GENERAL INFORMATION

Nudging flu vaccination by making it easy for patients to schedule a flu shot

Christopher Chabris, Ph.D.
cfchabris@geisinger.edu

September 25, 2022

IRB#: 2022-0500

BACKGROUND AND OBJECTIVES

On average, 8% of the US population gets sick from the flu each flu season (Tokars et al., 2018). Since 2010, the annual disease burden of influenza has included 9-45 million illnesses, 140,000-810,000 hospitalizations, and 12,000-61,000 deaths (CDC, 2020). 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 (CDC, 2019). Flu vaccination is especially important during the COVID-19 pandemic, to minimize flu/COVID-19 coinfections and conserve healthcare resources.

Two past Roybal pilots focused on outreach to patients with upcoming appointments (e.g., Milkman et al. 2021). However, many patients in the health system do not have any appointments during flu season. Messaging patients without a scheduled appointment with a way for them to easily self-schedule a flu shot may increase flu shot uptake across the health system.

The present study will test the effectiveness of a patient-facing nudge, encouraging patients without an upcoming appointment to get a flu shot. This study builds on Geisinger and Penn Medicine Roybal-funded pilots evaluating high-risk messages sent to patients with or without an upcoming appointment (Rosenbaum et al., 2021; Shermohammed et al., 2021), and timely notifications encouraging patients to get the flu shot at their upcoming appointment (e.g., Milkman et al. 2021).

Specific Aim

Evaluate via randomized controlled trial the efficacy of sending messages encouraging flu shots to patients with no scheduled appointment during flu season.

PROCEDURES

Research Design

Patients will be randomly assigned to one of up to six study arms. Outcomes during the 2022–2023 flu season will be compared between study arms.

Study Population

1) Primary target population

Inclusion Criteria:

- Included in one or both of the following two base patient lists:
    - Community Medicine Service Line (CMSL)/Marketing patient portal flu outreach list for Fall 2022
    - A list of patients obtained from Geisinger's Phenomics and Clinical Data Core (PACDC; see Data Sources below for more on this list)
- Aged 18 or older as of October 2022

- Has had a Geisinger encounter in the last 2 years as of October 2022
- Either of the following, as of October 2022:
    - Has a Geisinger PCP assigned in the Community Medicine, Pediatrics, or Internal Medicine service line
    - In the last 2 years, has completed an appointment in a Geisinger specialty on a list of specialties approved by system leadership for flu shot communications
- Has not received a flu-shot during the 2022–23 flu season as of ~1 week prior to the message date (timeline may be slightly different, depending on data pull logistics), according to the Electronic Health Record (EHR)
- Does not have a scheduled in-person primary care or in-person flu-shot-eligible specialty appointment in the 12 weeks following their assigned message send date, as of ~1 week prior to the message date (timelines may be slightly different, depending on data pull logistics or clinical guidance)
    - As of this writing, the team plans to define a flu-shot-eligible specialty appointments as appointments in departments that have historically documented or administered flu vaccine. However, this approach may change slightly based on changing clinical guidance.

Exclusion Criteria:
- The CMSL/Marketing list will include patients in Geisinger's 65Forward or Community Care populations. If necessary due to logistical constraints, we may exclude these 65Forward and/or Community Care patients from our study.
- Cannot be contacted via the communication modality being used in the study (e.g., patient portal, SMS), e.g., due to insufficient/missing contact information in the EHR or because they opted out
- Has an allergy to flu vaccines according to any EHR allergy table known to the study team
- Has a health maintenance modifier indicating they are permanently discontinued from receiving a seasonal flu shot
- Is on a list of dismissed patients

Unlike in previous pilots, with guidance from the director of Infectious Diseases at Geisinger, we will not explicitly exclude all patients with potential contraindications, because patients are expected to be screened for flu shot eligibility and prior vaccination by clinicians. However, clinical leadership subsequently advised us to avoid messaging patients with a flu vaccine allergy indicated in either of two EHR tables (an allergy table or a health maintenance modifier table). Therefore, we will exclude patients with flu vaccine allergies listed in these tables. Additionally, we will follow clinical guidance if it changes (e.g., if clinicians point out another allergy table that should be avoided), under the exclusion criterion "Has an allergy to flu vaccines in any EHR allergy table known to the study team."

Our messages will include a disclaimer stating that most people who think they shouldn't get a flu shot actually can and should, even people who have been told they have allergies, and directing patients to talk to their doctor with any concerns. We plan to also link to a myth-busting website, hosted by the Geisinger Marketing team, which includes information about flu shots and contraindications.

Recruitment and Enrollment
All patients will be recruited and enrolled from Geisinger; Massachusetts Institute of Technology (MIT)/National Bureau of Economic Research (NBER) collaborators will not be involved in recruitment or enrollment. A conservative anticipated enrollment number for this primary target

population is ~120,000. The minimum number of patients we plan to recruit is 60,000, with 10,000 per arm. If, due to unforeseen circumstances, there are fewer than 60,000 patients available to message, we will remove one or more message arms until there are at least 10,000 patients per arm. Only patients from this primary target population will be contacted.

Detailed Study Procedures

Every year, Geisinger Marketing, in collaboration with CMSL, sends messages to patients via the patient portal in late August or early September, along with a follow-up message later in the flu season. This year, the BIT is taking over the follow-up messages to test the most effective wording and timing for these messages.

In addition to patients on the CMSL/Marketing outreach list, the study will include patients who are on a general list of patients generated by PACDC but who were not included in the CMSL/Marketing list. We are using both lists in hopes of collecting data from a broad sample of Geisinger patients.

Participants will be randomized to receive, or not receive, a message prompting them to get a flu shot. The experimental arms include:

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

Messages will include a link redirecting patients to a page where they can self-schedule a flu shot.

The language of the attached drafts may change slightly as we are working with multiple teams at Geisinger, but we will not alter the content and overall message drastically.

Patients will be randomized to one of a few message send dates (e.g., mid-October, mid-November, or Mid-December; the exact dates will be determined in collaboration with the Marketing team). Although patients in the passive control group will not receive a message, they will be assigned to a send date as a comparison for those who receive messages on their assigned date.

Although we anticipate sending messages via the patient portal, we will use SMS, email, or another modality if logistically necessary.

All patients eligible for the study prior to the first send date will be randomized to an experimental arm and send date prior to the first message send date. Then, prior to each subsequent message send date, we will remove from the study patients who have already received a flu shot or who have an appointment newly scheduled in the 12 weeks after their scheduled message send date.

The planned primary outcome will be whether the patient self-schedules a flu shot appointment within 4 weeks of the patient's message send date (note that the patient needs to schedule the appointment in this timeframe, but the appointment can occur more than 4 weeks past the send date). (However, if it is determined that self-scheduling cannot be reliably extracted from the EHR, the primary outcome will be flu vaccination within 4 weeks of the message send date.) Secondary outcomes will include vaccination within 4 weeks of the message send date. Additional outcomes to be measured through the end of the flu season will include: rates of flu diagnoses (both using the most rigorous biological tests, "high confidence flu", and using broader criteria that also include diagnosis codes and treatment information, "likely flu"), flu complications, and rates of other relevant healthcare utilization outcomes such as ER visits, and hospitalizations. Finally, we will measure rates of COVID-19 vaccination in targeted patients.

Data Sources

The base sample will include patients who are on the Fall 2022 CMSL/Marketing patient-portal based flu outreach list, as described above.

In hopes of collecting data from a broad sample of Geisinger patients, we also will screen patients on a separate patient list obtained from **Geisinger's Phenomics and Clinical Data Core** (PACDC). These patients meet the following criteria:

1. Had had a primary care encounter at Geisinger (outpatient or telemedicine) between 10/1/2008 and 4/13/2022.
2. Were born in the year 2004 or later (i.e., those turning 18 in the year 2022 and older)
3. Were alive according to the EHR as of April 2022 when the dataset was last updated
4. Either:
    a. Currently have a Geisinger PCP assigned
    b. Have been in the EHR since at least September 2021 AND have had at least one encounter in 2020–2022

Based on retrospective data, the majority of patients who are on the CMSL/Marketing list will also be on the PACDC list. However, we plan to include patients who were on the CMSL/Marketing list but who were not on the PACDC list so that all eligible patients on the CMSL/Marketing list are sent a follow-up message (unless they are assigned to the passive control arm).

After we obtain the base sample lists from PACDC and CMSL/Marketing, **Business Intelligence & Advanced Analytics** (BIAA), working with PACDC, will pull a dataset to help us determine who meets our inclusion criteria and aid in NIH demographics reporting. This dataset will include demographic information, including patient birth date, race, ethnicity, and gender and/or sex. Finally, the dataset will include death date to ensure patients are living as of the date the data are extracted.

After the intervention is complete, we will obtain experimental outcome data for all population groups from BIAA & PACDC. This will include data on patient flu vaccination, diagnosis of flu, diagnosis of flu-like symptoms, presence of flu-associated complications, hospital visits, emergency department visits, and COVID-19 vaccination status. This dataset will additionally include patient characteristics that can serve as analysis covariates, such as: patient primary care provider and flu-related behavior and outcomes during previous flu seasons.

We may also request claims data from the Geisinger Health Plan (GHP; e.g., for claims related to flu vaccination, diagnosis, and complications). GHP claims data will be pulled by BIAA or the GHP data team (pending approval from Research Contracts).

STUDY DATA DETAILS

Data Management Procedures and Confidentiality

The complete, identified study data will be accessed only by a Geisinger data broker and by limited Geisinger investigators with appropriate training and a legitimate need to know (i.e., Geisinger Co-Is and PIs), and any appropriately trained Geisinger staff, (e.g., clinicians, data analysts) who have a need to review the data for purposes of their normal Geisinger role.

A limited dataset containing dates of service and ZIP codes may be shared with any non-Geisinger collaborators (e.g., Joseph Doyle and his team) under a Data Use Agreement (pending approval) in compliance with HIPAA's Privacy Rule and using data security protocols reviewed and approved by the Geisinger Security Office, Privacy Office, and Information Technology department.

All data will be electronic. Datasets with full identifying information will only be stored on Geisinger-managed, password-protected computers of the data brokers for the purpose of linking datasets from different sources.

Identifiable data gathered for this study will be retained for at least 3 years, as required by NIH policy, and will be deleted after 3 years or after analysis is complete. After the data have been fully analyzed, the deidentified dataset will be shared along with publications from this study. The deidentified data will not be destroyed or removed after any prespecified period of time has elapsed. We intend to permanently and securely archive the deidentified dataset at a research repository such as Open Science Framework (OSF) in order to be consistent with the best practices for open and reproducible science, as well as our obligation to the public as NIA-funded researchers.

All data analysis will be conducted by Gail Rosenbaum, Henri Santos, Amir Goren, or limited other Geisinger investigators with appropriate training, and our non-Geisinger Collaborators. We will analyze the data using standard behavioral research analysis methods, including computing bivariate correlations, using generalized linear models, using non-parametric models for non-normally distributed data, and entering variables as independent predictors in regression models to attempt to predict desired outcomes.

RESEARCH ACTIVITIES AT OTHER SITES

Geisinger is the lead research team for this multi-site study. Massachusetts Institute of Technology (MIT) and National Bureau of Economic Research (NBER) study personnel are considered not considered engaged in human subject research. Research activities conducted at MIT and NBER will be limited to data analysis, using limited data, as described above. MIT and NBER will not be involved in study recruitment/enrollment or intervention administration.

References

Centers for Disease Control and Prevention. (2019). Who needs a flu vaccine and when.

https://www.cdc.gov/flu/prevent/vaccinations.htm (Oct 11).
Centers for Disease Control and Prevention. (2020). Disease Burden of Influenza. https://www.cdc.gov/flu/ about/burden/index.html (Jan 10).
Milkman, K. L., Patel, M. S., Gandhi, L., Graci, H. N., Gromet, D., Ho, H., … Duckworth, A. L. (2021). A Mega-Study of Text-Based Nudges Encouraging Patients to Get Vaccinated at An Upcoming Doctor's Appointment. Available at SSRN: https://ssrn.com/abstract=3780267
Rosenbaum, G.M., Shermohammed, M., Goren, A., Lanyado, A., Metzger, C., Yesharim, R., Wolk, D.M., Doyle, J., Meyer, M.N., & Chabris, C.F. (2021). Effects of AI-determined high-risk warnings on flu vaccination rates: Two field experiments. Presented at the *11th Behavioral Science and Health Symposium*, University of Pennsylvania, Philadelphia, 1–2 December.
Shermohammed, M., Goren, A., Lanyado, A., Yesharim, R., Wolk, D. M., Doyle, J., *Meyer, M. N., & *Chabris, C. F. (2021). Informing patients that they are at high risk for serious complications of viral infection increases vaccination rates. *MedRxiv*. https://doi.org/10.1101/2021.02.20.21252015
Tokars, J.I., Olsen, S.J., & Reed, C. (2018). Seasonal incidence of symptomatic influenza in the United States. *Clinical Infectious Diseases, 66,* 1511–1518. PMID: 29206909