Study Title: Patient Portal Reminder/Recall for Influenza Vaccination in a Health System- RCT 3
Initial IRB Approval: 12/20/2017
RCT 3 IRB Approval: 8/14/2020
Clinical Trials Registration: NCT04533685

### 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 reminder/recall messages (direct appointment scheduling, no direct-appointment scheduling, pre-appointment, and no pre-appointment) encouraging influenza vaccinations sent to patient portal users, as well as the effectiveness of a pre-commitment prompt (pre-commitment prompt, no prompt) asking about a patient's intention to get the influenza vaccination, using a 2 x 2 x 2 nested factorial design.

### **Methods and Procedures**

We propose a two-arm randomized controlled trial, and a 2 x 2 x 2 nested factorial design within the treatment arm. Patients are randomized within UCLA primary care practices to intervention arms sent via the portal or a control group. Study arms: 1) standard of care control (no reminder messages, no pre-commitment prompt, except for UCLA employees sent a reminder), 2) direct appointment scheduling reminder, pre-appointment reminder, pre-commitment prompt, 3) direct appointment scheduling reminder, pre-appointment reminder, no pre-commitment prompt, 4) direct appointment scheduling reminder, no pre-appointment reminder, no pre-appointment reminder, no pre-appointment prompt, 5) direct appointment scheduling reminder, no pre-appointment reminder, no pre-commitment prompt 6) No direct appointment scheduling reminder, pre-appointment scheduling reminder, no pre-appointment reminder, pre-appointment reminder, no pre-commitment prompt, 7) No direct appointment scheduling reminder, pre-appointment scheduling reminder, no pre-commitment prompt, 8) No direct appointment scheduling reminder, no pre-commitment prompt, 9) No direct appointment scheduling reminder, no pre-commitment prompt, 9) No direct appointment scheduling reminder, no pre-commitment prompt, 9) No direct appointment scheduling reminder, no pre-commitment prompt, 9) No direct appointment scheduling reminder, no pre-commitment prompt, 9) No direct appointment scheduling reminder, no pre-commitment reminder, no pre-commitment prompt, 9) No direct appointment scheduling reminder, no pre-commitment reminder, no pre-commitment reminder, no pre-commitment prompt, 9)

Study Arm	Intervention/Treatment
No Intervention: Standard of care control	NA
No direct-scheduling or pre-appointment	
portal reminders + No pre-commitment	
prompt	
Participants do not receive any	
reminder/recall messages regarding influenza	
vaccination via the patient portal and do not	
receive a pre-commitment prompt asking if	
they plan to receive the influenza vaccine in	
the upcoming season	

Experimental: Direct appointment scheduling reminder + Pre-appointment reminder + Pre- commitment prompt Participants receive 1) reminder/recall messages regarding influenza vaccination via the patient portal with a link enabling direct scheduling, 2) a pre-appointment reminder that mention asking the provider for a flu vaccine, and 3) a pre-commitment prompt asking if they plan to receive the influenza vaccine in the upcoming season.	<ul> <li>Behavioral: Portal Reminders for Influenza</li> <li>Vaccination: Direct scheduling link: Patients</li> <li>receive reminder/recall messages via the</li> <li>patient portal to get an influenza vaccination</li> <li>that include a direct scheduling link, enabling</li> <li>the patient to directly schedule a flu vaccination</li> <li>only visit.</li> <li>Behavioral: Pre-Appointment influenza</li> <li>vaccination reminder: Patients receive modified</li> <li>pre-appointment reminders for upcoming</li> <li>scheduled appointments that include language</li> <li>encouraging patients to ask the provider for the</li> <li>flu vaccine.</li> <li>Behavioral: Pre-commitment prompt</li> <li>Patients receive a pre-commitment prompt</li> <li>asking about their intention to get an influenza</li> <li>vaccination.</li> </ul>
Experimental: Direct appointment scheduling reminder + Pre-appointment reminder + No pre-commitment prompt Participants 1) reminder/recall messages regarding influenza vaccination via the patient portal with a link enabling direct	Behavioral: Portal Reminders for Influenza Vaccination: Direct scheduling link: Patients receive reminder/recall messages via the patient portal to get an influenza vaccination that include a direct scheduling link, enabling the patient to directly schedule a flu vaccination only visit.
scheduling, and 2) a pre-appointment reminder that mention asking the provider for a flu vaccine, but do not receive a pre- commitment prompt asking if they plan to receive the influenza vaccine in the upcoming season.	Behavioral: Pre-Appointment influenza vaccination reminder: Patients receive modified pre-appointment reminders for upcoming scheduled appointments that include language encouraging patients to ask the provider for the flu vaccine.
Experimental: Direct appointment scheduling reminder + No pre-appointment reminder + Pre-commitment prompt Participants receive 1) reminder/recall messages regarding influenza vaccination via the patient portal with a link enabling direct	Behavioral: Portal Reminders for Influenza Vaccination: Direct scheduling link: Patients receive reminder/recall messages via the patient portal to get an influenza vaccination that include a direct scheduling link, enabling the patient to directly schedule a flu vaccination only visit.
scheduling, and 2) a pre-commitment prompt asking if they plan to receive the influenza vaccine in the upcoming season, but do not	Behavioral: Pre-commitment prompt

receive a pre-appointment reminder that	Patients receive a pre-commitment prompt
mention asking the provider for a flu vaccine.	asking about their intention to get an influenza
Experimental: Direct appointment scheduling	vaccination
reminder + No pre-appointment reminder +	Behavioral: Portal Reminders for Influenza
No pre-commitment prompt	Vaccination: Direct scheduling link: Patients
Participants receive 1) reminder/recall	receive reminder/recall messages via the
messages regarding influenza vaccination via	patient portal to get an influenza vaccination
the patient portal with a link enabling direct	that include a direct scheduling link, enabling
scheduling, but do not receive a pre-	the patient to directly schedule a flu vaccination
appointment reminder that mention asking	only visit.
the provider for a flu vaccine, or a pre- commitment prompt asking if they plan to receive the influenza vaccine in the upcoming season.	
Experimental: No direct appointment	Behavioral: Portal Reminders for Influenza
scheduling reminder + Pre-appointment	Vaccination: No direct scheduling link: Patients
reminder + Pre-commitment prompt	receive reminder/recall messages via the
Participants receive 1) reminder/recall	patient portal to get an influenza vaccination
messages regarding influenza vaccination via	(no direct scheduling link included).
the patient portal without a link enabling	Behavioral: Pre-Appointment influenza
direct scheduling, 2) a pre-appointment	vaccination reminder: Patients receive modified
reminder that mentions asking the provider	pre-appointment reminders for upcoming
for a flu vaccine, and 3) a pre-commitment	scheduled appointments that include language
prompt asking if they plan to receive the	encouraging patients to ask the provider for the
influenza vaccine in the upcoming season.	flu vaccine.
	Behavioral: Pre-commitment prompt Patients receive a pre-commitment prompt asking about their intention to get an influenza vaccination
Experimental: No direct appointment scheduling reminder + Pre-appointment reminder + No pre-commitment prompt	Behavioral: Portal Reminders for Influenza Vaccination: No direct scheduling link: Patients receive reminder/recall messages via the patient portal to get an influenza vaccination
Participants receive 1) reminder/recall	(no direct scheduling link included).
messages regarding influenza vaccination via	Behavioral: Pre-Appointment influenza
the patient portal without a link enabling	vaccination reminder: Patients receive modified
direct scheduling, and 2 a pre-appointment	pre-appointment reminders for upcoming
reminder that mentions asking the provider	scheduled appointments that include language
for a flu vaccine, but do not receive a pre-	encouraging patients to ask the provider for the
commitment prompt asking if they plan to	flu vaccine.

· · · · · · · · · · · · · · · · · · ·	
receive the influenza vaccine in the upcoming	
season.	
Experimental: No direct appointment	Behavioral: Portal Reminders for Influenza
scheduling reminder + No pre-appointment	Vaccination: No direct scheduling link: Patients
reminder + Pre-commitment prompt	receive reminder/recall messages via the
	patient portal to get an influenza vaccination
Participants receive 1) reminder/recall	(no direct scheduling link included).
messages regarding influenza vaccination via	
the patient portal without a link enabling	Behavioral: Pre-commitment prompt
direct scheduling, and 2)a pre-commitment	Patients receive a pre-commitment prompt
prompt asking if they plan to receive the	asking about their intention to get an influenza
influenza vaccine in the upcoming season,	vaccination
but do not receive a pre-appointment	
reminder that mentions asking the provider	
for a flu vaccine.	
Experimental: No direct appointment	Behavioral: Portal Reminders for Influenza
scheduling reminder + No pre-appointment	Vaccination: No direct scheduling link: Patients
reminder + No Pre-commitment prompt	receive reminder/recall messages via the
	patient portal to get an influenza vaccination
Participants receive 1) reminder/recall	(no direct scheduling link included).
messages regarding influenza vaccination via	
the patient portal without a link enabling	
direct scheduling, but do not a pre-	
appointment reminder that mentions asking	
the provider for a flu vaccine, or a pre-	
commitment prompt asking if they plan to	
receive the influenza vaccine in the upcoming	
season.	

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. Currently this includes 298,112 patients; 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 Measure: Receipt of >1 influenza vaccine among index patients between 10/1/2020-03/31/2021 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 10/1/2020-03/31/2021 among all included patients in identified households.