

Study Title: Improving Influenza Vaccination Delivery Across a Health System by the Electronic Health Records Patient Portal RCT 4

Initial IRB Approval: 12/20/2017

RCT 4 IRB Approval: 10/18/2021

Clinical Trials Registration: NCT05052190

-Terminated early-

Protocol

Brief Summary:

This trial is taking place in Los Angeles, CA among patients from primary care practices within the UCLA Health System.

Despite the Advisory Committee on Immunization Practices (ACIP) recommendation in 2010 that all people above 6 months of age should receive an annual flu vaccine, vaccination rates remain low. The investigators plan to assess the effectiveness of text and portal reminder/recall messages with direct appointment scheduling (pre-appointment, and no pre-appointment) encouraging influenza vaccinations sent to patient portal users using a 2 x 2 nested factorial design.

Methods and Procedures

Sub-optimal vaccination rates are a significant problem in the U.S., despite their effectiveness in preventing morbidity and mortality from vaccine-preventable illness. For influenza specifically, annual epidemics of influenza cause substantial morbidity in the U.S. with up to 40,00-80,000 deaths/year and many hospitalizations, emergency and outpatient visits, and significant costs.

Reminder/recall (R/R), sent by phone, mail or other modality, can improve child and adult influenza vaccination rates. However, the majority of pediatric or adult primary care practices do not conduct R/R. Barriers are lack of finances, personnel, and algorithms to identify eligible patients.

A technological breakthrough that might overcome these barriers involves patient portals--secure, web-based communication systems, embedded within electronic health records (EHRs), for patients and providers to communicate with each other via email and the internet. Portals are used by about half of Americans and half of UCLA patients. Another is text messaging at the health system level.

This randomized controlled trial will assess the effectiveness of reminders messages sent to portal users, encouraging influenza vaccination, on increasing influenza vaccination rates within a health system. Patients will be randomized into three groups: 1) one-third of patients will receive reminder letters via the portal, 2) one-third will receive reminders via text messages sent by the health system and 3) one-third will not receive reminders.

Patients in the reminder arms will be further randomized (separately) for two additional components: 1) direct appointment scheduling and 2) pre-appointment reminders.

Direct scheduling: The convenience of scheduling an appointment for influenza vaccination may increase the likelihood that patients receive an influenza vaccination. Patients receiving reminders will be randomized to receive one of two types of reminder letters: 1) one half will

receive flu vaccine reminder letters with a link to the MyChart direct appointment scheduling page and 2) one half will receive flu vaccine reminder message without the direct appointment scheduling link.

Pre-appointment flu reminders: Finally, a missed opportunities for vaccination occurs when patients are eligible for vaccination but are not offered a vaccine at their medical appointment. Pre-appointment reminders, sent in advance of an upcoming appointment, encouraging the patient talk to their doctor about influenza vaccination, may increase the likelihood of that patient receiving a vaccine. Patients will be randomized to one of two groups: 1) one half will receive modified pre-appointment reminders that mention influenza vaccination and 2) one half will receive the standard pre-appointment reminders for an upcoming appointment (no mention of influenza vaccination).

Interventions that apply Behavioral Economics principles in vaccine promotion messaging can increase vaccine receipt. We will include ownership language in the pre-appointment messages. Additionally, the convenience of reminders sent via text and with a Direct Appointment Schedule link included enables patients to self-schedule a flu vaccine only visit, reducing friction for vaccine receipt.

For the primary analysis, the primary outcome will be the patient's end of flu season vaccination status. Intervention effects will be assessed using mixed effects log-binomial models. Models will contain terms for messaging modality (text v. portal v. none), pre-appointment reminders (sent v. not sent), and direct scheduling link (included v. not included).

The R/R text and portal messages (with and without direct scheduling links) and pre-appointment reminders and will all begin in October of 2021. Languages: messages will be in English.

Health Literacy: We will use plain language <7th grade reading level per Flesch-Kincaid analysis.

Eligibility: Our EHR will identify subjects who are eligible for either 1 or 2 influenza vaccinations based on ACIP algorithms (2 are recommended for children <9 years who have not had prior vaccination).

Inclusion criteria

Inclusion criteria will involve-- all UCLA primary care patients over 4 months of age who have made at least 1 visit to the practice within the prior 3 years and who have signed up for MyUCLAhealth (UCLA's portal) and have used the portal at least once within 12 months, from these patients, index patients per household will be randomly selected.

a. Active patient: We selected >1 visit in 3y based on our prior studies and the literature to focus the intervention on active patients; practices do not have a good mechanism to inactivate patients.

b. Focusing on Portal Users: We can only send portal R/R messages to patients who have signed up for the portal. Since some patients sign up for the portal but never use it we will restrict our inclusion criteria to patients who used the portal within 12m (75% of UCLA patients). This standard has been applied before. We will assess intervention effects for the included population, and also for the entire practice, since the impact of the intervention reflects the extent of portal penetration.

Exclusion criteria

Patients will be excluded if they are not a patient at one of the 67 primary care practices within UCLA's Health System, and/or if they do not meet the above specified requirements for being an active patient or portal user.

Main Outcomes and Measures

Primary Measures:

- 1) Receipt of >1 influenza vaccine among index patients between 9/1/2022-4/1/2023 as documented in the EHR which is supplemented electronically by the health system with influenza vaccination data from external sources (e.g., pharmacies) and claims data.
- 2) Receipt of >1 influenza vaccine among pediatric index patients between 9/1/2022-4/1/2023 as documented in the EHR which is supplemented electronically by the health system with influenza vaccination data from external sources (e.g., pharmacies) and claims data.

Secondary Measures: Receipt of annual influenza vaccine between 10/14/2021-4/1/2022 among all included patients in identified households.

Arms	Assigned Interventions
Active Comparator: Text Message R/R with Direct Appointment Schedule Link Participants in this arm will receive up to 3 R/R messages by text. R/R message will be sent with a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment.	Behavioral: Text Message R/R with Direct Appointment Schedule Link Participants in this arm will receive up to 3 R/R messages by text reminding them to get a flu vaccine with a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment.
Active Comparator: Text Message R/R without Direct Appointment Schedule Link	Behavioral: Text Message R/R without Direct Appointment Schedule Link

<p>Participants in this arm will receive up to 3 R/R messages by text with no link to schedule an appointment.</p>	<p>Participants in this arm will receive up to 3 R/R messages by text reminding them to get a flu vaccine without a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment.</p>
<p>Active Comparator: Text Message R/R with Direct Appointment Schedule Link + text Pre-Appointment Reminder</p> <p>Participants in this arm will receive up to 3 R/R messages by text. R/R message will be sent with a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment. Participants will receive a Pre-Appointment Reminder via text when they schedule a visit during the study period.</p>	<p>Behavioral: Text Message R/R with Direct Appointment Schedule Link</p> <p>Participants in this arm will receive up to 3 R/R messages by text reminding them to get a flu vaccine with a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment.</p> <p>Behavioral: Text Pre-Appointment Reminder</p> <p>Participants will receive a Pre-Appointment Reminder via text when they schedule a visit during the study period advising them to get the flu vaccine at their upcoming appointment.</p>
<p>Active Comparator: Text Message R/R without Direct Appointment Schedule Link + Text Pre-Appointment Reminder</p> <p>Participants in this arm will receive up to 3 R/R messages by text. R/R message will be sent without a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment. Participants will receive a Pre-Appointment Reminder via text when they schedule a visit during the study period.</p>	<p>Behavioral: Text Message R/R without Direct Appointment Schedule Link</p> <p>Participants in this arm will receive up to 3 R/R messages by text reminding them to get a flu vaccine without a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment.</p> <p>Behavioral: Text Pre-Appointment Reminder</p> <p>Participants will receive a Pre-Appointment Reminder via text when they schedule a visit during the study period advising them to get the flu vaccine at their upcoming appointment.</p>

<p>Active Comparator: Portal Message R/R with Direct Appointment Schedule Link</p> <p>Participants in this arm will receive up to 3 R/R messages by portal. R/R message will be sent with a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment.</p>	<p>Behavioral: Portal Message R/R with Direct Appointment Schedule Link</p> <p>Participants in this arm will receive up to 3 R/R messages by portal. R/R message will be sent with a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment.</p>
<p>Active Comparator: Portal Message R/R without Direct Appointment Schedule Link</p> <p>Participants in this arm will receive up to 3 R/R messages by portal. R/R message will be sent without a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment.</p>	<p>Behavioral: Portal Message R/R without Direct Appointment Schedule Link</p> <p>Participants in this arm will receive up to 3 R/R messages by portal. R/R message will be sent without a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment.</p>
<p>Active Comparator: Portal Message R/R with Direct Appointment Schedule Link + Portal Pre-Appointment Reminder</p> <p>Participants in this arm will receive up to 3 R/R messages by portal. R/R message will be sent with a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment. Participants will receive a Pre-Appointment Reminder advising them to ask their doctor for the flu vaccine at their upcoming appointment via portal when they schedule a visit during the study period.</p>	<p>Behavioral: Portal Message R/R with Direct Appointment Schedule Link</p> <p>Participants in this arm will receive up to 3 R/R messages by portal. R/R message will be sent with a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment.</p> <p>Behavioral: Portal Pre-Appointment Reminder</p> <p>Participants will receive a Pre-Appointment Reminder via the portal advising them to ask their doctor for the flu vaccine at their upcoming appointment via text when they schedule a visit during the study period.</p>
<p>Active Comparator: Portal Message R/R without Direct Appointment Schedule Link + Portal Pre-Appointment Reminder</p> <p>Participants in this arm will receive up to 3 R/R messages by portal. R/R message</p>	<p>Behavioral: Portal Message R/R without Direct Appointment Schedule Link</p> <p>Participants in this arm will receive up to 3 R/R messages by portal. R/R message will be sent without a Direct Appointment Scheduling link and</p>

<p>will be sent without a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment. Participants will receive a Pre-Appointment Reminder advising them to ask their doctor for the flu vaccine at their upcoming appointment via portal when they schedule a visit during the study period.</p>	<p>instructions to make a flu vaccine appointment.</p> <p>Behavioral: Portal Pre-Appointment Reminder</p> <p>Participants will receive a Pre-Appointment Reminder via the portal advising them to ask their doctor for the flu vaccine at their upcoming appointment via text when they schedule a visit during the study period.</p>
<p>No Intervention: No R/R Message or Pre-Appointment Reminder</p> <p>Participants do not receive any flu vaccine R/R message or Pre-Appointment Reminder advising them to ask their doctor for the flu vaccine at their upcoming appointment during the specified flu season.</p>	