

Study Title: Improving Influenza Vaccination Delivery Across a Health System by the Electronic Health Records Patient Portal RCT 5

Initial IRB Approval: 12/20/2017

RCT 5 IRB Approval: 8/18/2022

Clinical Trials Registration: NCT05525494

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, as well as the effectiveness of tailored portal reminder/recall messages based on responses from pre-commitment prompt asking which time and which place they plan to receive their influenza vaccine using a 2 x 2 nested factorial design.

Methods and Procedures

We propose a three-arm randomized controlled trial, and a 2 x 2 nested factorial design within the intervention arms. Patients are randomized within UCLA primary care practices into 1) receiving text based R/R messages with direct scheduling link, 2) portal-based R/R messages with direct scheduling link, or 3) the control group. Patients randomized to the intervention arms will receive reminders if they are due for influenza vaccine.

Nested within the portal reminder arm, we will have two additional components for which patients will be randomized separately: 1) A pre-commitment prompt, asking patients which time (September, October, November or December) and which place (UCLA, pharmacy, workplace or school, or other) they plan to get their Influenza vaccine with tailored monthly messages based on responses (pre-commitment message with tailored recall messages with direct scheduling vs. standard (“fixed”) portal reminders with direct scheduling); 2) A pre-appointment reminder encouraging patients to ask for their influenza vaccine at their upcoming appointment (pre-appointment reminder encouraging influenza vaccination vs. standard pre-appointment reminder not mentioning influenza vaccination)

Nested within the text message reminder arm, we will have one additional component for which patients will be randomized separately: 1) A pre-appointment reminder encouraging patients to ask for their influenza vaccine at their upcoming appointment (pre-appointment reminder encouraging influenza vaccination vs. standard pre-appointment reminder not mentioning influenza vaccination).

Spacing of R/R messages: The pre-commitment prompt will be sent in September, direct appointment scheduling and no direct appointment scheduling reminders will be sent one time per month until record of vaccine receipt appears in the patient EHR in October, November, and December. The pre-appointment reminders will be sent 2-4 days in advance of scheduled visits.

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 9/1/2022-4/1/2023 among all included patients in identified households.

Study Arm	Intervention/Treatment
<p>Active Comparator: Text Fixed R/R Messages with Direct Appointment Schedule Link + Text Pre-Appointment Reminders</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 Fixed R/R Messages with Direct Appointment Schedule Link</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.</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.</p>
<p>Active Comparator: Text Fixed R/R Messages with Direct Appointment Schedule Link</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.</p>	<p>Behavioral: Text Fixed R/R Messages with Direct Appointment Schedule Link</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.</p>
<p>Active Comparator: Portal Pre-Commitment Prompt, Tailored R/R Messages w/ Direct Scheduling + Pre-Appointment Reminders</p> <p>Participants in this arm will receive a pre-commitment prompt message by portal in September. Tailored R/R messages will be sent monthly by portal based on time and place selected by patients (up to 3). R/R message will be sent with a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment.</p> <p>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 Pre-Commitment Prompt with Tailored R/R Messages with Direct Appointment Schedule Link</p> <p>Participants in this arm will receive a pre-commitment prompt message by portal in September. Tailored R/R messages will be sent monthly by portal based on time and place selected by patients (up to 3). 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 advising them to ask their doctor for the flu vaccine at their upcoming appointment</p>

	via portal when they schedule a visit during the study period.
Active Comparator: Portal Pre-Commitment Prompt with Tailored R/R Messages with Direct Appointment Schedule Link Participants in this arm will receive a pre-commitment prompt message by portal in September. Tailored R/R messages will be sent monthly based on time and place selected by patients (up to 3). R/R message will be sent with a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment.	Behavioral: Portal Pre-Commitment Prompt with Tailored R/R Messages with Direct Appointment Schedule Link Participants in this arm will receive a pre-commitment prompt message by portal in September. Tailored R/R messages will be sent monthly by portal based on time and place selected by patients (up to 3). R/R message will be sent with a Direct Appointment Scheduling link and instructions to make a flu vaccine appointment.
Active Comparator: Portal Fixed R/R Messages with Direct Appointment Schedule Link + Portal Pre-Appointment Reminder 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.	Behavioral: Portal Fixed R/R Messages with Direct Appointment Schedule Link 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. Behavioral: Portal Pre-Appointment Reminder 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.
Active Comparator: Portal Fixed R/R Messages with Direct Appointment Schedule Link 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.	Behavioral: Portal Fixed R/R Messages with Direct Appointment Schedule Link 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.
No Intervention: No R/R Message or Pre-Appointment Reminder	

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.