

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

Michael Ho, MD, PhD & Sheana Bull, PhD, MPH



VA

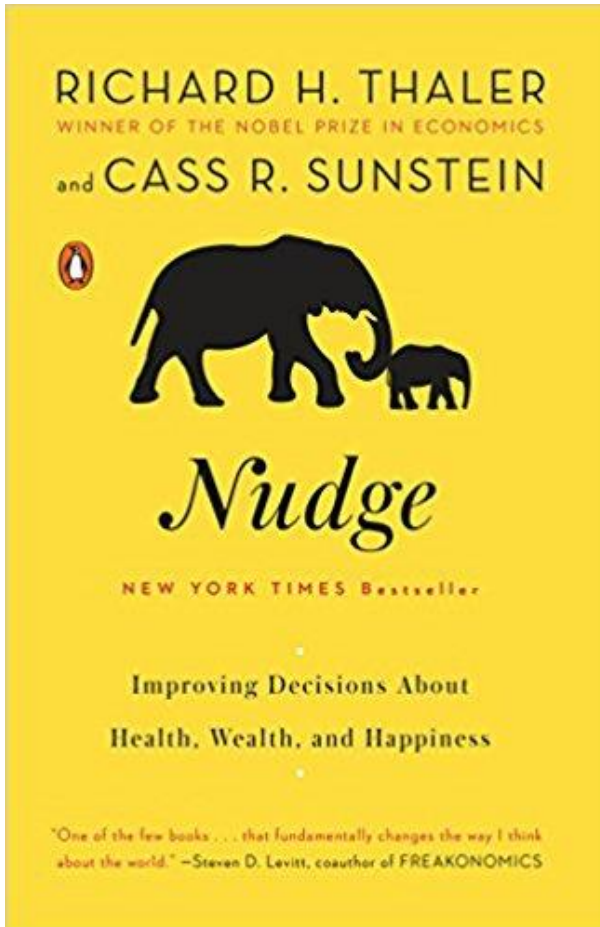


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# What is a Nudge?



“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.”

# 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



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# Patient Population

- Adult cardiovascular patients diagnosed with  $\geq 1$  condition of interest, prescribed  $\geq 1$  medication of interest, with a refill gap of at least 7 days

Condition	Classes of medications
Hypertension	Beta-blockers (B-blockers), Calcium Channel Blocker (CCB), Angiotensin converting enzyme inhibitors (ACEi), Angiotensin Receptor Blockers (ARB), Thiazide diuretic
Hyperlipidemia	HMG CoA reductase inhibitor (Statins)
Diabetes	Alpha-glucosidase inhibitors, Biguanides, DPP-4 inhibitors, Sodium glucose transport inhibitor, Meglitinides, Sulfonylureas, Thiazolidinediones, and statins
Coronary artery disease	PGY-2 inhibitor (Clopidogrel, Ticagrelor, Prasugrel, Ticlopidine), B-blockers, ACEi or ARB and statins
Atrial fibrillation	Direct oral anticoagulants, B-blockers, CCB

## Setting

Family medicine and internal medicine clinics in the Denver Metro area

- *Denver Health*
- *UCHealth*
- *VA Eastern Colorado Health System*

# UG3 Progress

## Study Start-up

- Obtained regulatory approval across the 3 HCS
- Established a Nudge Project-specific Stakeholder Panel
- Convened a Protocol Review Committee
- Developed a message library
  - Refined through N of 1 interviews
  - Vetted by Stakeholder Panel
- Established patient identification, eligibility, and randomization procedures



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# Assessing medication data

	ALL MEDS
Patients eligible for study that have filled at least 1 medication class of interest in 2017, n	12,493
Patients meeting Inclusion Criteria with a 7-day gap in 2017, n	10,284
N Classes – Median (IQR)	2 (1, 4)
Days Follow-up – Median (IQR)	365 (349, 365)
Days Supply for each prescription– Median (IQR)	90 (60, 90)
Any 7 Day Gap (%)	97.6%
Multiple 7 Day Gaps (%)	81.9%
Prop Days Covered – Median (IQR)	0.616 (0.297, 0.826)

# Testing Ability to Assess Clinical events

Outcome	Outcomes of interest (DH)
Systolic BP - Mean (SD) mm Hg	131.2 (17.9)
Diastolic BP - Mean (SD) mm Hg	78.7 (10.8)
LDL - Mean (SD)	85.5 (38.6)
Hemoglobin A1c - Mean (SD)	7.8 (1.9)
All Cause Hospitalization (1 Yr.)	8.7% (792/9149)
All Cause ED Visit (1 Yr)	18.6% (1700/9149)
Procedures	
PCI	0.5% (45/9119)
CABG	0 (0/9119)
Cardioversion	2.6% (9/352)

# Intervention arms for the pragmatic trial

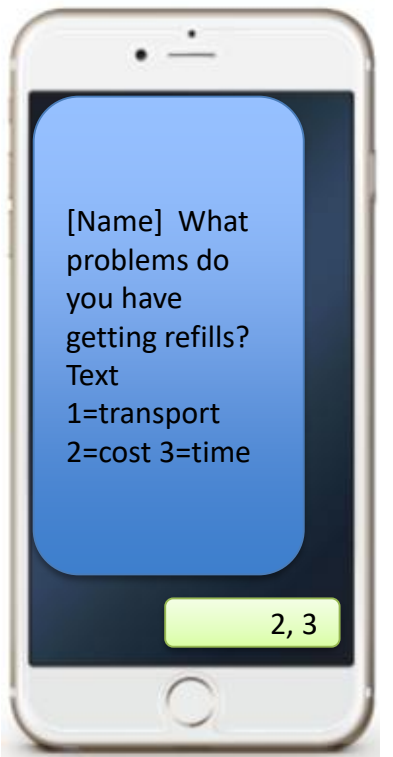
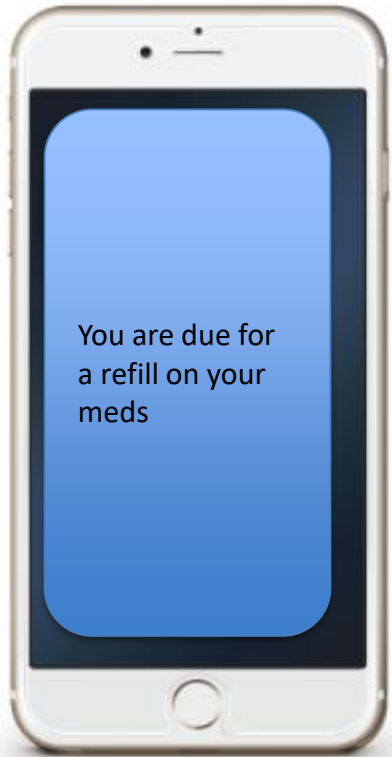
- 1. Do not opt out
- 2. Refill gap  $\geq 7$  days
- 3. Randomize

Usual Care

Generic Texts

Optimized Texts

Optimized Texts + AI Chat Bot





# Examples of messages

- Did you know? When you make a promise to someone else you're more likely to stick to it. Will you commit to picking up your med and staying healthy? Text 1=yes, I'll do it today; 2=I'll get to it later in the week
- Patients at the [VA/DH/UCH] tell us--when they stay on top of their med refills they have fewer challenges in managing their condition. Click on this link for pharmacy hours, phone, parking: [URL]
- Did you know: most people who take medications take more than 3 of them each day. It can be a lot to remember!

# Pilot study

- Sent opt-out letters to 600 eligible patients across 3 HCS

Phase I: Deliver messages to ~30 patients per site, testing for functionality

	<b>DONE</b>	<b>STOP</b>	<b>Spanish language</b>
	<i>If you have already filled your prescription let us know by replying DONE</i>	<i>Text STOP to unsubscribe</i>	<i>Participants that requested Spanish language texts</i>
<b>Total (n=88)</b>	<b>23 (26.1%)</b>	<b>3 (3.4%)</b>	<b>3 (3.4%)</b>

Phase II: Trial intervention to eligible patients at Denver Health and the VA

	<b>DONE</b>	<b>STOP</b>	<b>Spanish language</b>
<b>Total (n=209)</b>	<b>33 (15.8%)</b>	<b>4 (2.0%)</b>	<b>10 (4.8%)</b>

# Lessons Learned

## Study Preparation

- **Hospital data**

- Some systems did not consistently record cell phone number in the appropriate place, resulting in cell phone numbers not being imported in the research database.
- **Solution:** We worked with an EPIC analyst to import cell phones into the research database, and hope to find a method of capturing cell phone numbers in the research database moving forward.

- **Opt-out mailings**

- Returned packets came back 2 weeks after they were sent, leading to difficulties sending new packets to new patients
- Opt-out forms continued to come back after opt-out deadline
- **Solution:** Extend to 5 weeks prior to study

- **Identifying the best common data denominators across 3 HCS**

- Comparing definitions (i.e., hospitalization) and nuances in how data are captured (i.e., inpatient vs outpatient labs)
- **Solution:** Team of analysts identified limitations across each system and worked with clinicians on the Nudge team to create variable definitions compatible at each HCS



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# Lessons Learned

## Communications

- Our project involves 26 investigators and staff over three HCS
- **Solution to ensuring all involved are able to actively participate in the project:**
  - **Meeting schedules**
    - Weekly meetings
      - Co-PI's & PM
    - Monthly meetings
      - Co-PI's and Project Officer
      - Steering Committee Calls
      - Calls with co-PI's and site leads
      - Budget meetings
      - Workgroups
      - Bi-monthly meetings
      - All Hands meetings
  - **Visual communications**
    - Mapping out processes (Process for triaging messages, etc)
    - Mapping data drives

# Lessons Learned

## Analysis Plan

- **Primary Outcome**
  - We revised our primary outcome to focus on adherence, defined by the proportion of days covered in the year after randomization for the initial medication(s) in which a patient has a 7-day gap.
    - This definition of the primary outcome was chosen to assess the impact of the intervention of patients' medication behavior
- **Secondary Analysis**
  - We will also use alternative definitions for adherence:
    - All medications patient gapped on during the follow-up period, and calculating PDC from the time of gap
    - All medications patient was prescribed at baseline

# Transition Issues

## Facility follow through

- At two of our three HCS, patients get their medications through both pharmacies within the HCS and through outside pharmacies (Walgreens, CVS, etc). Our plan was to obtain pharmacy refill data for patients that fill at outside pharmacists via Surescripts.
- At one HCS, this was unexpectedly stymied due to a contractual issue.
- **Solution:** Delay enrollment of patients at one HCS for at least 1 year compared to the other 2 HCS for the UH3 study.

# Sustainability

## Facility Follow Through

- Adding more clinics at the 2 other HCS
  - To address the potential of not being able to enroll patients at 1 of our HCS, we increased enrollment at the other 2 HCS.
  - With the addition of the new clinics, we will have sufficient statistical power to detect a clinically important difference in our primary outcome even without 1 HCS.



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# Data Sharing Plan

- *Current data plan*
  - *Data remain behind each institution's firewall*
  - *Messages are sent by a centralized team*
  - *Messages are transmitted via separate web-based portals*
- *Data Sharing*
  - *Technical and practical knowledge*
  - *Data collection instruments and assessment algorithms*
  - *Message library*
  - *De-identified patient-level data*



# Questions?

michael.ho@ucdenver.edu

sheana.bull@ucdenver.edu



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