

Study Title: Community-Academic Partnership to Address COVID-19 Among Utah Community Health Centers

NCT Number: 04939532

Document Date: February 23, 2022

SCALE-UP Utah is a patient level Population Health Management study. The intervention uses CHC patient records to proactively reach patients for COVID-19 screening and testing. This PHM intervention includes a randomization component between two interventions, text messaging (TM) or text messaging with patient navigations (TM+PN).

This study involves 7 Community Health Centers across Utah. The research team has notices of privacy practices for the participating clinics that each indicate patient information may be used for research purposes.

Text messaging (TM) and text messaging with patient navigation (TM+PN)

Overview:

Patients in the TM condition will receive HIPAA-compliant bidirectional text messages. Texts will include a brief message regarding COVID-19 risk and will screen for if the patient or someone in their close social network should get tested. Patients who reply “yes” will receive additional messages with a recommendation to be tested in-clinic or at home. Additionally, they will receive in-clinic testing locations/hours/phone and/or patient will be able to request an at-home testing kit, and resources about what to do if they test positive. At-home test kits are FDA approved, free of cost to the participant, and sent on behalf of the participants' clinic. Patients who reply “no” will receive a text with the clinic phone number and a note to call if anything changes.

Patients in the TM+PN condition will receive the same text messages and testing/vaccination options as the patients in the TM condition. Text messages will include a brief message regarding risk and will screen for if the patient should get tested or vaccinated. In addition to the text message, patients in the TM+PN condition will receive the option for a phone conversation with a Community Health Worker for patient navigation. The Patient Navigation includes practical advice from navigators to address barriers to testing such as logistics, transportation, and expenses. A Patient Navigator can also assist with a patient request for an at-home test.

Step One:

Primary Data Extraction

To identify the cohort for the PHM intervention, a small subset of EHR data will be manually extracted from the CHCs as text files generated by EHR reports. The first set of EHR reports will contain all patients seen at each of the CHCs in the last 3 years. Subsequent reports will be obtained weekly, including all encounters in the previous week. Data fields will include risk factors such as age, gender, body mass index, encounter diagnoses for medical co-morbidities, patient demographics (e.g., zip code, insurance status, preferred language, race/ethnicity); as well as cellphone number for text messaging and patient navigation. Participating CHCs will share these clinical encounter reports with AUCH, who will then securely transfer the data to the University

of Utah study team. The data will then be hosted at the U of U Center for High Performance Computing.

Secondary Data Inclusion:

A secondary data source for this project will be vaccination records from the Utah Statewide Immunization Information Systems (USIIS). USIIS is a voluntary collection system. Individuals may opt-out of sharing their vaccine records with USIIS at anytime. In accordance with Utah Code 26-3-7(3) Utah Department of Health allows researchers to request access to USIIS data for "valid research." This data sharing will be covered through a data use agreement between the University of Utah and Utah Department of Health.

The process for this matched collection is as follows... Participating Community Health Centers will send USIIS a list of patients participating in SCALE UP. These records will include patient identifiers such as name, DOB, address, primary clinic, and MRN. Community Health Centers routinely send patient information to USIIS. This transfer of data is routine clinical practice and covered through DUAs between the clinics and USIIS. USIIS will then perform a match between the lists from the CHCs and their vaccination records. USIIS will then send the University of Utah the matched data sets. These records will include name, DOB, address, primary clinic, MRN, and COVID-19 vaccination administration details. This transfer will take place over a HIPPA compliant platform and be stored securely at the Center for High Performance Computing. These data matches and transfer from USIIS to the SCALE UP team will occur as frequently as every two weeks to ensure that researchers are using the most up to date vaccination records for patients.

An additional secondary data collection will include de-identified testing counts from the COVID testing database at the Utah Department of Health. The COVID testing outcomes being shared with the UofU will be de-identified aggregate counts of COVID test outcomes.

The process for obtaining these de-identified counts is as follows...The UofU will send UDOH an identifiable list of patients participating in SCALE UP. This list will include basic demographics needed for matching such as name, DOB, and gender. This list will also include a timestamp for the time when the patient received the texting intervention. This transfer of data will be detailed and approved through a data transfer agreement involving the community health centers, the Association for Utah Community Health, The University of Utah Office of Sponsored Projects, The University of Utah IRB, and the Utah Department of Health. Once UDOH receives the data, their office will perform a match with COVID testing outcomes in their COVID testing outcomes database. Next UDOH will aggregate the counts of testing outcomes and send UofU a de-identifiable count of testing outcomes. This transfer will take place over a HIPPA compliant platform and be stored securely at the Center for High Performance Computing. These data matches and transfers will occur 1-3 times throughout the course of the study.

Step Two: Cohort Selection & Randomization

Once the data are securely housed at the Center for High Performance Computing, the study team will determine inclusion criteria. Cohort selection will be based on EHR data considering factors such as age, race/ethnicity, language, relevant medical comorbidities, and residence in hotspot areas. These selection criteria are consistent with recommendations from UDOH and the CDC.

Once the cohort selection criteria are determined, patients who fit within the bounds will be randomly assigned by the U of U research team to either the TM or TM+PN intervention.

Step Three: Implementation

SCALE-UP Utah will send HIPPA-compliant bidirectional texts, which is a communication method routinely used by the CHCs, to patients in high risk cohorts. Text messages will be designed by the research team and sent using a HIPPA compliant text messaging service. The text messaging service will retrieve the patient cohort from the study database to send the TMs to the patients. The text messages will appear to the patients as having originated from their CHC. As part of their general CHC care, patients have agreed to be contacted by their CHC and text message communication is one of those established contact methods. Text messages will be repeated weekly, as needed, to continuously screen for COVID-19 testing and vaccination eligibility and to provide updates. Every text message will include the option to reply STOP to cease receiving text messages at any time.

Patients in the TM condition will receive the HIPAA-compliant bidirectional texts. Text messages will include a brief message regarding risk and will screen for if the patient or someone in their close social network should get tested. Patients who reply “yes” will receive additional messages with a recommendation to be tested, testing locations/hours/phone, and/or have the ability to request a free at-home test be sent to their home on behalf of their CHC, and resources about what to do if they test positive. Patients who reply “no” will receive a text with the clinic phone number and a note to call if anything changes.

Patients in the TM+PN condition will receive the same text messages as the patients in the TM condition. Text messages will include a brief message regarding risk and will screen for if the patient should get tested. Patients who reply “yes” will receive a notice that a Community Health Worker will contact them for patient navigation. The Patient Navigation includes practical advice from navigators to address barriers to testing such as logistics, transportation, and expenses. Patient Navigators will also talk to patients about free at-home testing and patients will have the option to request a free at-home test sent to the patient on behalf of their CHC. The duration of patient navigator involvement will vary from patient to patient, depending on the complexity of the case. If a patient declines PN they will no longer receive PN intervention. For the remaining patients, the PN intervention will continue until testing is completed.

AUCH Community Health Workers will be trained by research staff to serve as patient navigators and contact those patients in need of assistance. AUCH currently employs numerous Community Health Workers to perform patient navigation for various reasons (e.g., colorectal cancer screening, etc), therefore patient navigation is not beyond the standard of care for CHC patients.

To avoid duplication and potential inconsistencies, patients who test positive for COVID-19 will be managed based on current procedures already offered by UDOH, AUCH, and CHCs. For example, UDOH is notified of all CHC patients who test positive and conducts extensive contact tracing. AUCH and UDOH currently have multiple initiatives for helping patients who test positive with additional resources, including a community health worker program to support COVID-19 positive and/or high-risk patients in quarantine. The text messaging and patient navigation arms of the study will proactively provide patients with access to informative resources describing what would happen if they test positive and where to seek help. Patients that request free at-home testing will not be required to share their results with their CHC but will receive health education in case they test positive by their Patient Navigator.

Data transfer:

Throughout the course of the study, on a quarterly basis, the study team will send de-identified patient data and study outcomes to project's sponsor, The National Institutes of Health. This process has been detailed and approved through data transfer agreements involving the community health centers, the Association for Utah Community Health, The University of Utah Office of Sponsored Projects, The University of Utah IRB, Utah Department of Health, and Duke University, which is housing the data for the National Institutes of Health. The patient data agreed to be transferred includes age, race/ethnicity, gender, preferred language, insurance status, tobacco use status, chronic disease diagnoses, outcome of COVID screening, COVID lab test order and results, and COVID vaccine administration.

Throughout the course of the study, the study team will send patient data and corresponding intervention data (text message timestamps) to a project partner, Utah Department of Health. This process will be detailed and approved through a data transfer agreement involving the community health centers, the Association for Utah Community Health, The University of Utah Office of Sponsored Projects, The University of Utah IRB, and Utah Department of Health. The patient data to be transferred includes PHI needed for matching study participants to the UDOH testing database. This includes basic demographics (name, DOB, gender) as well as the timestamp of the time the participant received the text message intervention.