Personalized patient data and behavioral nudges to improve adherence to chronic cardiovascular medications (The Nudge Study)

Text Messaging at Scale in Diverse Health Systems to Support Adherence to Cardiac Medications

Michael Ho, MD, PhD & Sheana Bull, PhD, MPH
University of Colorado Denver
NIH Collaboratory Grand Rounds, January 11, 2019
Objectives

• Background
• Overview of the Nudge Study
• Progress to date
• Next steps for this year
• Plans for UH3 grant
Adherence is low among patients with chronic cardiovascular disease

15,767 patients at a large community based HMO

Ho PM. et al. AHJ. 2008.
Large impact of medication non-adherence
Patient-reported non-adherence behaviors

Non-Adherent Behaviors, Past 12 Months

- Missed a dose: 57%
- Forgot if took: 30%
- Did not refill in time: 28%
- Took a lower dose: 22%
- Did not fill new Rx: 20%
- Stopped taking: 14%
Patient-reported non-adherence behaviors

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National Community Pharmacist Assoc.
Medication Adherence in America: A National Report 2013
Reasons for non-adherence

Self-Reported Reasons for Non-Adherence

- Forgot: 42%
- Ran out: 34%
- Away from home: 27%
- Trying to save money: 22%
- Had side effects: 21%
- Was too busy: 17%
- Rx wasn’t working: 17%
- Didn’t think Rx was needed: 16%
- Didn’t like taking it: 12%
Reasons for non-adherence

Self-Reported Reasons for Non-Adherence
What is a Nudge?

“A nudge is any aspect of the choice architecture that alters people’s behavior in a predictable way without forbidding any options or significantly changing their economic incentives. To count as a mere nudge, the intervention must be easy and cheap to avoid. Nudges are not mandates.”

“Putting the fruit at eye level counts as a nudge. Banning junk food does not.”
Nudges are increasingly being used in healthcare to change behavior
Cellphones are ubiquitous in the US

- ~91% of US adults have a cellphone
  - 88% have unlimited text messaging
- Even among older adults (age > 65), it is estimated that 71% have a cell phone
- 94% of those 70+ years old send weekly text messages

Pew Research Center
Tatango [Internet]
Objectives of the Nudge Study

• To employ population level pharmacy data and delivery of nudges via cell phone text messaging and artificially intelligent (AI) interactive chat bot to improve medication adherence and patient outcomes
Nudge Aims for Year 1 (UG3 phase)

- **Aim 1**: With input from Veterans at the VA and patients at DH And UC Health, develop (a) a nudge message library and (b) chat bot content library both of which would be specifically tailored to users

- **Aim 2**: Figure out who isn’t picking up their meds within the VA, UC Health and Denver Health

- **Aim 3**: Conduct a pilot test of the Nudge system within the VA, DH and UCHealth
  - Phase I: Rolling out this week to 15 persons per study arm (5 per site) regardless of medication refill gaps
  - Phase II: For the rest of the patients in the pilot, we will monitor prospectively for a 7-day refill gap. Once they have a 7-day gap, they will be randomized to one of the study arms and delivered the text message(s).
UH3 Specific Aims (Years 2-5)

1. Conduct a pragmatic patient-level randomized intervention across 3 HCS to improve adherence to chronic CV medications.
   a) The primary outcome will be medication adherence defined by the proportion of days covered (PDC) using pharmacy refill data.
   b) Secondary outcomes will include intermediate clinical measures (e.g., BP control), CV clinical events (e.g., hospitalizations), healthcare utilization, and costs.

2. Evaluate the intervention using a mixed methods approach and applying the RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) framework.
   a) Assess the context and implementation processes to inform local tailoring, adaptations and modifications, and eventual expansion of the intervention within the 3 HCS more broadly and nationally.
Nudge will be conducted within diverse healthcare settings

- Denver Health
- Veteran’s Affairs
- UCHealth
Patients with cardiovascular conditions will be included

- Adult cardiovascular patients at one of participating HCS diagnosed with ≥ 1 condition of interest, prescribed ≥ 1 medication of interest, with a refill gap of at least 7 days

<table>
<thead>
<tr>
<th>Condition</th>
<th>Classes of medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>Beta-blockers (B-blockers), Calcium Channel Blocker (CCB), Angiotensin converting enzyme inhibitors (ACEi), Angiotensin Receptor Blockers (ARB), Thiazide diuretic</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>HMG CoA reductase inhibitor (Statins)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Alpha-glucosidase inhibitors, Biguanides, DPP-4 inhibitors, Sodium glucose transport inhibitor, Meglitinides, Sulfonylureas, Thiazolidinediones, and statins</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>PGY-2 inhibitor (Clopidogrel, Ticagrelor, Prasugrel, Ticlopidine), B-blockers, ACEi or ARB and statins</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>Direct oral anticoagulants, B-blockers, CCB</td>
</tr>
</tbody>
</table>
Intervention arms for the proposed pragmatic trial

User registration and randomization

- Usual Care
- Generic Texts
- Optimized Texts
- Optimized Texts + AI Chat Bot

**You are due for a refill on your meds**

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

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

2, 3
Aim 1: With input from Veterans at the VA and patients at DH And UC Health, develop (a) a nudge message library and (b) chat bot content library both of which would be specifically tailored to users

• Using an N of 1 study design, we have interviewed 31 persons across three systems to get their feedback on message design and content
Day 1 continued...

A. We noticed that you haven't refilled at least one of your meds. Reply 1 to let us know that you'll get them refilled in the next 2 days.

B. Will you get your refill? Reply 1 for yes.

C. We know you're busy - when do you think you'll pick up your medication refills? Reply 1=today, 2=tomorrow, 3=the day after that.

Nudge

Personalized patient data and behavioral nudges to improve adherence to chronic cardiovascular medications

University of Colorado Denver | UCHealth | Denver VA | Denver Health
<table>
<thead>
<tr>
<th>Offensive</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Don’t Understand</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Don’t Like</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>TOTAL NEGATIVE (SUM of first 3 variables)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Positive Response</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Other suggestions or feedback for specific messages</td>
<td>UCH116 “Positive simple quick reminder”</td>
<td>UCH116 “big brother like”</td>
</tr>
</tbody>
</table>

We noticed that you haven’t refilled at least one of your meds. Reply 1 to let us know that you’ll get them refilled in the next 2 days.

Will you get your refill? Reply 1 for yes.

We know you’re busy - when do you think you’ll pick up your medication refills? Reply 1=today, 2=tomorrow, 3=the day after that.
N of 1 interviews
Progress & Findings

• “I like that the messages put the ownership on self.”

• “I like the ones that relate to a hospital stay. I’ve been in the hospital and once you have done that you will want to avoid it in the future. It’s good motivation for me to stay out of the hospital.”

• “The message validates my feelings that it is hard to take meds. Realizing a break down in your body, the meds are the confirmation of that.”

• “This message makes me smile. It lightens it up and this can be a serious topic so it is nice to smile.”
N of 1 interviews
Progress & Findings

Examples of messages that received negative feedback

B

C

C

Just do it

Did you for your ?
Text 1=yes, 2=not yet

Joe always remembers his meds—he makes a habit of going every Friday since the pharmacy is right near his favorite meadow spot! Make a healthy habit by planning your regular medication pick up
Nudge Aims for Year 1

- **Aim 2**: Figure out who isn’t picking up their meds within the VA, UC Health and Denver Health
Retrospectively identified patients who would potentially be eligible to be enrolled: CV diagnosis, prescribed medication class, initial 7-day gap
Aim 3: Conduct a pilot test of the Nudge system within the VA, DH and UCHealth

- **Opt-out packets** were sent to 600 total patients meeting inclusion criteria (200 patients per each HCS) in December
  - Packet included an information sheet, opt-out sheet, self-addressed and stamped envelope
  - Two-week deadline to return opt-out form
- Secondary opt-out opportunity in each text message
**Aim 3:** Conduct a pilot test of the Nudge system within the VA, DH and UCHealth

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<table>
<thead>
<tr>
<th></th>
<th>Patients that opted-out</th>
<th>Packets returned by USPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCHealth</td>
<td>22 (11.0%)</td>
<td>6 (3.0%)</td>
</tr>
<tr>
<td>Denver Health</td>
<td>12 (6.0%)</td>
<td>3 (1.5%)</td>
</tr>
<tr>
<td>Denver VA</td>
<td>36 (18.0%)</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>70 (11.7%)</strong></td>
<td><strong>9 (1.5%)</strong></td>
</tr>
</tbody>
</table>
Aim 3: Conduct a pilot test of the Nudge system within the VA, DH and UCHealth

- Phase 1 of pilot rolling out this week to 15 persons per study arm (5 per site)
  - Purpose is to establish feasibility and usability
- Phase II: For the rest of the patients in the pilot, we will monitor prospectively for a 7-day refill gap. Once they have a 7-day gap, they will be randomized to one of the study arms and delivered the text message(s).
## Initial findings from feasibility and usability

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Location</th>
<th>Response</th>
<th>Study Arm</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/7/18</td>
<td>12:04 PM</td>
<td>UCH</td>
<td>STOP</td>
<td>Generic messages</td>
<td></td>
</tr>
<tr>
<td>1/7/18</td>
<td>12:08 PM</td>
<td>UCH</td>
<td>DONE</td>
<td>Generic messages</td>
<td></td>
</tr>
<tr>
<td>1/7/18</td>
<td>12:01 PM</td>
<td>DH</td>
<td>DONE</td>
<td>Generic messages</td>
<td></td>
</tr>
<tr>
<td>1/7/18</td>
<td>12:01 PM</td>
<td>DH</td>
<td>Español</td>
<td>Optimized</td>
<td>JW opted out of DH_Pilot_Optimized Arm and opted into DH_Pilot_Optimized_Spanish Arm</td>
</tr>
<tr>
<td>1/7/18</td>
<td>12:01 PM</td>
<td>VA</td>
<td>DONE</td>
<td>Generic Messages</td>
<td></td>
</tr>
<tr>
<td>1/7/18</td>
<td>12:01 PM</td>
<td>VA</td>
<td>DONE</td>
<td>Chatbot Messages</td>
<td></td>
</tr>
<tr>
<td>1/7/18</td>
<td>1:40 PM</td>
<td>UCH</td>
<td>STOP</td>
<td>Chatbot Messages</td>
<td></td>
</tr>
<tr>
<td>1/7/18</td>
<td>4:20 PM</td>
<td>UCH</td>
<td>STOP</td>
<td>Chatbot Messages</td>
<td>Patient first responded “Help, which meds didn’t I get refills for?” then replied STOP</td>
</tr>
<tr>
<td>1/7/18</td>
<td>12:27</td>
<td>DH</td>
<td>Español</td>
<td>Chatbot Messages</td>
<td>JW opted out of DH_Pilot.Chatbot Arm and opted into DH_Pilot.Chatbot_Spanish Arm</td>
</tr>
<tr>
<td>1/7/18</td>
<td>12:52</td>
<td>DH</td>
<td>Español</td>
<td>Chatbot Messages</td>
<td>JW opted out of DH_Pilot.Chatbot Arm and opted into DH_Pilot.Chatbot_Spanish Arm</td>
</tr>
<tr>
<td>1/7/18</td>
<td>2:13 PM</td>
<td>VA</td>
<td>DONE</td>
<td>Chatbot Messages</td>
<td></td>
</tr>
</tbody>
</table>

### Table: Call Logs

<table>
<thead>
<tr>
<th>Body</th>
<th>MMS</th>
<th>Campaign</th>
<th>Received</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
<td>DH_Chatbot_Pilot</td>
<td>Today at 11:55AM MST</td>
<td>✗ ✗ ✗</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>DH_Chatbot_Pilot</td>
<td>1/9/2019 3:48PM MST</td>
<td>✗ ✗ ✗</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>DH_Chatbot_Pilot</td>
<td>1/9/2019 3:45PM MST</td>
<td>✗ ✗ ✗</td>
</tr>
<tr>
<td>Done</td>
<td></td>
<td>DH_Nudge_Generic_Pilot</td>
<td>1/9/2019 2:23PM MST</td>
<td>✗ ✗ ✗</td>
</tr>
<tr>
<td>Don’t know what it is</td>
<td></td>
<td>DH_Nudge_Generic_Pilot</td>
<td>1/9/2019 2:06PM MST</td>
<td>✗ ✗ ✗</td>
</tr>
<tr>
<td>Yo lo hice</td>
<td></td>
<td>DH_Chatbot_Pilot</td>
<td>1/9/2019 2:06PM MST</td>
<td>✗ ✗ ✗</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>DH_Optimize_Spanish</td>
<td>1/7/2019 3:07PM MST</td>
<td>✗ ✗ ✗</td>
</tr>
<tr>
<td>Español</td>
<td></td>
<td>DH_Chatbot_Pilot</td>
<td>1/7/2019 12:52PM MST</td>
<td>✗ ✗ ✗</td>
</tr>
<tr>
<td>Español: Po. favor</td>
<td></td>
<td>DH_Chatbot_Pilot</td>
<td>1/7/2019 12:27PM MST</td>
<td>✗ ✗ ✗</td>
</tr>
<tr>
<td>Done</td>
<td></td>
<td>DH_Nudge_Generic_Pilot</td>
<td>1/7/2019 12:01PM MST</td>
<td>✗ ✗ ✗</td>
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</tr>
</tbody>
</table>
Nudge preparation for UH3 grant

• **Following our pilot, we will:**
  • Draft a trial protocol
  • Share with our Protocol Review Committee
  • Submit to our NIH advisory team
Project Leadership

**Co-Principal Investigators**

- Michael Ho, MD, PhD  
  Professor of Medicine, University of Colorado Denver  
  Staff Cardiologist, Eastern Colorado Health Care (Veterans Affairs)
- Sheana Bull, PhD, MPH  
  Director, mHealth Impact Laboratory  
  Professor, Colorado School of Public Health, University of Colorado Denver

**Clinical Site Leads**

- UCHealth: Amber Khanna, MD & Larry Allen, MD  
- Denver Health: Pamela Peterson, MD, MSPH  
- Denver VA: Michael Ho, MD, PhD

**Project Manager**

Lisa Sandy, MA

**NIH Leadership**

- Holly Nicastro, PhD, MD  
  Program Director, Clinical Applications and Prevention Branch, National Heart, Lung, and Blood Institute  
- Nicole Redmond, MD, PhD, MPH  
  Medical Officer, National Heart, Lung, and Blood Institute

**Workgroup leadership**

**Stakeholder Workgroup**

- Daniel Matlock, MD, MPH  
- Rebecca Guigli, MPH

**Administrative Workgroup**

- Pamela Peterson, MD, MSPH  
- Lisa Sandy, MA  
- Phat Luong, MS

**Data & Statistics Workgroup**

- Gary Grunwald, PhD  
- David Magid, MD  
- Thomas Glorioso, MS  
- Meg Plomondon, MSPH, PhD

**Mobile Health Workgroup**

- Sheana Bull, PhD, MPH  
- Laura Scherer, PhD  
- Joy Waughtal, MPH  
- Catia Chavez, MPH

**Implementation & Dissemination Workgroup**

- Russell Glasgow, PhD  
- Christopher Knoepke, PhD, MSW

**Protocol Review Committee**

- Bruce Bender, PhD  
- Zindel Segal, PhD  
- William Vollmer, PhD
Questions?