Lottery Incentive Nudges to Increase Influenza Vaccinations

NCT05012163

2/3/2022

Statistical Analysis Plan

Brief Summary

In the current study, the study team will explore whether small incentives are effective at promoting flu vaccine uptake. The study is designed to assess whether people are more likely to get vaccinated when sent a message offering a $1 Pennsylvania scratch-off lottery ticket, a message offering $1 in cash, an active control message with no incentive, or no message (standard of care). A primary hypothesis is that the scratch-off messages will outperform the $1 cash messages, active control messages (encouraging respondents to get the flu shot at their upcoming appointment) and the standard of care, representing the ambient healthcare system and public health campaigns to increase vaccination.

Power analysis

The study team planned to enroll at least 9,806 patients per study arm. Assuming a baseline vaccination rate of 50%, this sample would allow 80% power to detect a 2% absolute percentage-point difference, or a 4% relative difference, between any two groups.

In August, 2021, we completed an analysis of the anticipated number of eligible patients in the study. This analysis suggested that our sample would be large enough to run four study arms (i.e., we projected that we would enroll more than 39,224 participants, but fewer than 49,030, the number that would have been required to add a fifth arm). Therefore, we proceeded with running only the priority four pre-registered study arms, and we anticipate enrolling a total of at least 39,224 patients across those four groups.

Sample and Randomization

The sample includes patients who have an upcoming primary or specialty appointment where they can get a flu shot, and who, according to Geisinger's records, have not yet received a flu shot in the 2021–22 flu season. Patients are also age 18 or older, are not contraindicated for flu shots, and have an assigned Geisinger PCP. All patients are also eligible to receive text messages from Geisinger.

The four study groups include:

1. Pennsylvania (PA) Lottery Scratch-Off Financial Incentive - Participants in this arm receive a message stating that they will receive a PA lottery $1 scratch-off ticket if they get a flu shot at an upcoming appointment. The message will mention that they could win $5,000 (the top prize for the scratch-off game).
2. Certain Cash Payout Financial Incentive - Participants in this arm receive a message stating that they will receive $1 in cash if they get a flu shot at an upcoming appointment.
3. Reminder / Active Control (No Financial Incentive) - Participants in this arm receive a message stating that they can get a flu shot at an upcoming appointment. These participants will not be offered a financial incentive for getting a flu shot.
4. No Intervention: No Treatment Control - No additional contact beyond standard Geisinger flu shot communications

Each day, the study team receives a list of eligible patients with flu-shot-eligible appointments in the upcoming 3 days. Patients with appointments in 3 days are randomized into the 4 groups described above. Those in groups 1-3 receive their first messages 3 days prior to their appointment.

All patients who are sent 3-day messages are sent 1-day messages, as long as they appear on the list of eligible patients the day prior to their appointment. There are two reasons patients may not appear in that list: 1) their appointment is rescheduled and they no longer have a flu-shot-eligible appointment scheduled on that date, or 2) Geisinger records are updated indicating the patient got a flu shot after randomization but before the 1-day reminder list is created, rendering the patient ineligible for a flu shot at their appointment.

In cases where a patient cancels their appointment or reschedules it for a different day, they are not sent a 1-day message.

In cases where a patient reschedules their appointment to a different time on the same day, or where the patient has a different flu-shot-eligible appointment on the same day, the patient is still sent a 1-day reminder message.

Project status

Study recruitment is complete. We have extracted and analyzed data for the primary outcome. We have not yet extracted or analyzed data for any secondary outcomes.

In August, 2021, on the advice of our clinical collaborators, we intended to change the secondary outcome time frame for flu diagnosis to be measured on April 30, 2022 rather than March 31, 2022. We also intended to change the secondary outcome time frame for flu complications to be measured on July 31, 2022 rather than March 31, 2022. These dates are consistent with a study timeline we submitted to the NIH in August 2021. However, we neglected to make these changes to our preregistration on clinicaltrials.gov. The original version of this Statistical Analysis Plan included the previous secondary outcome dates, which were copied from the clinicaltrials.gov preregistration.

Additionally, our earlier Statistical Analysis Plan version did not include a preregistered time frame for 2022-23 flu shots. We intend to measure this outcome as of December 31, 2022, to be consistent with the date we measured flu shots in the 2021-22 flu season (December 31, 2021).

This modified Statistical Analysis Plan and our clinicaltrials.gov page now reflect our corrected secondary outcome time frames and our estimated study completion date (December 31, 2022, the date we will measure 2022-23 flu shots). The secondary outcome time frames, the clarified time frame for 2022-23 flu shots, and this Project status section are the only changes from the original Statistical Analysis Plan.

Planned Analyses

Primary Outcome

Flu vaccination at appointment [Time Frame: 3 days after patient is randomized]

Question 1: Can lottery incentives increase flu vaccination rates better than equivalent-value cash payouts, active control messages, or no messages?

Analysis 1a (Confirmatory): We will test the hypothesis that patients who are sent messages with promise of an official state lottery ticket if they get vaccinated (patients randomized to message group 1) will exhibit improved flu vaccination rates compared with patients who are sent messages offering a certain $1 cash payout if they get vaccinated (group 2).

Analysis 1b (Confirmatory): We will test the hypothesis that patients who are sent messages with promise of an official state lottery ticket if they get vaccinated (patients randomized to message group 1) will exhibit improved flu vaccination rates compared with patients who are sent active control messages (group 3).

Analysis 1c (Confirmatory): We will test the hypothesis that patients who are sent messages with promise of an official state lottery ticket if they get vaccinated (patients randomized to message group 1) will exhibit improved flu vaccination rates compared with patients who are sent no messages (group 4).

For analyses 1a through 1c, we will run an OLS regression, with a dummy variable coding for no message (group 4), active control message (group 3), cash (group 2), or state lottery (group 1).

Question 2: Do active control messages encouraging flu shots at an upcoming appointment increase flu vaccination rates?

Analysis 2 (Confirmatory): We hypothesize that patients who are sent active control messages encouraging them to get a flu shot without any associated incentives (group 3) will be more likely to get vaccinated than those in the no-contact control group (group 4). To assess this hypothesis, we will employ OLS regression with a categorical predictor variable coding for group (group 3 vs. group 4).

Question 3: Do small cash incentives increase flu vaccination more than active control messages or no messages?

Analysis 3a (Exploratory): We will test whether patients sent text messages promising small cash incentives in exchange for vaccination (group 2) are more likely to get vaccinated than those who are sent active control messages (group 3).

Analysis 3b (Exploratory): We will test whether patients sent text messages promising small cash incentives in exchange for vaccination (group 2) are more likely to get vaccinated than those who are not sent any messages (group 4).

For Analyses 3a and 3b, we will run one OLS regression, with a dummy variable coding for no message (group 4), simple message (group 3), or cash (group 2).

We will not correct for multiple comparisons in the analyses above, as adjustment is not appropriate for individual testing, where each result must be statistically significant to reject its associated

individual null hypothesis (Rubin, 2021). That is, each significant result is an indicator of a specific null hypothesis rejection and has no direct bearing on the success of other hypotheses or the overall study.

Sensitivity analyses and robustness checks

Some patients lived at the same address, but we decided to randomize patients independently, without accounting for whether a household member was also in the study. Therefore, some patients may have been assigned to different groups from their household members. Alternatively, it is possible household members were assigned to the same group. Either possibility may affect the impact of our intervention (e.g., the same messages received by multiple household members may reinforce the message and strengthen the impact of the messages, while different messages could cause confusion and weaken the messages' effectiveness). To ensure findings do not depend on such interactions between patients residing at the same address, we will run a sensitivity analysis by removing all patients who share an address with another patient in the study and computing the same analyses listed above.

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.

On 10/6/21, we realized that we had enrolled patients based on their age on the date of their appointment rather than their age on the date of randomization, when we sent the 3-day messages. There were 2 patients enrolled who turned 18 in the 3 days between enrollment and their appointment date. These patients were removed from the study and will be excluded from all analyses.

We will use an intent-to-treat approach for our statistical analyses, including all patients who were randomized. However, we will also run the analyses described above with the subset of patients who, according to text-message records from Twilio, received both 3-day and 1-day reminder messages. This robustness check will exclude patients who were randomized but were never sent messages for a variety of reasons (e.g., their phone numbers were inactive, they were on a do-not-contact list that the research team did not have access to prior to randomization). Additionally, we will exclude patients who were sent only a 3-day message, but who were not sent a 1-day message. We will also exclude a limited number of patients who received repetitions of the same message due to technical glitches outside the study team's control.

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

Secondary outcomes

We will use the approaches described in analyses 1-3 above to evaluate the impact of the intervention on the secondary outcome measures listed in the pre-registration:

1. Flu vaccination within 7 days [Time Frame: Within 7 days of when patient is randomized]

Received flu vaccination

2. Flu diagnosis [Time Frame: During the 2021-22 flu season (Up to 8 months, from the time the patient is randomized through April 30, 2022)]

   Received a "high confidence flu" diagnosis (with positive polymerase chain reaction [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)

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

3. Flu complications [Time Frame: During the 2021-22 flu season (Up to 11 months, from the time the patient is randomized through July 31, 2022)]

   Diagnosed with flu-related complications

4. Flu vaccination (among subject cohabitants) within 28 days [Time Frame: Within 28 days of when the study subject is randomized]

   Cohabitant of study subject received flu vaccination

   This analysis will exclude patients who are both cohabitants of a subject and subject themselves

Additional exploratory analyses

1. Age

   Young adults tend to be more motivated by large rewards compared with older adults. We will therefore test the hypothesis that the scratch-off intervention, which entails the possibility of winning large cash rewards, is particularly effective in younger patients. We will test this hypothesis by running a Generalized Additive Model, testing for interactions between age and experimental group. We will also run an OLS regression including binned age (18-24, 35-44,45-54, 65+), experimental group, and their interaction, to test whether scratch-off tickets are most effective in the youngest age group (18-24) relative to older age groups.

2. Appointment type

   We enrolled patients in this study for upcoming primary or specialty care appointments that stock flu vaccine. We will run an OLS regression to test whether there was a difference in flu vaccination as a function of the appointment type and experimental group.

3. Socioeconomic status (SES)

   Patients with lower socioeconomic status may be more motivated by the scratch-off ticket or the $1 cash versus those with higher SES. We will test for possible SES effects in two regressions, each including a proxy variable for SES. In one regression, we will include a variable coding for binned median income in the patient’s ZIP code on file (<60% of state

median income, 60-100% of state median income, 100-140% of state median income, >140% of state median income). In the other analysis, we will include a variable coding for line of business (Medicaid, Medicare, commercial/other). In both regressions, we will test for an interaction between the SES proxy variable and experimental group.

4. Lottery popularity by region

   Patients who live in areas where playing the lottery is more popular may be more motivated by scratch-off tickets than those who live in areas where playing the lottery is less common. We will test whether scratch-off tickets are relatively more effective at promoting vaccination in counties with higher PA lottery ticket sales relative to counties with lower sales.

5. Sex

   Males tend to gamble more than females, so we will test the hypothesis that scratch-off tickets outperform other messages to a greater degree in males compared with females. We will run an OLS regression testing for an interaction between sex and experimental group.

6. Previous year flu vaccination

   Some patients may receive a flu shot every year absent financial incentives. For these patients, financial incentives may be no more effective than an active control message, or the system standard of care. Conversely, our intervention may be more effective in those who do not get vaccinated habitually. We will test whether our small-incentive interventions are differently effective in those who received a flu shot last year compared with those who did not. To this end, we will run an OLS regression to test whether 2021-22 flu vaccination varies as a function of 2020-21 flu vaccination status, experimental group, and their interaction.

7. Vaccination during the 2022-23 flu season

   Patients who are vaccinated against the flu after our intervention may ultimately develop a vaccination habit and be more likely to get vaccinated in the following flu season absent incentives. Or, once incentives are removed, they may be less likely to get vaccinated without the incentive. Therefore, we will explore whether any vaccination findings from this study extended into the 2022-23 flu season. We will measure flu vaccination in the 2022-23 flu season as of 12/31/2022 (aligned with our primary completion date of 12/31/2021 for vaccinations in the 2021-22 flu season).

8. COVID-19 vaccination and diagnosis

   Vaccination against one disease is often a predictor of vaccination against other diseases, but this is less clear in the highly politicized context of COVID-19. We will run regression models to test for differences in intervention effectiveness in patients who have been diagnosed with or vaccinated against COVID-19 prior to being enrolled in the study. We will

also test whether study condition and vaccination status influences decisions to receive a COVID-19 vaccine or COVID-19 diagnosis after the study period.