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

Initial IRB Approval: 12/20/2017

RCT 5 (LADHS) IRB Approval: 8/29/2022

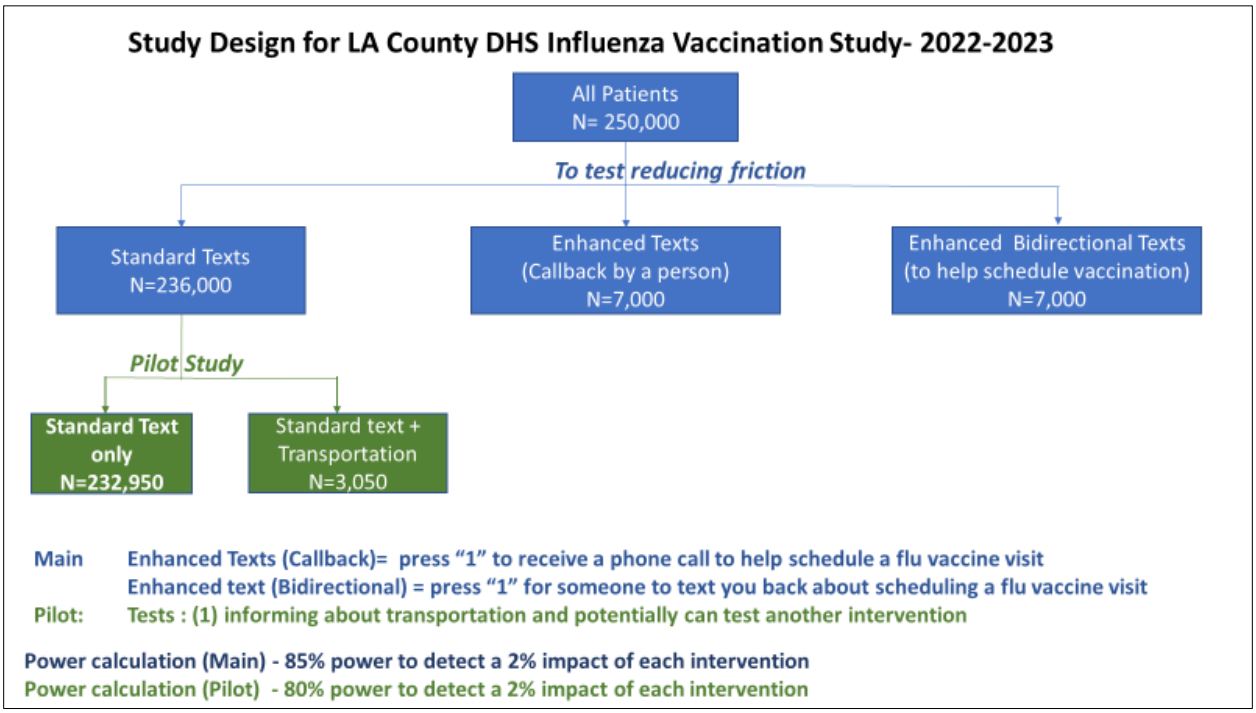
Clinical Trials Registration: NCT05535777

Significance:
Previous studies have shown that low-cost, behavioral nudges through texting can increase influenza vaccination uptake compared to usual care. However, there are limited studies that evaluate the effect of decreasing friction/barriers to scheduling especially within safety net populations. This study will examine the effect of strategies to reduce friction/barriers to scheduling including bidirectional text messages, texts for patients to call for direct scheduling without wait time, and texts highlighting MediCal health plan transportation resources on influenza vaccination rates in adults within the 2022-2023 flu season.

Objectives:
This will be a randomized clinical trial (RCT) to test the impact of text message innovations on receipt of influenza vaccination during the 2022-23 season. Specifically, we will simultaneously test, using a comparative effectiveness trial design, the effect of the following 3 interventions, all compared to standard text messages:

- Enhanced texting (with a callback by a trained call-center staff member to schedule a vaccine visit if the patient presses "1" in response to the text
- Enhanced Bidirectional texting- with a texting response from a trained call-center staff member who will help the patient schedule a vaccine visit through a series of back-and-forth texts
- Provision of transportation information- with information within the text messages that highlight to patients that MediCal will pay for transportation to a vaccine visit

Study Design:
The study design is shown in this figure. Intervention arms are described below.



We will send the total patient population of around 250,000 one of several types of text message reminders.

Selection of Patients:

Patient eligibility: Any patient who is deemed by LADHS to be an LADHS patient will become the patient denominator. Primary care patients who are empaneled to a primary care provider within DHS are assigned as follows: (1) assigned through managed care plans, (2) self-pay but linked with a provider, or (3) uninsured but assigned. We will include all patients over 6 months of age.

Identification of families (i.e., households): We will group families using one of two possible methods. First, LADHS has an identifier that ties family members together. It is called the "Family Budget Unit." We will explore this method. If it does not work, we will use another method that we have utilized successfully in the UCLA-based study from which this study is derived. We will assume that people living in the same address belong to the same family. As a secondary measure, we use a telephone number as a linking number (i.e., if two people have the same telephone number, we assume they are from the same household).

We will randomly allocate families to one of the study arms shown above and send family members the allocated text message. All family members will therefore receive the same text message. This is meant to reduce confusion among patients. For the analysis, we will randomly select one index patient per household for analysis. This follows Cochrane criteria for being included in meta-analyses. We will attempt to affiliate index patients with practices, and randomize patients (families) within these practices.

Assignment to the intervention: All patients will be eligible for the intervention. There are no specific inclusion or exclusion criteria. Since we will send up to 3 text messages in October-December 2022, we will search the EHR for whether or not the patient received an influenza vaccination this season. If yes, the patients will be dropped form the denominator of patients needing a text message reminder. We will search the EHR prior to each of the text message rounds.

Review of medical records is needed in order to obtain the information about (a) influenza vaccination dates this upcoming season, and (b) address (in order to group patients into households as described above. We will review the EHR prior to each round of text messages to see if patients had received an influenza this season.

Description of the Interventions:
Text messages will begin to be sent in early October. We will randomly spread out the calls throughout the day and week in order to minimize unnecessary overload for the call center when patients text back a "1" response that they would like a call or text message to help them. We can do this by randomizing patients into batches so that there is no systematic time-of-day or day-of-week for any patients. We will send up to 3 reminders this upcoming season.

Standard Texts (n=232,950): Patient randomized to this study arm will receive up to 3 text messages, reminding them about the importance of influenza vaccination. The messages themselves are shown below. The standard texts will include a clinic call back number and patient portal self-scheduling for patients to schedule their influenza vaccines. The direct scheduling texts includes a direct number to an agent that can help schedule and answer questions on the phone in real time. The texts with a direct number to schedule will link a specified phone number to call and schedule. This number would be answered by a central agent quickly and a patient could schedule their flu shot at any clinic site. This specific phone number would not go through the multiple option menus a patient would normally experience when calling their clinic.

Standard Texts with Transportation (n=3,050): The standard texts with transportation includes phone number for patients to reserve transportation to a vaccination appointment based on MediCal health plan transportation resources.

Enhanced Texts- Callback by a person (n=7,000): Patient randomized to this study arm will receive a phone call back by a call center agent if they press "1" in response to a question on the original text message. The call center agent's job is to schedule patients for clinical visits. These call center agents will be trained by our faculty and staff and will have the usual HIPAA and other patient confidentiality training.

Enhanced Bidirectional Texts- to help schedule a vaccine visit (n=7,000): Patients randomized to this study arm will receive a text message from a call center agent if they press "1" in response to a question on the original text message. The bidirectional texts will have an agent who can answer questions and schedule an appointment through text message back-and-forth conversations with the patient. Bidirectional texts will be exchanged on a HIPAA compliant bidirectional text messaging platform. The patient will use the regular SMS function on their cellphone and the agent will receive and respond to the bidirectional text on the HIPAA compliant platform.

Text Message Wording:
The wording of each of the text messages is shown in the figure below. We will have these translated into Spanish. LADHS patients have the option of receiving text messages in English or Spanish.

Prepped Text Messages for DHS Flu Campaign 2022 - 2023

Standard Text:
#PCMH#: #FirstName#, your flu shot is ready! Call your clinic at #ExternalRefNo# or visit the LA Health Portal at http://bit.ly/BookFluShot if you want this shot held for you.

Standard Texts (+ Transportation)
#PCMH#: #FirstName#, your flu shot is ready! Call your clinic at #ExternalRefNo# or visit the LA Health Portal at http://bit.ly/BookFluShot if you want this shot held for you. You can call #Health Plan Phone Number# to schedule a free ride your flu shot through #Health Plan Name#

Examples (Transportation)

- **Standard Texts (+ Transportation) - LA Care**
  #PCMH#: #FirstName#, your flu shot is ready! Call your clinic at #ExternalRefNo# or visit the LA Health Portal at http://bit.ly/BookFluShot if you want this shot held for you. You can call 888-839-9909 to schedule a free ride for your flu shot through your LA Care health plan.
- **Standard Texts (+ Transportation) - Health Net**
  #PCMH#: #FirstName#, your flu shot is ready! Call your clinic at #ExternalRefNo# or visit the LA Health Portal at http://bit.ly/BookFluShot if you want this shot held for you can call 855-253-6863 to schedule a free ride for your flu shot through your Health Net health plan.

Enhanced Prompt for Phone Scheduling:
#PCMH#: #FirstName#, your flu is ready! Call our direct number xxx-xxx-xxxx to connect with an agent to hold this flu shot and schedule an appointment now.

Bidirectional Texts:
#PCMH#: #FirstName#, your flu shot is ready! Reply Y if you want this shot held for you and an agent will text you back to schedule an appointment.

For more details, please see:
https://docs.google.com/document/d/12ERynaBMjzpIpjcPJDoBCu-8GA7cVBbYV8zko3mCBnM/edit

And a brief here:

https://docs.google.com/document/d/1Au5l7zjVqJSpQzi5NF7YvLR07mmyaMlz89dpDHWOob8/edit

Data Management:
All study data, including CAIR2 data and DHS EMR and administrative data will be prepared by the DHS-CTSI Informatics Core in accordance with the DHS Research Oversight Board policy. Dr. Abhat will submit all data requests to the DHS helpdesk, which includes verification of procedural compliance with IRB and ROB approval screening for DHS-based research. Only HIPAA-limited or deidentified data sets will be transferred for analysis purposes; compliance with the DHS secure data transfer process to UCLA and/or USC will be managed by Dr. Abhat as DHS Principal Investigator. Any links between identified data and deidentified data will be stored only on DHS premises. Patient contact lists and personalized data elements will be exclusively maintained on premises by the Informatics Core, responsible for implementing the patient assignment and personalization templates.

*Statistical Analysis of Randomized Trial***.** We will perform separate evaluations of the impact of the text enhancements (callback and bidirectional texting) on the one hand, and transportation messaging on the other hand. For both analyses, we will use multivariable log-binomial regression models with vaccination status at the end of the campaign as the outcome variable. Regressions will include indicators for each intervention as fixed effects, with the standard text condition as the reference group, and potentially clinic random effects, depending on retrospective analysis results. Models will also adjust for patient age, gender, race/ethnicity, insurance, and whether the patient was vaccinated in at least one of the prior two flu seasons. Secondary analysis will include subgroup interactions with intervention indicators to assess heterogeneity of treatment effects. In exploratory analyses, we will investigate interactions between interventions, questions related to modality of message delivery, as well as whether encounter type, click rates on messages, and distance to the health care facility from the home address affect influenza vaccination rates.

In addition, we will evaluate the loss to follow-through rates (scheduling an appointment, but did not complete the appointment) by patient demographics, as distance to the health care facility from the home address).

For the evaluation of text enhancements, we will perform a 3-fold Bonferroni correction accounting for pairwise comparison of intervention arms, using a two-sided significance level of 0.017. For the evaluation of transportation messaging, we will use a two-sided significance level of 0.05. All analyses will be intention-to-treat, and will be performed using SAS v. 9.4 (SAS Institute Inc., Cary, NC).