Nudging Flu Vaccination by Making it Easy for Patients to Schedule a Flu Shot

Statistical Analysis Plan

NCT05493787

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Scientific Background and Objectives

The 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. Past work from the study team focused on encouraging flu shots for patients with upcoming appointments. However, many patients in the health system do not have any appointments during flu season.

Eligible patients without an upcoming appointment were randomized to a passive control group (no message), an active control group (a basic message stating that the patient can get a flu shot at Geisinger) or one of several other messages informed by behavioral science ("ease", "waiting for you", "protect yourself - rare outcomes", or "protect yourself - frequent outcomes"). Patients were randomly assigned to one of two message send dates. Messages were sent via patient portal and included a link redirecting patients to a page where they could self-schedule a flu shot.

Methods

Patients eligible for the study as of late October 2022 were randomized to a send date (11/8/22 or 12/6/22) and to one of the following study arms:

1. Passive control: No message
2. Active control: A message that simply stated that patients can get a flu shot at Geisinger
3. Ease: A message that emphasized the ease of getting a flu shot at Geisinger
4. Waiting for you: A message that stated the patient's flu shot was "waiting" for them at Geisinger
5. Protect yourself (rare outcomes): A message that emphasized the rare, dangerous outcomes of getting the flu (e.g., hospitalization, pneumonia), and stated that the flu shot can offer protection from those outcomes
6. Protect yourself (frequent outcomes): A message that emphasized the outcomes that frequently occur in people with the flu (e.g., fever, chills, missing important events), and stated that the flu shot can offer protection from those outcomes

All messages included a link redirecting patients to a page where they could self-schedule a flu shot.

Prior to the second message send date, we removed from the study patients who were randomized to the second send date but were no longer eligible (e.g., because they already received a flu shot or who had an appointment newly scheduled).

The final sample includes 139,503 patients.

Power Analysis

The sample size above allows 80% power to detect an increase in flu vaccination rates from 35% to 36.24% with two-tailed alpha = .05 for any comparison between message arms.

Project Status

All intervention messages have been sent. Data have not yet been extracted from the electronic health records by the study team.

Planned Analyses

Primary Outcome: *Flu shot self-scheduling [Time Frame: Within 4 weeks of the patient's message send date]*

Secondary Outcome: *Flu vaccination [Time Frame: Within 4 weeks of the patient's message send date]*

We will run the following analyses for both the primary and secondary outcomes:

Question 1: Do any of the message versions increase flu shot self-scheduling or flu vaccination relative to no message?

Analysis 1: We will test the hypothesis that all messages significantly increase self-scheduling and vaccination relative to no message. For each outcome, we will run an OLS regression including a categorical predictor variable coding for each individual arm, with arm 1 (no message) as the baseline.

Question 2: Are any of the messages that contain nudge language informed by behavioral science (arms 3–6) more effective than a simple reminder message (active control, arm 2)?

Analysis 2: We will test the hypothesis that messages in arms 3–6, which contain additional nudge language informed by behavioral science, are more effective than active control messages. For each outcome, we will run an OLS regression including a categorical predictor variable coding for each individual message arm (arms 2–6), with arm 2 (active control) as the baseline.

Question 3: Are the arms that include nudge language (arms 3–6) differently effective at promoting self-scheduling or vaccination?

Analysis 3: For each outcome, we will run an OLS regression with a categorical variable coding for nudge arm (arms 3–6). Pairwise comparisons between arms will be corrected using Tukey's HSD.

Question 4: Is it more effective to send a flu shot message in November or December?

Analysis 4: We will run an OLS regression including a binary variable coding for whether or not the patient was sent a message (no message - arm 1; message - arms 2–5), another binary variable coding for send date, and their interaction.

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. We may run additional sensitivity analyses or robustness checks.

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 significant 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 patient's study start 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 patient's study start 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 patient's study start date through July 31, 2023.

   [Time Frame: Up to 11 months]

4. ER visits

   Number of ER visits from the patient's study start date through July 31, 2023.

   [Time Frame: Up to 11 months]

5. Hospitalizations

   Number of hospitalizations from the patient's study start 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 patient's study start date through April 30, 2023).

[Time Frame: Up to 8 months]

Additional Exploratory Analyses

1. Difference in message version effectiveness by send date

   The group of patients included in our November message send may differ meaningfully than patients included in our December message send: the group in December had relatively more time to get vaccinated before receiving our messages, but still did not get vaccinated. Therefore, it is possible that which particular message is most effective varies as a function of send date.

   To explore this possibility, we will run an OLS regression including message arm (with no message coded as baseline), send date (November, December) and their interaction.

2. Age and gender

   Messages might be differently effective as a function of age and gender.
   To test the relation between flu shots, age and gender, we will run an OLS regression including binned age (18–24, 25–34, 35–44,45–54, 65+), gender, and their interaction. We will also test for an interaction between age, gender, and study arm.

3. Patients who opened the messages as a function of message type

   We will test whether message open rates vary by experimental arm. Open rates may vary because message subjects varied by experimental arm to correspond to message content. We will run an OLS regression including categorical variable coding for arm number (arms 2–6, the arms that were sent messages) with message open within 4 weeks of the message send date as the dependent variable. We will correct for multiple comparisons using Tukey's HSD.

4. Primary and secondary analyses among patients who opened the message

   We will run primary and secondary analyses #2–4 above, limiting our sample to patients who opened their messages within 4 weeks of receiving them. In this analysis, we will also remove from the sample patients who scheduled vaccination appointments or were vaccinated before opening their message.

5. Prior year flu shots

   We will test whether patients are more or less responsive to our messages as a function of whether they received a flu shot in the 2021–22 flu season. To this end, we will run an OLS regression with a predictor variable coding for experimental arm, a binary predictor coding for whether the patient received a flu shot in the 2021–22 season, and their interaction.