CMSL Ambulatory Sensitive Condition Nudge Study 2

Study Protocol with Statistical Analysis Plan

November 18, 2025

Study Protocol

Background

The project aims to evaluate a nurse-led intervention to reduce inappropriate emergency department (ED) use among adult patients seen at Geisinger's Community Medicine Service Line (CMSL) clinics. The intervention occurs immediately following an appointment where a patient receives a diagnosis of an ambulatory sensitive condition (ASC; i.e., a condition considered to be a risk factor for near-term ED use). The evaluation will compare eligible patients with an ASC who were randomly assigned to receive follow-up outreach (patient portal message and/or call) from a nurse (who was automatically prompted via the Epic electronic health record system to initiate outreach) with those who were randomly assigned to receive standard care. Analyses will be intent-to-treat. The primary outcome is ED use in the week (i.e., 7 days) following the appointment.

We ran an earlier version of this intervention (NCT06798389). The current study is modified based on results and clinical guidance. Specifically, more conditions will be included as qualifying ASCs for enrollment. Patients under 30 will be excluded. And rather than calling all patients as in the original study, patient portal users may be contacted via the portal instead of or in addition to a phone call. Finally, in the first study, the intervention was differentially effective by age group (<45, 45–64, 65+). Our primary analysis will be conducted separately by age group, though we will conduct an analysis combining across age groups.

We will run the study until we reach at least 4,330 patients in each of the following age groups: patients aged 30–45, patients aged 45–64, patients aged 65+. Therefore, our estimated sample size is at least 4,330x3 = 12,990.

We may be required to do an interim data pull and/or stop the study early at the direction of clinical or operational leaders.

Objectives

The study will evaluate an intervention aimed at reducing ED use following ASC diagnoses via nurse post-appointment calls. Analyses will assess whether ED use is lower in the patients receiving the intervention vs. those in the control arm.

Design

This study is a randomized controlled trial with two study arms. Patients will be randomized to have their nurses receive or not receive outreach via Epic (the night following their appointment).

Methods

At the end of an eligible patient’s CMSL appointment, a patient will be assigned to one of the following study arms, based on which of several ranges of randomized numbers that patient was originally assigned in their electronic chart:

> **Current standard practice (control arm):** Patients will not be included in a nurse follow-up contact list.

Nurse nudge: Following their visit and ASC diagnosis, patients in this arm will be included on an automated list for a nurse follow-up call and/or MyChart message. Note that, although the nurses will be prompted to contact the patients, not all patients will be contacted.

Power Analysis

With 4,330 patients per age group (30–44, 45–64, 65+), we would have 80% power to detect a 1.0% absolute decrease in ED visits between the active arm and the control arm, with two-tailed alpha of .15, assuming a 2.6% baseline rate of subsequent ED visits within 7 days. The target effect size and baseline rate were taken from a trial testing a previous iteration of this intervention at Geisinger.

Project Status

The intervention began on 5/29/2025. No data have been extracted from the electronic health record as of the date this document was uploaded (11/18/2025).

Statistical Analysis Plan

Planned Analyses

Primary Outcome: *ED visit [Time Frame: within 7 days post-appointment]*

Question: Does outreach decrease ED visits?

Analysis (Confirmatory): We will test the hypothesis that automatic Epic notification decreases the likelihood patients will visit the ED in the 7 days following the day of their appointment. We will run an OLS regression including a categorical predictor variable coding for experimental arm (0 = control arm, 1 = outreach arm).

Other pre-specified outcomes:

1. *Nurse call to patient [Time frame: within 7 days post-appointment]*

   Question: Does the nurse nudge increase post-appointment nurse calls to patients?

   Analysis (Confirmatory): We will test the hypothesis that automatic Epic notification increases the likelihood that nurses will call patients in the 7 days following the day of their appointment. We will run an OLS regression including a categorical predictor variable coding for experimental arm (0 = control arm, 1 = outreach arm).

2. *Nurse message to patient [Time frame: within 7 days post-appointment]*

   Question: Does the nurse nudge increase post-appointment nurse MyChart messages to patients?

   Analysis (Confirmatory): We will test the hypothesis that automatic Epic notification increases the likelihood that nurses will send MyChart messages to patients in the 7 days following the day of their appointment. We will run an OLS regression including a

categorical predictor variable coding for experimental arm (0 = control arm, 1 = outreach arm).

3. *Nurse call or message to patient [Time frame: within 7 days post-appointment]*

   Question: Does the nurse nudge increase post-appointment nurse calls or MyChart messages to patients?

   Analysis (Confirmatory): We will test the hypothesis that automatic Epic notification increases the likelihood that nurses will either call or send MyChart messages to patients (according to the eligibility criteria described above) in the 7 days following the day of their appointment. We will run an OLS regression including a categorical predictor variable coding for experimental arm (0 = control arm, 1 = outreach arm).

Analysis Notes

Recent work suggests that OLS regressions are appropriate in randomized experiments with binary outcome variables such as ours (Gomila, 2021).

We will report heteroskedasticity-robust standard errors.

The primary analysis will include only the first encounter for each patient in the study. However, we will run a sensitivity analysis including all encounters with standard errors clustered at the patient level.

Additionally, some patients may have been included in a trial of an earlier version of the same intervention. We will run two sensitivity analyses to see if previous inclusion in the study affects the results: 1. We will add a binary covariate to indicate whether they were in the previous study; and 2. We will rerun the analyses described above without patients who were in the previous study.

Reference

Gomila, R. (2021). Logistic or linear? Estimating causal effects of experimental treatments on binary outcomes using regression analysis. *Journal of Experimental Psychology: General*, *150*(4), 700-709. https://doi.org/10.1037/xge0000920