

ANALYTIC PLAN FOR PROTOCOL A Pilot Study of Hypertension Management Using Remote Patient Monitoring Study 1

PRINCIPAL INVESTIGATOR:

Stephen D. Persell, MD, MPH
Professor of Medicine, Division of General Internal Medicine & Geriatrics
Director, Center for Primary Care Innovation
Telephone Number: (312) 503-6464
Email Address: spersell@nm.org

VERSION DATE: 1/26/21

Start date 11/19/2020

Define primary study cohort as of this date

Define secondary study cohort as of this date

Define matched control cohort as of this date (attempt to match pilot to control at rate of 4:1 for primary and 2:1 for secondary)

Groups of interest:

- Patients meeting **primary patient population** criteria at the study start date
 - Adults aged 65 to 85 years at the time of the study start date AND
 - One or more office or telehealth visits in the year preceding the study start date at the eligible NM primary care sites AND
 - Medicare or Medicare Advantage insurance on study start date AND
 - Last two office blood pressures elevated (either ≥ 140 mmHg systolic or ≥ 90 mmHg diastolic) in the past 2 years AND
 - Diagnosis of hypertension in the year preceding the study start date (problem list or encounter diagnosis : all of the subcodes of I10, I11, I12, I13, I15) AND
 - Not meet the exclusion criteria
 - Persistent atrial fibrillation as indicated in the EHR
 - Exclude if “permanent atrial fibrillation or persistent atrial fibrillation” [I48.1, I48.2] (active problem list or two encounter diagnoses in past 2 years)
 - Stage IV or more severe kidney disease, defined as the most recent estimated glomerular filtration rate < 30 per $1.73m^2$ or currently on renal replacement therapy (i.e. hemodialysis or peritoneal dialysis) [N18.4, N18.5, N18.6]
 - Diagnosis of dementia as indicated in the electronic health record [all subcodes of F01-F03, all subcodes of G30, all subcodes of G31]
- Patients meeting **secondary patient population** criteria at the study start date
 - Meet criteria for primary population OR
 - Diagnosed hypertension but did not have the last two office blood pressures ≥ 140 mmHg systolic or ≥ 90 mmHg diastolic OR
 - No diagnosis of hypertension in the past year but did have the last office blood pressure ≥ 140 mmHg systolic or ≥ 90 mmHg diastolic

- Control group matched based on the primary study criteria
- Control group matched based on the secondary study criteria.

Matching criteria

- Sex
- Age (+/- 5 years)
- Mean SBP from T-365d to T-183d (+/- 10 mm Hg)
- Mean SBP from T-182d to T-0d (+/- 10 mm Hg)
- Number of office visits to primary care in the past year categories : 1, 2, 3-4, 5+

Assess for time 0 (11/19/2020)

Characteristics of study populations and matched control populations.

At time 0, 1 month (12/18/2020), 3 months (2/18/2020) and 6 months (5/18/2020) describe for each group:

- The proportion of patients who satisfy the performance measure Controlling High Blood Pressure (NQF 0018)
- The systolic blood pressure at the most recent face-to-face office visit

At time 1 month (12/18/2020), 3 months (2/18/2020) and 6 months (5/18/2020) describe for each group:

- Number of antihypertensive medication intensifications between the study start and the measure date

Hypothesis testing—perform separately for primary and secondary populations

H1: Antihypertensive medication intensification will be greater in pilot clinic(s) with RPM compared to contemporaneous control clinic(s).

Compare at 1, 3, and 6 months the number of medication intensifications between study group and control group using Poisson regression (if variance of medication intensifications is approximately equal to the mean) or otherwise negative binomial regression with study group as the independent variable.

H2: The proportion of patients who satisfy the performance measure Controlling High Blood Pressure (NQF 0018) will be greater in pilot clinic(s) with RPM compared to contemporaneous control clinic(s).

Compare at 1, 3, and 6 months the proportion of patients in the study group and control group who satisfy the performance measure Controlling High Blood Pressure (NQF 0018) using logistic regression with study group and baseline systolic blood pressure as independent variables.

H3: The systolic blood pressure at the most recent office visit will be lower in pilot clinic(s) with RPM compared to contemporaneous control clinic(s).

Compare at 1, 3, and 6 months the systolic blood pressure at the most recent face-to-face office visit among patients in the study group and control group using linear regression with study group and baseline systolic blood pressure as independent variables.

RPM enrolled patient analyses

We will explore the trajectories of blood pressure for individuals who are prescribed RPM.

We will describe all patients who are enrolled in RPM at their enrollment date and follow their blood pressure outcomes at 1, 3, and 6 months from their enrollment (or until the study end date).

We will retrospectively, at the end of the study end date, identify matched controls (4:1) for patients enrolled in RPM selected from patients in the non-pilot clinics and matched on the same baseline criteria (assessed at the time of RPM ordering). We will perform comparisons analogous to those described above for the primary cohort.