

Decreasing ED Utilization by Nudging Patients to Call Their Providers or Triage Nurse After  
Women's Health Procedures (NCT04567849)

Statistical Analysis Plan

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## Statistical Analysis Plan

### Brief Summary

In the present study, patients will be sent a message via patient portal after completing a medical procedure with information regarding how to call Geisinger if they have medical issues or concerns post-procedure. Researchers will assess if these patients are more likely to contact Geisinger with post-procedure medical concerns and decrease emergency department (ED) utilization.

### Project Status

Data collection is ongoing. The study team has looked at data for the purposes of identifying if messages are relevant to the patient's procedure and to ensure data are being recorded correctly. Data have been collected on 3,187 patients as of the most recent data pull.

### Power Analysis

We anticipate a ~5.8% ED utilization rate based on historic data among Women's Health patients who underwent surgical or clinical procedures. We expect to achieve about 80% power to observe a 20% reduction in visits (to 4.6% ED utilization) in either of the intervention arms relative to the control arm at a two-tailed  $p < .05$  with  $N = 5,766$  per group. This power analysis allows us the ability to detect an effect for outcomes that contrast each condition with baseline separately. Some outcomes contrast data from pooled experimental arms with the control arm. We should have power to detect an even smaller effect for outcomes that involve pooled data for experimental arms.

### Change in Time Frames

In our original preregistration, our primary outcomes and some secondary outcomes were to be measured at 12 months after the intervention began. Other secondary outcomes had 5 month timeframes. However, because recruitment has been slower than expected, we extended our outcome timeframes. Outcome timeframes that were originally 12 months have been changed to 18 months. Outcome timeframes that were originally 5 months have been changed to 12 months. At 12 months, we expect to be powered to detect at least a 25% relative decrease in ED utilization. At 18 months, we expect to be powered to detect a 20% relative decrease in ED utilization, as outlined above.

### Estimated Sample Sizes

Patients will be randomly assigned to 1 of 3 arms:

1. Control
2. Call your provider
3. Call tele-nurse

Estimated enrollment for each arm is listed below, with intervention arms highlighted in blue:

Arm	Estimated Enrollment
1. Control	5,766
2. Call your provider	5,767
3. Call tele-nurse	5,767
<b>Total</b>	<b>17,300</b>

## Planned Analyses

### Primary Outcomes

1. Phone calls [ Time Frame: N = 17,300 or 18 months, whichever occurs first ]

**Question 1:** Do patient portal messages sent after a delivery, procedure, or surgical discharge increase calls to the provider or tele-nurse?

*Analysis 1 (Confirmatory):* We will test the hypothesis that patients who are sent messages with contact information for their provider or tele-nurse are more likely to call (either phone number) within the 30 days following their procedure than those who are not sent messages. To this end, we will run an OLS regression with a binary outcome variable coding for calls (1 = call, 0 = no call) and a dummy-coded predictor variable coding for condition (1 = message, 0 = no message).

**Question 2:** Are messages that encourage calls to the tele-nurse more effective at increasing calls compared with messages that encourage calls to providers?

*Analysis 2 (Exploratory):* We will test whether tele-nurse messages or provider messages are more effective at promoting calls within the 30 days following a procedure by running an OLS regression with a binary outcome variable coding for calls (1 = call, 0 = no call) and a dummy-coded predictor variable coding for condition (1 = tele-nurse, 0 = provider).

**Question 3:** Do messages that encourage calls to the tele-nurse increase calls compared to sending no messages?

*Analysis 3 (Confirmatory):* We will test the hypothesis that patients who are sent messages encouraging them to call the tele-nurse line are more likely to call within the 30 days following their procedure than those who are not sent messages. We will run an OLS regression with a binary outcome variable coding for calls (1 = call, 0 = no call) and a dummy-coded predictor variable coding for condition (1 = tele-nurse message, 0 = no message).

**Question 4:** Do messages that encourage patients to call their provider increase calls compared to sending no messages?

*Analysis 4 (Confirmatory):* We will test the hypothesis that patients who are sent messages encouraging them to call their provider are more likely to call within the 30 days following their procedure than those who are not sent messages. We will run an OLS regression with a binary outcome variable coding for calls (1 = call, 0 = no call) and a dummy-coded predictor variable coding for condition (1 = provider message, 0 = no message).

2. ED utilization [ Time Frame: N = 17,300 or 18 months, whichever occurs first ]

**Question 1:** Do messages sent after a delivery, procedure, or surgical discharge result in fewer ED visits?

*Analysis 1 (Confirmatory):* We will test the hypothesis that patients who are sent messages encouraging them to call their provider or tele-nurse are less likely to visit the ED within the 30 days following their procedure than those who are not sent messages. To this end, we will run an OLS regression with a binary outcome variable coding for ED visits (1 = visit, 0 = no visit) and a dummy-coded predictor variable coding for condition (1 = message, 0 = no message).

**Question 2:** Are messages that encourage calls to the tele-nurse more effective at decreasing ED visits compared to messages that encourage calls to providers?

*Analysis 2 (Exploratory):* We will test whether tele-nurse messages or provider messages are more effective at decreasing ED visits within the 30 days following a procedure by running an OLS regression with a binary outcome variable coding for ED visits (1 = visit, 0 = no visit) and a dummy-coded predictor variable coding for condition (1 = tele-nurse, 0 = provider).

**Question 3:** Do messages that encourage calls to the tele-nurse decrease ED visits compared to sending no messages?

*Analysis 3 (Confirmatory):* We will test the hypothesis that patients who are sent messages encouraging them to call the tele-nurse line are less likely to visit the ED within the 30 days following their procedure than those who are not sent messages. We will run an OLS regression with a binary outcome variable coding for ED visits (1 = visit, 0 = no visit) and a dummy-coded predictor variable coding for condition (1 = tele-nurse message, 0 = no message).

**Question 4:** Do messages that encourage patients to call their provider increase calls compared to sending no messages?

*Analysis 4 (Confirmatory):* We will test the hypothesis that patients who are sent messages encouraging them to call their provider are less likely to visit the ED within the 30 days following their procedure than those who are not sent messages. We will run an OLS regression with a binary outcome variable coding for ED visits (1 = visit, 0 = no visit) and a dummy-coded predictor variable coding for condition (1 = provider message, 0 = no message).

### **Notes, sensitivity analyses and robustness checks**

*Primary Outcome 1* determines if the patient makes *any* phone call about their procedure to their provider or the tele-nurse line, regardless of their condition. For example, a provider call from a patient in the tele-nurse condition will count as a call, even though the patient did not call the number instructed in the message. This approach allows us to control for the fact that provider phone numbers are better known than the tele-nurse phone number, so there will be a higher rate of provider calls compared with tele-nurse calls, regardless of message condition.

It is difficult to determine if a call is about the patient's procedure. The team is preemptively removing from the dataset reasons that are not relevant to procedures (see list below) as determined by clinical partners. However, it is not possible to anticipate all call reasons that may

be relevant or irrelevant to the precipitating procedure. The team will clean the data again prior to analysis using the following method:

- The study team will aggregate *all* call reasons entered in the EHR for calls from all study participants.
- The team's clinical partners, blind to the patients' experimental conditions, will sort the reasons into those that are likely to be about the procedure and those that are not relevant to the procedure. Alternatively, a non-expert on the study team may pre-sort reasons blind to experimental conditions, and clinical partners will confirm the pre-sorted list.

Analyses of the primary outcome will be limited to calls about the procedure. A robustness check will include data for all calls (except those preemptively filtered from the dataset) from study patients, regardless of the call reason. A more restrictive robustness check will also be conducted, excluding data for calls with more ambiguous reasons that may only occasionally be relevant to the patient's procedure.

*Primary Outcome 2* focuses on ED visits and includes any ED visit regardless of reason, as even seemingly irrelevant visits (e.g., for a car accident) may be in some way related to the patient's procedure. If sufficient data are available to assess ED visit reasons, we may run a robustness check including only reasons deemed relevant to the patient's procedure by our clinical partners.

Recent work suggests that OLS regressions are appropriate in randomized experiments with binary outcome variables such as ours (Gomila, 2021). However, as a robustness check, we will also run the regressions described above as logistic regressions instead of OLS regressions.

As an additional robustness check, we will run OLS regression analyses controlling for sex, binned age (18–24, 25–34, 35–44, 45–54, 65+), and interactions among sex and age as covariates.

### *Secondary Outcomes*

We will use the approaches described above to evaluate the impact of the intervention on the secondary outcome measures listed in the pre-registration:

1. Phone calls [ Time Frame: 12 months ]
2. ED utilization [ Time Frame: 12 months ]
3. Phone calls – surgical patients only [ Time Frame: N = 17,300 or 18 months, whichever occurs first ]
4. ED utilization – surgical patients only [ Time Frame: N = 17,300 or 18 months, whichever occurs first ]
5. Phone calls – surgical patients only [ Time Frame: 12 months ]
6. ED utilization – surgical patients only [ Time Frame: 12 months ]

### **Additional exploratory analyses**

1. Phone calls to provider vs. tele-nurse

Our primary outcome does not distinguish calls to the provider from calls to the tele-nurse line. This analysis will test the hypothesis that participants in the provider condition call their providers at higher rates than those in the tele-nurse condition, and conversely,

whether those in the tele-nurse condition call the tele-nurse at higher rates than those in the provider condition.

To test this hypothesis, we will run two separate regressions: one for calls to the provider and one for calls to the tele-nurse line. In each regression, we will include a dummy coded variable for patient condition (provider, tele-nurse, control).

## 2. Visit acuity

It is important to prevent unnecessary ED visits without discouraging patients from visiting the ED when necessary. We will therefore assess the relationship between message condition and ED visit acuity. Acuity levels will be derived from the visit acuity level in the patient's electronic health record, and/or will be based the NYU ED Algorithm, depending on data availability.

## 3. Patient portal messages

In addition to testing whether calls differ by message condition, we will also examine if patients in either condition are more likely to send a patient portal message to their provider. It is plausible that portal messaging may be affected since the intervention involves contact via the patient portal. We will run all analyses proposed for the first primary outcome (phone calls) on patient portal messages to test this question.

## 4. Timing of ED visit

Patients who seek care at night or on the weekend may have fewer alternative options compared to patients who seek care during the weekday during normal clinic hours. We will test whether the effect of messages on ED visits is particularly pronounced during the daytime hours by running an OLS regression with a binary timing variable (1 = normal clinic hours, 0 = off hours [night time or weekend]), experimental group, and their interaction.

## 5. Age

Patients of different ages may respond differently to our different message conditions. For instance, patients of some ages might feel more comfortable calling their provider, while patients of other ages might be more inclined to call the tele-nurse. We will test for this possibility by running an OLS regression including binned age (18–24, 25–34, 35–44, 45–54, 65+), experimental group, and their interaction.

### **Call and portal message reasons that have been preemptively filtered from our dataset**

- History questionnaire submission
- Precert not needed
- Lost previous prescription
- Appointment canceled
- Social services documentation
- COVID-19 outreach – results pending
- COVID-19 screening
- Med request

- Medication management
- Pre cert/prior auth
- Forms request
- Letter request
- Encounter created in error