Nudging High-acuity Emergency Department Patients to Schedule a Follow-up Visit
(NCT06535347)

Study Protocol with Statistical Analysis Plan

August 9, 2024

Study Protocol

Background

The goal of this campaign is to reduce unnecessary emergency department (ED) visits/encourage patients with high acuity visits who have a Geisinger primary care provider (PCP) in the Community Medicine Service Line (CMSL) assigned to follow up with an appropriate provider (their PCP or a specialist) in the future. In this campaign, patients will be assigned to receive or not receive outreach following ED discharge that is aligned with this goal. Outreach will occur via a text message, as well as information added to the patient's after visit summary (AVS), and will include a call to action for the patient to schedule a follow-up appointment with their PCP or a specialist. The SMS messages and AVS will include a phone number to call to schedule an appointment. The SMS messages will also include a hyperlink to self-schedule an appointment. The study will assess whether ED use differs across patients in different outreach conditions. It will also examine whether patients followed through on the message-specific calls to action in the messages differently across conditions.

Objectives

The study will involve randomized assignment of patients to different versions of outreach, including a treatment arm that encourages patients in non-emergent situations to call their PCP's office or a specialist. Patients will also be provided a number to call through which they can schedule an appointment with a provider. SMS messages will include a hyperlink to self-schedule an appointment with a provider. Both SMS text messages (at 1 day, or 1 day and 8 days, post-discharge) and AVS (printed or available via patient portal upon discharge) will be used for active outreach. The control arm will receive the current standard system outreach and AVS. Data will be analyzed to determine which version is most effective at reducing ED use.

Design

This study is a randomized controlled trial with three study arms. Patients will be randomized to receive or not receive SMS texts (at 1 day or 1 and 8 days post discharge) and a modified AVS upon ED discharge.

Methods

At the time of an eligible patient's discharge from the ED, that 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:

1. **Current standard practice (control arm):** Patients in this arm will receive the current standard AVS and whatever typical system outreach occurs.
2. **Follow-up scheduling single notice (treatment arm):** Patients in this arm will receive suggestions for non-ED follow-up care with their PCP or a specialist via SMS messages at 1 day post discharge and in their AVS. The outreach will include a scheduling phone number to call. SMS messages will include a hyperlink to self-schedule with a Geisinger provider.
3. **Follow-up scheduling notice plus reminder (treatment arm):** Patients in this arm will receive suggestions for non-ED follow-up care with their PCP or a specialist via SMS messages at 1 and 8 days post discharge and in their AVS. The outreach will include a

scheduling phone number to call. SMS messages will include a hyperlink to self-schedule with a Geisinger provider.

Power Analysis

With 7,500 patients, we would have 80% power to detect a 3.0% absolute decrease in ED visits between each active arm and the control arm, with two-tailed alpha of .15, assuming a 33% baseline rate of subsequent ED visits within 120 days. The target effect size and number of patients are largely informed by practical considerations regarding the acceptable duration of the intervention (maximum of 6 months, regardless of whether the full sample is achieved), with an effect deemed useful if achieved.

Project Status

As of August 9, 2024, when this document was uploaded, no messages have been sent or data collected or analyzed.

Statistical Analysis Plan

Planned Analyses

Primary Outcome: *ED visit [Time Frame: within 120 days following day of discharge]*

Question: Does outreach decrease ED visits when including information about follow-up care?

Analysis (Confirmatory): We will test the hypothesis that SMS text plus AVS outreach (with or without reminder) decreases the likelihood patients will visit the ED in the 120 days following day of discharge. We will run an OLS regression including a categorical predictor variable coding for experimental arm (0 = control arm, 1 = single message arm, 2 = message plus reminder arm).

Other Pre-specified Outcomes

We will run the analysis described above on the following additional outcomes:

1. PCP/specialist appointment scheduled

   PCP/specialist appointment scheduled (yes/no)

   [Time Frame: within 7 days following day of discharge]

2. PCP/specialist visit attended

   PCP/specialist appointment attended (yes/no)

   [Time Frame: within 7 days following day of discharge]

3. PCP/specialist appointment scheduled

   PCP/specialist appointment scheduled (yes/no)

   [Time Frame: within 14 days following day of discharge]

4. PCP/specialist visit attended

   PCP/specialist appointment attended (yes/no)

   [Time Frame: within 14 days following day of discharge]

5. PCP/specialist appointment scheduled

   PCP/specialist appointment scheduled (yes/no)

   [Time Frame: within 30 days following day of discharge]

6. PCP/specialist visit attended

   PCP/specialist appointment attended (yes/no)

   [Time Frame: within 30 days following day of discharge]

7. PCP/specialist appointment scheduled

   PCP/specialist appointment scheduled (yes/no)

   [Time Frame: within 60 days following day of discharge]

8. PCP/specialist visit attended

   PCP/specialist appointment attended (yes/no)

   [Time Frame: within 60 days following day of discharge]

Analysis Notes

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

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