Assessing the Relative Efficacy of Communication Modalities for Messages Promoting Flu Shots

Study Protocol with SAP

NCT05509270

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Study Protocol

Scientific Background

The Centers for Disease Control (CDC) recommends a flu vaccination to everyone aged 6+ months, with rare exception; almost anyone can benefit from the vaccine, which can reduce illnesses, missed work, hospitalizations, and death. Flu shots are particularly important for patients at high risk of experiencing severe outcomes.

During the 2020-21 and 2021-22 flu seasons, the study team sent messages to Geisinger patients in the top 10% of risk for flu and complications according to an artificial intelligence algorithm. Messages that told patients they were at high risk significantly increased their likelihood of getting vaccinated.

Objectives

The present study extends previous work by testing which modality or modalities are most effective at boosting flu shot rates in patients at high risk. In previous campaigns, patients received messages via all communication modalities patients were eligible for (mailed letter, SMS text, and/or patient portal message). In this study, patients were randomized to receive high-risk messages in one or more modalities.

Design

This study is a randomized controlled trial with up to 6 study arms, depending on modality eligibility. Patients were randomized to receive high-risk messages in one or more modalities they were eligible for.

Methods

The sample included 43,225 patients. Patients were first divided into the following *modality groups* according to the modalities they were eligible for:

A. Letter + Patient portal + SMS (29,505 patients)
B. Letter + Patient portal (4,980 patients)
C. Letter only (4,366 patients)
D. Letter + SMS (4,364 patients)
E. Patient portal + SMS (8 patients)
F. SMS only (2 patients)

Note: there were no eligible patients who had Patient portal access only.

Then, each modality group was randomized across *study arms* the patients were eligible for:

1. Control (no message)
2. Letter only
3. Patient portal only
4. SMS only
5. Patient portal + SMS

6. Letter + Patient portal + SMS

For example, patients who are eligible to receive a letter and an SMS (*modality group D*) were randomized to Control (*study arm 1*), Letter only (*study arm 2*), or SMS only (*study arm 4*).

Note: Due to power limitations, we did not test all possible combinations of modalities (e.g., we did not include a Letter + SMS study arm).

Power Analysis

Our primary analysis sample includes patients in *modality group A,* with patients eligible for all three modalities. This group includes between 4,916 and 4,919 patients per arm. This sample size allows 80% power to detect an increase in flu vaccination rates from 35% to 37.7% with alpha = .05.

Project Status

All intervention messages have been sent. Letters were sent on 9/6/22. Patient portal messages and SMS were sent on 9/8/22, to match the date when the majority of patients were expected to receive the letter (i.e., 2 days after the letters are sent). The primary outcome date was 10/4/22.

As of this writing, the study team has not yet obtained or analyzed any outcome data from the study.

Statistical Analysis Plan

Analysis Exclusion Criteria

We will remove patients from analysis who received a flu shot prior to 9/6/22, the study start date, because they could not have been influenced by our nudge messages to get a flu shot.

Planned Analyses

Primary Outcome: *Flu vaccination within 4 weeks of the first message send date [Time Frame: 4 weeks after the first messages are sent in the study]*

The primary analysis sample will be patients in *modality group A*, who are eligible for all 3 modalities and were randomized across all study arms. We will address the following four questions in this primary analysis sample:

Question 1: Are flu shot rates higher when a high-risk flu shot message is sent in any modality or combination of modalities independently compared to when no message is sent?

Hypotheses:
1.a. Flu shot rates will be higher in the Letter only arm than the Control arm
1.b. Flu shot rates will be higher in the Patient portal only arm than the Control arm
1.c. Flu shot rates will be higher in the SMS only arm than the Control arm
1.d. Flu shot rates will be higher in the Patient portal +SMS arm than the Control arm
1.e. Flu shot rates will be higher in the Letter + Patient portal + SMS arm than the Control arm

Analysis 1 (Confirmatory): We will run an OLS regression with a categorical independent variable coding for study arm with the Control arm coded as baseline. All 5 hypotheses above will be tested within the same regression.

Question 2: Which modality on its own most effectively increases flu shots?

Analysis 2 (Exploratory): We will run an OLS regression with a categorical independent variable coding for study arm, including only patients randomized to be sent messages in one modality (Letter only, Patient portal only, SMS only). We will test for significant pairwise differences in flu vaccination rates between the study arms by running Tukey's HSD test.

Question 3: Are Patient portal and SMS messages better in combination than either modality alone?

Analysis 3 (Exploratory): We will run an OLS regression including patients in the Patient portal only, SMS only, and Patient portal + SMS arms, with a categorical independent variable coding for study arm. The Patient portal + SMS arm will be coded as baseline, so the individual Patient portal and SMS modalities can be compared directly against the combination of the two modalities.

Question 4: Is there value to sending a letter in addition to Patient portal and SMS messages?

Analysis 4 (Exploratory): We will run an OLS regression comparing the Patient portal + SMS study arm to the Letter + Patient portal + SMS arm, with a categorical independent variable coding for study arm.

Analyses with additional modality groups

We also will run the following **additional analyses on the primary outcome:**

Within *modality groups B* and *D* (Letter + Patient portal, Letter + SMS, respectively), we will run Analyses 1 and 2 (comparing active study arms to the control arm, and comparing active study arms to one another).

For *modality group C* (Letter only), we will run Analysis 1, comparing the letter arm to control.

Because there are so few patients in *modality groups E* (8 patients) and *F* (2 patients), we will not separately analyze data on these groups.

Finally, we will run Analyses 1 and 2 on the entire sample, with all modality groups combined.

Sensitivity Analyses and Robustness Checks

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

Other Pre-specified Outcomes

Other Pre-specified Outcomes listed below include flu outcomes (diagnosis, complications) and COVID-19 vaccination. If there are any differences in these outcomes as a function of study arm, the mechanism would almost certainly be increased flu vaccination. Therefore, we will only run analyses on Other Pre-specified Outcomes for analyses above where there is a difference in flu vaccination.

1. High confidence flu diagnosis

   Patient received a flu diagnosis via a positive polymerase chain reaction (PCR)/antigen/molecular test (yes/no) during the 2022-23 flu season (from the first message send date through April 30, 2023).

   [Time Frame: Up to 8 months]

2. "Likely flu" diagnosis

   Received a "high confidence flu" diagnosis (with positive PCR/antigen/molecular test) and/or "likely flu" diagnosis (as assessed via International Classification of Disease [ICD] codes or Tamiflu administration or positive PCR/antigen/molecular test) (yes/no) during the 2022-23 flu season (from the first message send date through April 30, 2023).

   Note that "likely flu" is a superset of the "high confidence flu" diagnoses.

   [Time Frame: Up to 8 months]

3. Flu complications

   Diagnosed with flu-related complications (yes/no) from the first message send date through July 31, 2023.

   [Time Frame: Up to 11 months]

4. ER visits

   Number of ER visits from the first message send date through July 31, 2023.

   [Time Frame: Up to 11 months]

5. Hospitalizations

   Number of hospitalizations from the first message send date through July 31, 2023.

   [Time Frame: Up to 11 months]

6. COVID-19 vaccination rates

   Received at least one COVID-19 vaccination (yes/no) during the 2022-23 flu season (from the first message send date through April 30, 2023).

   [Time Frame: Up to 8 months]

Additional Exploratory Analyses

1. Age and gender

   While older patients tend to be aware of their increased vulnerability, younger patients may be more surprised to learn of their high-risk status. Additionally, our previous work suggests that males and females are differently likely to get vaccinated as a function of age, with younger females *more* likely to get vaccinated than males, and older females *less* likely to get vaccinated than older males.

   We will therefore run an OLS regression including binned age (18-24, 35-44,45-54, 65+), gender, and their interaction.

   We will also test for an interaction between age, gender and study arm, as people of different ages and genders may be differentially receptive to different modalities.

2. Timing of shot

   We will run regression models to test whether intervention messages influenced the timing (time elapsed since the beginning of the intervention, September 6, 2022) of flu shots.

3. Risk level

   As in our studies in the 2020-21 and 2021-22 flu seasons, patients who were in the top 3% of risk were told they were in the top 3% of risk, while those in the next 7% (i.e., the top 4-10% of risk) were told they were in the top 10% of risk. We will test whether flu vaccination rates differ across risk level (top 3%, top 10%) and whether risk level interacts with study arm among patients in *modality group A* who have access to all 3 modalities.