Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications (Nudge)

Principal Investigators
Michael Ho, MD, PhD; and Sheana Bull, PhD, MPH

Sponsoring Institution
University of Colorado

ClinicalTrials.gov Identifier
NCT03973931

Collaborators
• UCHealth
• Denver Health
• VA Eastern Colorado Health Care System

NIH Institute Providing Oversight
National Heart, Lung, and Blood Institute (NHLBI)

Program Official
Lawrence Fine, MD, DrPH (NHLBI)

Project Scientist
Nicole Redmond, MD, PhD, MPH (NHLBI)

ABSTRACT

Nearly half of patients do not take their cardiovascular medications as prescribed, resulting in increased morbidity, mortality, and healthcare costs. Interventions to improve adherence—such as patient education, reminders, pharmacist support, and financial incentives—have produced inconsistent results due to limited study designs. Mobile and digital technologies for health promotion and disease self-management offer an opportunity to adapt behavioral "nudges" using ubiquitous mobile phone technology to facilitate medication adherence.

The Nudge study will use population-level pharmacy data to deliver nudges via mobile phone text messaging and an artificial intelligent (AI) interactive chat bot with the goal of improving medication adherence and patient outcomes in 3 integrated healthcare delivery systems. During the planning phase, the Nudge study team developed and piloted a technology-based nudge message library and a chat bot library of optimized interactive content for a range of diverse patients. Patients of interest are those with chronic cardiovascular conditions who take medications to treat hypertension, atrial fibrillation, coronary artery disease, diabetes, or hyperlipidemia. Episodes of nonadherence to prescribed medications are identified through gaps in medication refills. Participants are randomized to one of 4 study arms: usual care (no intervention), generic nudge (text reminder), optimized nudge, and optimized nudge plus interactive AI chat bot.
INTERVENTION ARMS FOR THE PRAGMATIC TRIAL

User registration and randomization

Usual Care

Generic Texts

You are due for a refill on your meds

Optimized Texts

[Name] Congrats! You’ve filled meds on time at least 60% of the time. Make it 100%!

Optimized Texts + AI Chat Bot

[Name]: What problems do you have getting refills? Text 1=transport 2=cost 3=time

WHAT WE’VE LEARNED SO FAR

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some health systems did not consistently record cell phone numbers in the appropriate place, resulting in cell phone numbers not being imported in the research database.</td>
<td>Study team worked with an EPIC analyst to import cell phone numbers into the research database.</td>
</tr>
<tr>
<td>There were challenges in comparing definitions (eg, hospitalization) and nuances in how data are captured (eg, inpatient versus outpatient labs).</td>
<td>A team of analysts identified limitations across each system and worked with clinicians on the study team to create variable definitions compatible at each health system.</td>
</tr>
<tr>
<td>Due to a contractual issue, the study team was not able to obtain pharmacy data at one participating health system.</td>
<td>Team decided to delay enrollment of patients for at least 1 year at that health system and re-assess whether enrollment will be possible at the health system after they obtain more data. They will increase enrollment at the other 2 systems.</td>
</tr>
</tbody>
</table>

“Ideally, if people are doing a better job of refilling their meds, they can stay more adherent to their medications, and ultimately, have better health outcomes.”

SELECTED PUBLICATIONS & PRESENTATIONS

• Presentation: Presentation to the NIH Pragmatic Trials Collaboratory Steering Committee (2023)
• Article (Study Design): The NUDGE Trial Pragmatic Trial to Enhance Cardiovascular Medication Adherence: Study Protocol for a Randomized Controlled Trial (2021)
• Article: Leave Me Out: Patients’ Characteristics and Reasons for Opting Out of a Pragmatic Clinical Trial Involving Medication Adherence (2021)

Access the complete set of Nudge resources.