they did or did not act upon the information.

BP Activate Protocol

Background and Significance

Over 70 million Americans have hypertension (HTN). We spend \$46 billion to treat HTN each year, yet more than 40% of patients with HTN have BP above their recommended goals. Getting these patients with uncontrolled HTN to achieve their recommended BP goals would prevent 56,000 cardiovascular events and 13,000 deaths, and produce 4.5 billion dollars in net cost savings annually. Nearly 90% of patients with uncontrolled HTN have made a doctor's visit in the last year but the ineffectiveness of short, infrequent doctor visits and inadequate BP measurements contributes to clinical inertia (physicians failing to intensify treatment) and patient non-adherence. Healthcare systems implementing treatment protocols and investing in patient care management can achieve BP control rates approaching 90% of their patient populations, but such programs are expensive and require substantial reorganization and centralized management that is often not realistic. The problem can be categorized in two ways: (1) Healthcare providers do not have the time and tools needed to gather and synthesize all the relevant information needed to provide individualized treatment recommendations for their patients. (2) Patients dismiss high BP readings, and resist treatment.

Reminding patients with uncontrolled hypertension at their last visit to make an appointment to talk with their doctor is a standard population health approach to improving BP control. We believe that providing patients with a summary of their blood pressure measurements and medications, and specific medication adjustments to consider based on their medical history, may help activate them so that they are more likely to talk to their clinician and consider a BP medication change.

Aim

This study aims to assess the effectiveness of the BP Report letter with personalized BP medication recommendations, compared with Control letters and no intervention, at shortening time to appointment, time to visit, time to medication change, and time to achievement of BP goal.

Hypothesis

Patients with uncontrolled hypertension who receive a BP Activate Report letter, versus Control letter, will have 1) shorter time to scheduling an appointment, 2) shorter time to completed visit where they can discuss blood pressure management with their provider, and 3) shorter time to medication intensification or documented BP control compared to patients who do not receive a mailed letter.

Study Design

We will deliver a letter to patients with apparently uncontrolled blood pressure designed to activate them to schedule a visit (if they don't have one already), come to their scheduled visit, and to discuss BP issues with their clinician. We will test 2 versions of that letter:

- 1) a BP Activate Report letter that includes computerized algorithm recommendations (EngageRx algorithm; see IRB#19-29493) for medication changes they should discuss with their clinician.
- a Control letter suggesting they talk to their clinician about their blood pressure (without BP history or specific medication recommendations)

Study Subjects

<u>Target Population</u>: Patients with uncontrolled hypertension

Inclusion Criteria:

- Patient is a primary care patient of a clinician in a general internal medicine clinic at UCSF
- Lowest SBP>140 or lowest DBP>90 at last visit in general internal medicine clinic
- Last visit in general internal medicine clinic was < 2 years ago
- EngageRx algorithm determines that a medication intensification step is indicated

Exclusion Criteria

- Primary language is not English
- Patient's provider indicates (through an active opt-out process) that they do not want the patient to receive a BP Activate letter

Analysis Plan

We will use simple time-to-event analysis to produce Kaplan-Meier plots and use a log-rank test to compare outcomes by randomized group, overall and by randomization strata and other patient characteristics. We may use Cox proportional hazards regression to adjust for patient characteristics.

Sample Size Justification

With 100:100 randomly assigned to each group, we expect >80% power to detect a statistically significant difference in time to completed visit if the true difference between the two arms is 18%/month vs. 9%/month respectively. Analyses by strata and baseline characteristics will have less power.