Pre-visit Questionnaire to Increase Influenza Vaccinations

Study Protocol with Statistical Analysis Plan

NCT05508698

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Study Protocol

Scientific Background

Almost everyone ages 6 months or older can benefit from the influenza vaccine, which can reduce illnesses, missed work, hospitalizations, and death by reducing the likelihood of contracting influenza.

Objectives

The purpose of this study is to assess, prospectively, the effect on flu vaccination rates of a pre-visit questionnaire that asks patients to indicate their preferences for a flu shot at an upcoming appointment. Responses to the questionnaire are shown to clinicians via additional text in an existing flu shot alert. The investigators hypothesize that the pre-visit questionnaire will lead to increased flu vaccination compared with standard practices.

Design

This study is a randomized controlled trial with 2 study arms. Patients were pre-randomized to receive (or not receive) a one-item, pre-visit questionnaire about the flu shot. Questionnaire responses are shown to clinicians in an existing flu shot alert.

Methods

Patients were pre-randomized to two study arms in July 2022:

1. Passive Control: No change to standard of care for flu vaccines
2. Pre-visit Questionnaire: One-item questionnaire in online patient portal and additional information in the flu shot alert.

(Note that patients new to Geisinger after pre-randomization are not included in the study.)

Patients are enrolled in the study if they have a flu-shot-eligible appointment scheduled 14 days or less prior to their appointment.

Appointments are flu-shot-eligible if the appointment department administers flu shots (according to an EHR classification list) at the time the appointment questionnaire becomes available (14 days prior to the appointment for appointments scheduled 14 days or more before the appointment, or on the day the appointment is scheduled for appointments scheduled less than 14 days in advance).

For those in the passive control arm, we will retrospectively identify flu-shot-eligible appointments based on the departments and date ranges observed in the questionnaire arm. For example, if questionnaires were sent to patients in the questionnaire arm for appointments in a given department from 9/1/22–12/31/22, an appointment in that same department in that date range will be considered flu-shot-eligible for a patient in the passive control group.

Additionally, patients are enrolled if, according to the EHR, they have not yet received a flu shot at the time the questionnaire becomes available (or at the time it would have become available for the passive control group).

Power Analysis

We expect that about 165,000 patients will be enrolled in the study (~82,500 per arm). This sample size allows 80% power to detect an increase in flu vaccination rates from 35% to 35.7% with two-tailed alpha = .05 for any comparison between study arms.

Project Status

Patients were pre-randomized to their study arms in July 2022. Enrollment was complete on 4/1/23, after which the flu shot alerts were turned off across the system. Data collection continued until the primary outcome date of 4/8/23 (7 days after the final appointments). This updated version of the statistical analysis plan specifies slightly modified inclusion criteria for analysis, to correct as well as possible, and in an unbiased manner, for differences in how MyChart questionnaires were actually implemented relative to what was intended. No outcomes data were compared across study arms, and final outcomes data were not pulled or reviewed prior to uploading this document.

Statistical Analysis Plan

Planned Analyses

Primary Outcome: *Count of patients with a flu vaccination [Time Frame: Up to 21 days]*

Outcome Description: Patient received a flu vaccine (yes/no) between the day questionnaires became available for the patient's first scheduled flu-shot-eligible appointment and 7 days following the appointment. Questionnaires were available 14 days prior to the appointment date for appointments scheduled at least 14 days in advance. Questionnaires were available on the day the appointment was scheduled for appointments scheduled less than 14 days in advance.

Note that control patients did not receive a flu shot questionnaire, but they may have received other questionnaires from the health system 14 days before their appointment. We will conduct subgroup analyses for people who had responded to MyGeisinger pre-visit messages in the previous year and those who did not.

Question: Does a pre-visit questionnaire that allows patients to indicate their flu shot preferences increase the likelihood that they will get a flu shot?

Analysis (Confirmatory): We will test the hypothesis that a pre-visit flu-shot questionnaire increases the likelihood that patients will get a flu shot. We will run an OLS regression to examine whether flu vaccination differs as a function of experimental arm.

Analysis Notes

To identify the primary analysis sample, we will limit the dataset to the first flu shot-eligible appointment for which each enrolled patient was scheduled. We will then further limit the

dataset to appointments where patients were expected to receive a questionnaire (or for those in the passive control group, where the patient would have been expected to have received a questionnaire), as defined further here:

- The appointment was in a department and entailed an encounter type that was supposed to trigger a questionnaire (even if a questionnaire was not always triggered)
- The patient was not marked as contraindicated for the flu vaccine in the flu shot BPA for the 150 days prior to the questionnaire
- The patient had a “flu shot overdue” health maintenance topic (HMT) as of two days prior to the questionnaire launch date, ensuring sufficient time for the HMT to successfully trigger the questionnaire (given that a large proportion of questionnaires were not triggered when the HMT was too recent), OR the appointment was between 9/1/22 and 9/15/22, at which time the questionnaires were triggered regardless of the HMT status

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

As the treatment variation is at the individual level, we will report heteroskedasticity-robust standard errors. We will also explore the impact of clustering these standard errors at the clinic and clinic-date levels to allow for dependence across observations within these clusters. We will also investigate heterogeneity across clinics that vary along characteristics of interest, including prior-year vaccination rates.

We may run additional robustness checks. These checks may include focusing on additional inclusion/exclusion criteria (e.g., including subsequent visits with questionnaires for a given patient) and subpopulations (e.g., different visit types).

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. Count of patients with a 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. Count of patients with a "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. Count of patients with 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]

7. Count of patients with a flu vaccination during the 2022-2023 season

   Patient received a flu vaccine (yes/no) during the 2022-23 flu season (from the patient's appointment date through April 30, 2023)

   [Time Frame: Up to 8 months]

Additional Exploratory Analyses

1. Age and sex

   People of different ages and sexes may react differently to the questionnaire. To test the relation between flu shots, age, and sex, we will run an OLS regression including binned patient age (18–24, 25–34, 35–44, 45–54, 65+), sex, and their interaction.

   We will additionally test for an interaction between age, sex, and study arm, as people of different ages and sexes may be differentially receptive to different alert versions.

   We may also test whether alert effectiveness varies by clinician age and/or sex.

2. Number of appointments with a flu shot questionnaire

   Patients may have received more than one flu-shot questionnaire during the flu season. We will explore whether vaccination rates increased with more exposure to the flu-shot questionnaire in the experimental group compared with those in the control group who had the same number of eligible appointments but were not sent the questionnaire.

3. Appointment department/specialty

   Some departments give more flu shots than others. We will test if alerts with or without questionnaire responses are differentially effective as a function of department or specialty, to see if some versions are particularly helpful for under-performing departments or specialties.

4. Contamination analysis

   Although randomization was at the patient level, the alert portion of the intervention was directly experienced by clinicians rather than patients. Many clinicians encountered patients and their assigned alerts for both experimental arms. We will explore whether contamination was present in our data due to clinicians' exposure to multiple experimental conditions (e.g., by examining results as a function of clinic-level variation in the number of patients randomly assigned to each arm and/or as a function of the duration of exposure to the information).