

# 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



U.S. Department  
of Veterans Affairs



University of Colorado  
Denver | Anschutz Medical Campus

# Objectives

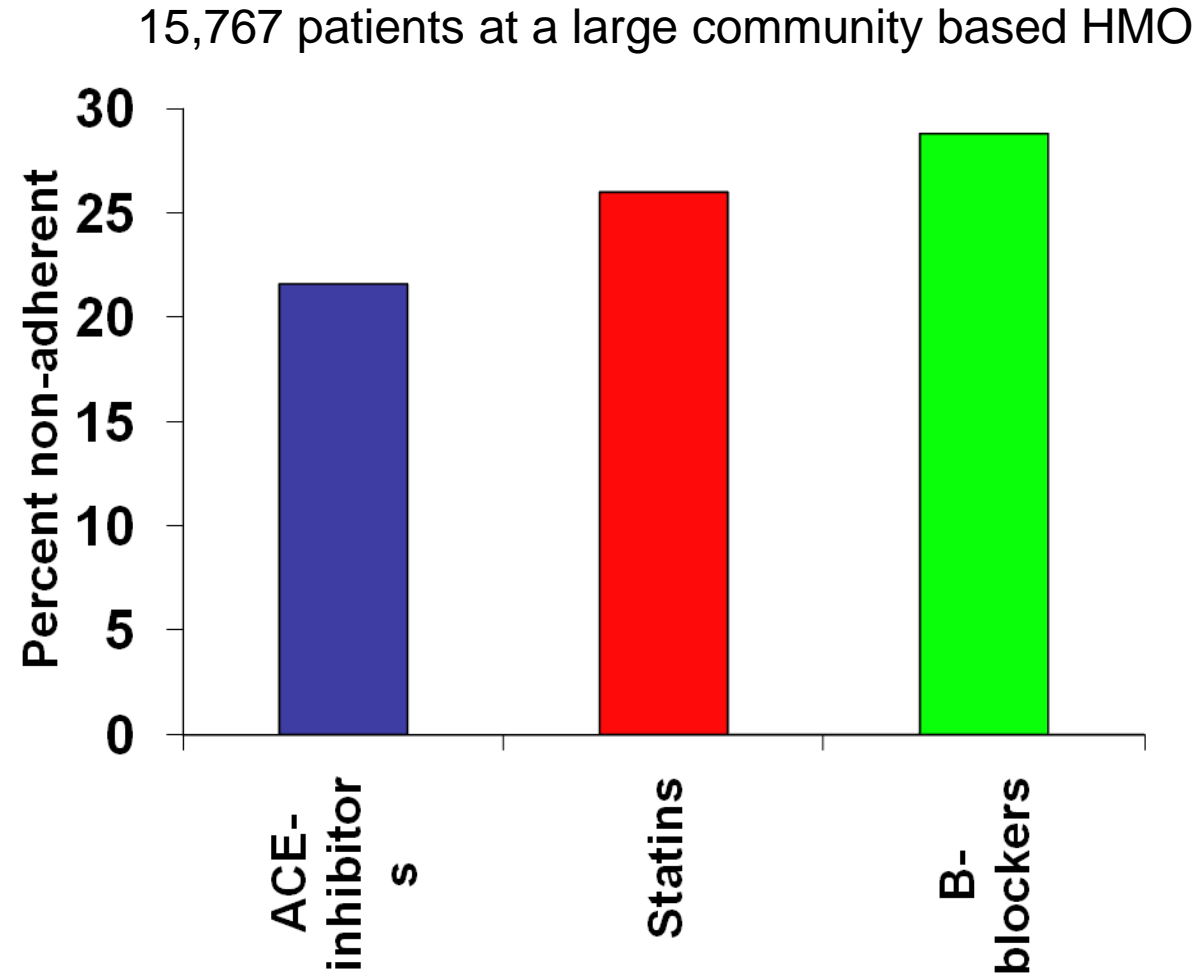
- Background
- Overview of the Nudge Study
- Progress to date
- Next steps for this year
- Plans for UH3 grant



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# Adherence is low among patients with chronic cardiovascular disease

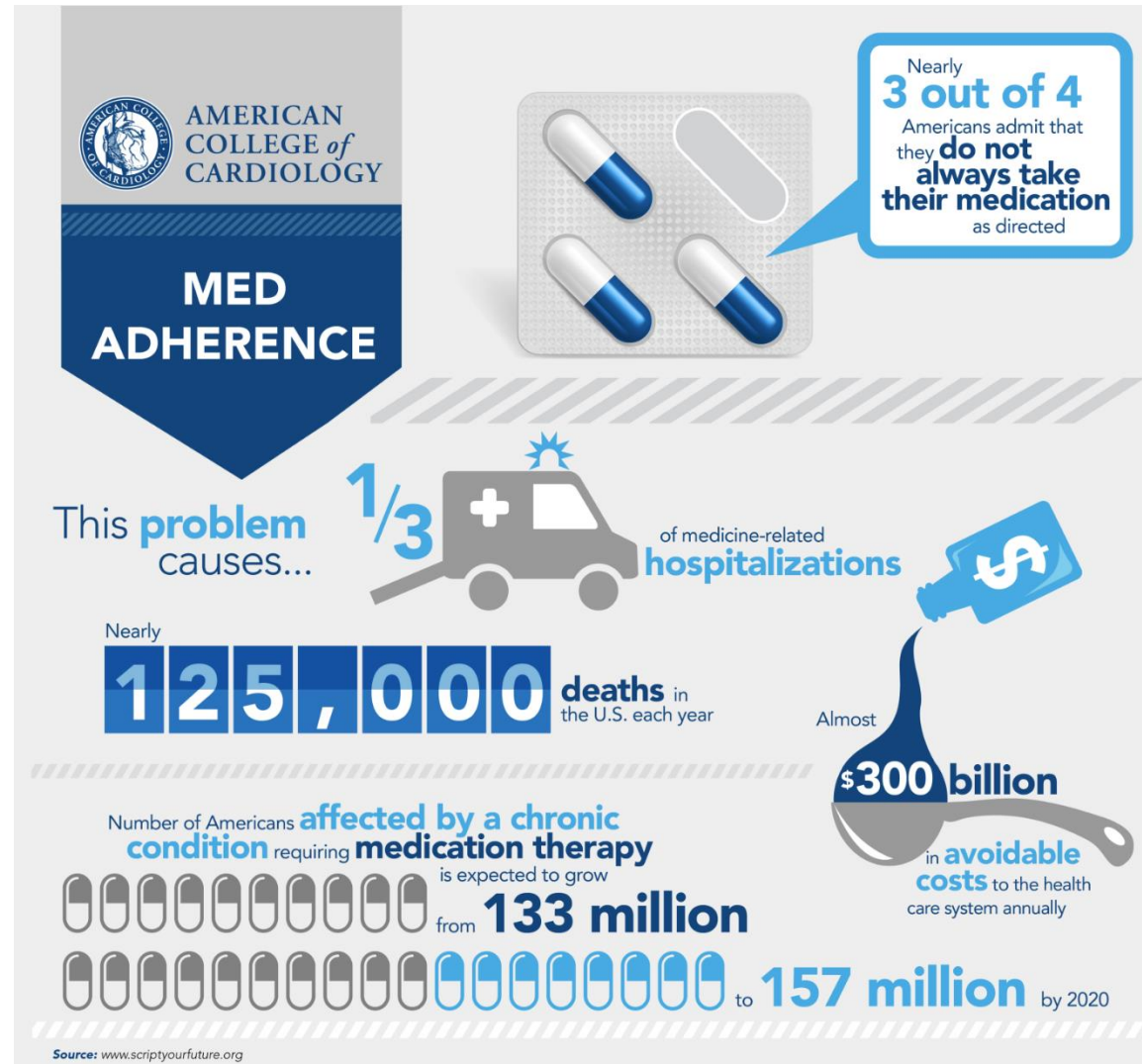


Ho PM. et al. AHJ. 2008.



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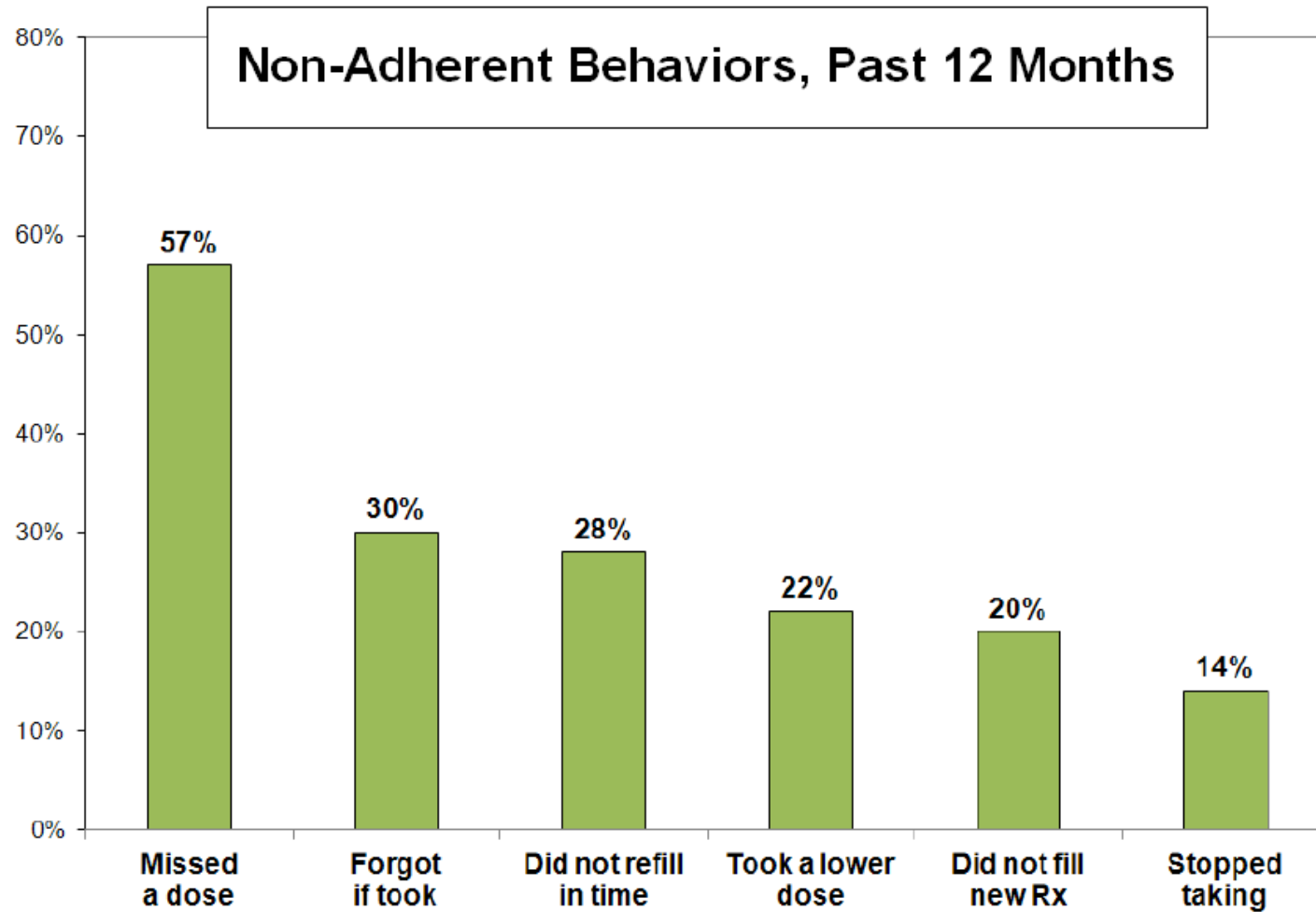
# Large impact of medication non-adherence



**Nudge**

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# Patient-reported non-adherence behaviors

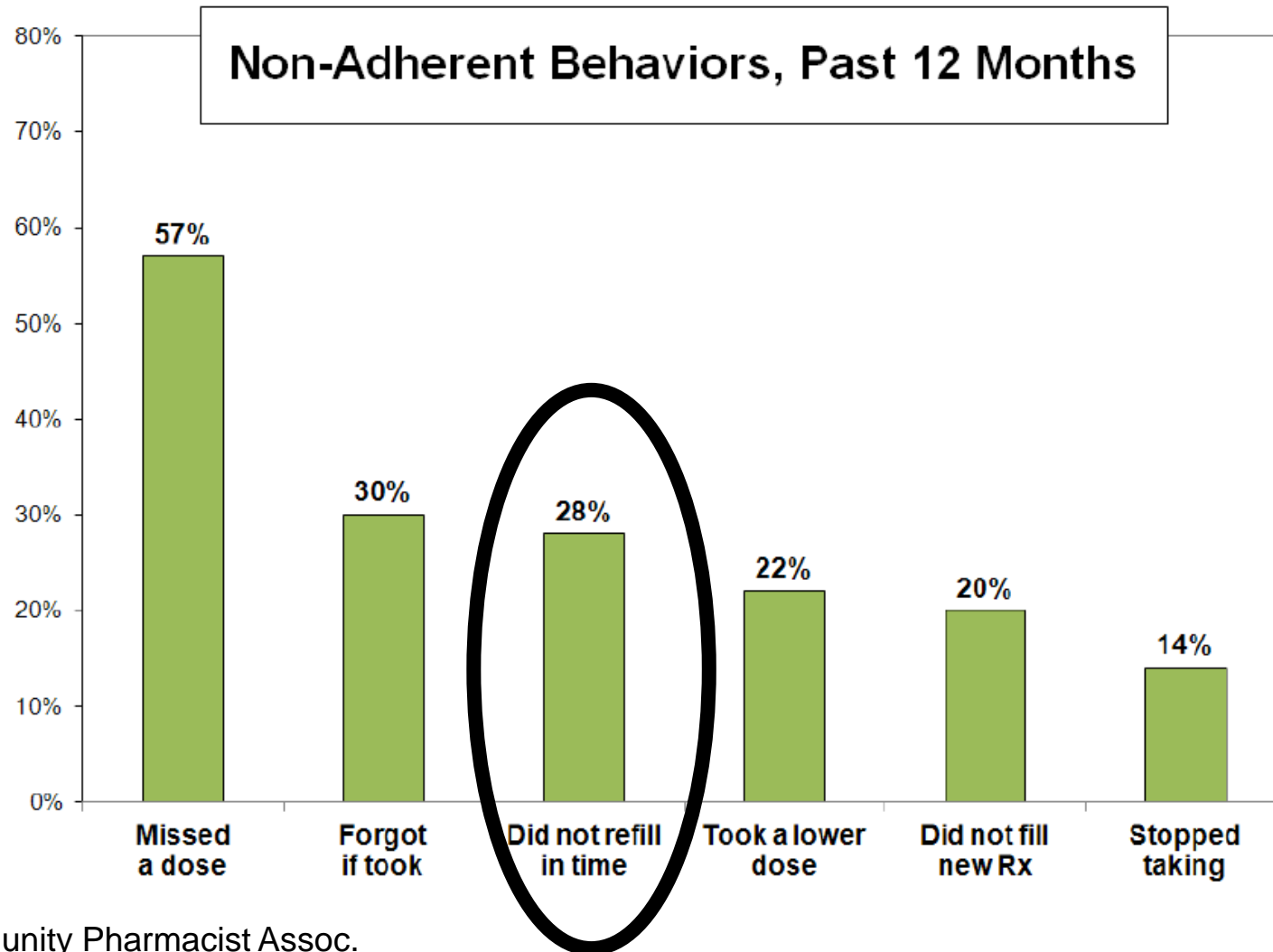


National Community Pharmacist Assoc.  
Medication Adherence in America: A National Report 2013



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# Patient-reported non-adherence behaviors

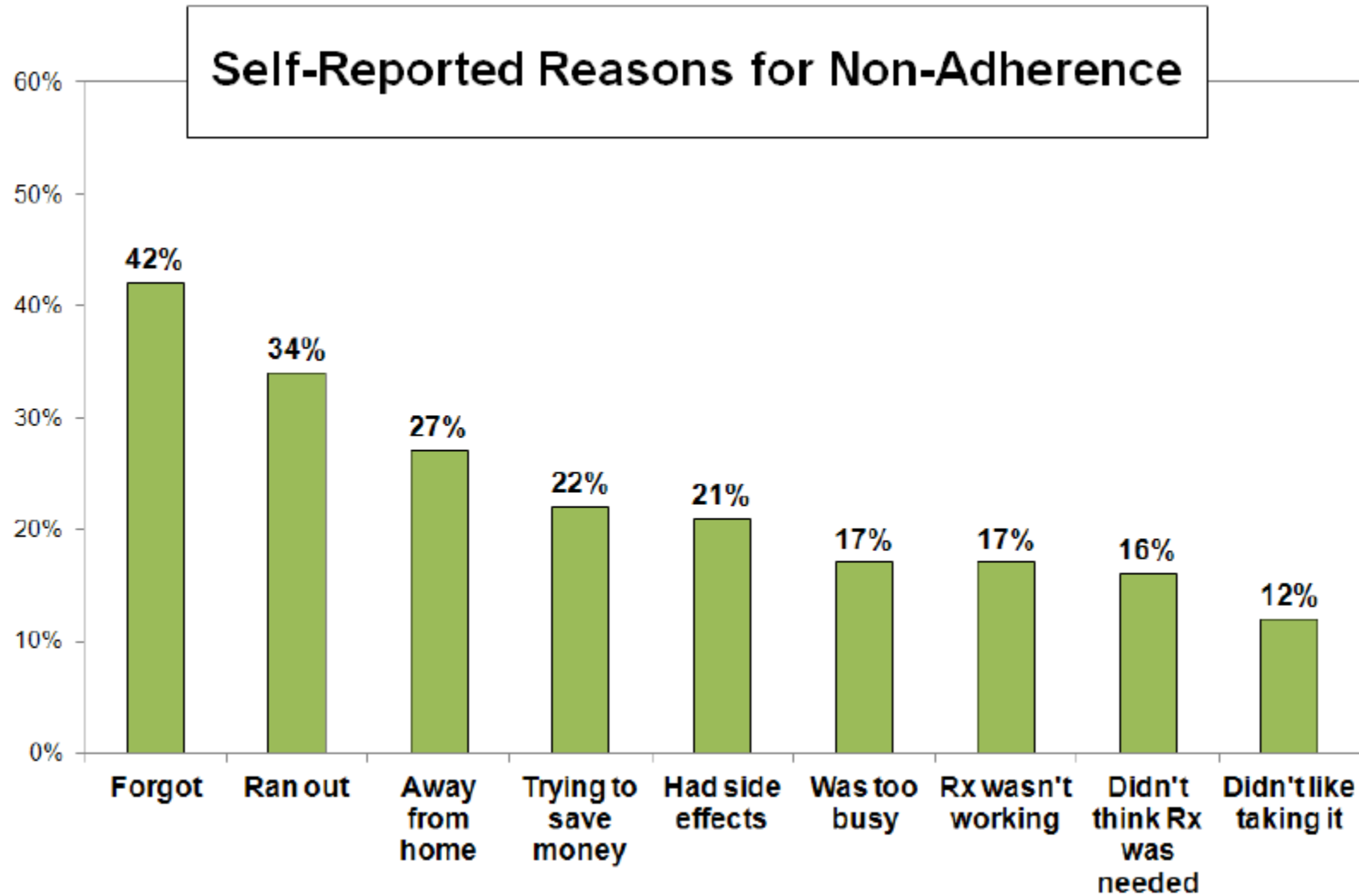


National Community Pharmacist Assoc.  
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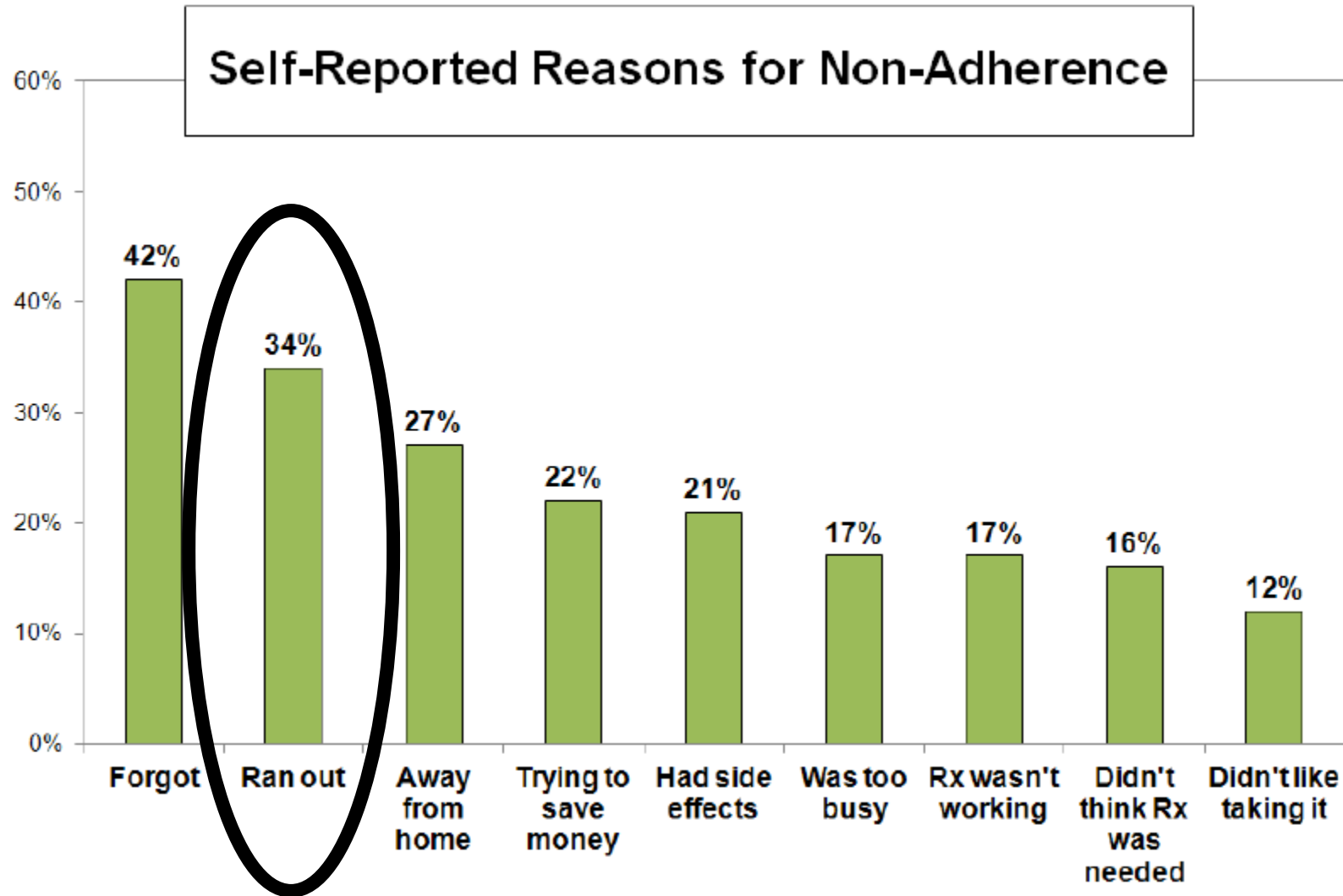
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# Reasons for non-adherence



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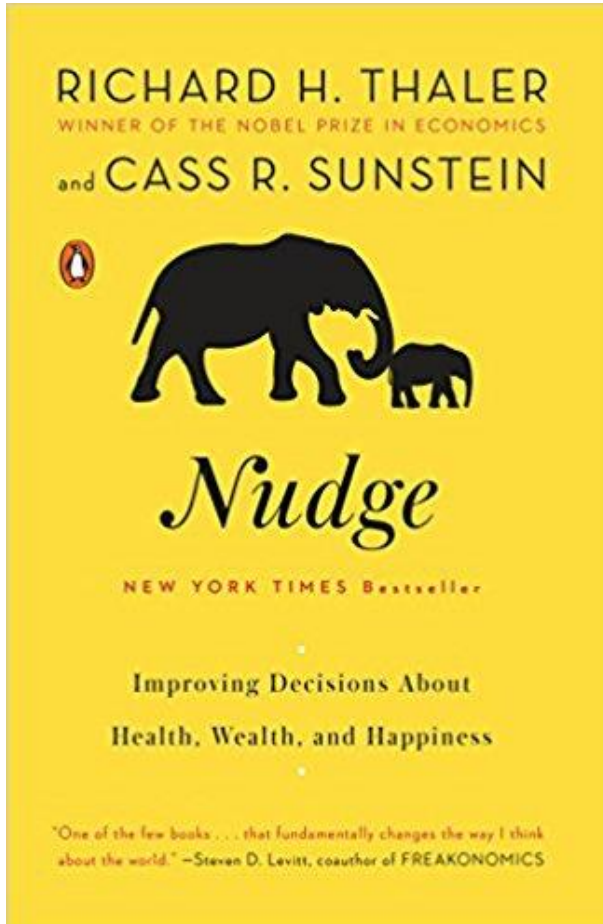
# Reasons for non-adherence



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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.”



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# Nudges are increasingly being used in healthcare to change behavior

## Nudge Units to Improve the Delivery of Health Care

Mitesh S. Patel, M.D., M.B.A., Kevin G. Volpp, M.D., Ph.D., and David A. Asch, M.D., M.B.A.

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

### A Randomized, Controlled Trial of Financial Incentives for Smoking Cessation

Kevin G. Volpp, M.D., Ph.D., Andrea B. Troxel, Sc.D., Mark V. Pauly, Ph.D., Henry A. Glick, Ph.D., Andrea Puig, B.A., David A. Asch, M.D., M.B.A., Robert Galvin, M.D., M.B.A., Jingsan Zhu, M.B.A., Fei Wan, M.S., Jill DeGuzman, B.S., Elizabeth Corbett, M.L.S., Janet Weiner, M.P.H., and Janet Audrain-McGovern, Ph.D.

SUPPLEMENT

Annals of Internal Medicine

### Using Default Options Within the Electronic Health Record to Increase the Prescribing of Generic-Equivalent Medications

A Quasi-experimental Study

Mitesh S. Patel, MD, MBA, MS\*; Susan Day, MD, MPH; Dylan S. Small, PhD; John T. Howell III, MD; Gillian L. Lautenbach, MD; Elliot H. Nieman, MD; and Kevin G. Volpp, MD, PhD

JAMA Internal Medicine | Original Investigation

### Effect of a Game-Based Intervention Designed to Enhance Social Incentives to Increase Physical Activity Among Families: The BE FIT Randomized Clinical Trial

Mitesh S. Patel, MD, MBA, MS; Emelia J. Benjamin, MD, ScM; Kevin G. Volpp, MD, PhD; Caroline S. Fox, MD, MPH; Dylan S. Small, PhD; Joseph M. Massaro, PhD; Jane J. Lee, PhD; Victoria Hilbert, MPH, RD; Maureen Valentino, BA; Devon H. Taylor, MPH; Emily S. Manders, BS; Karen Mutalik, BS; Jingsan Zhu, MBA, MS; Wenli Wang, MS; Joanne M. Murabito, MD, ScM

# 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

# 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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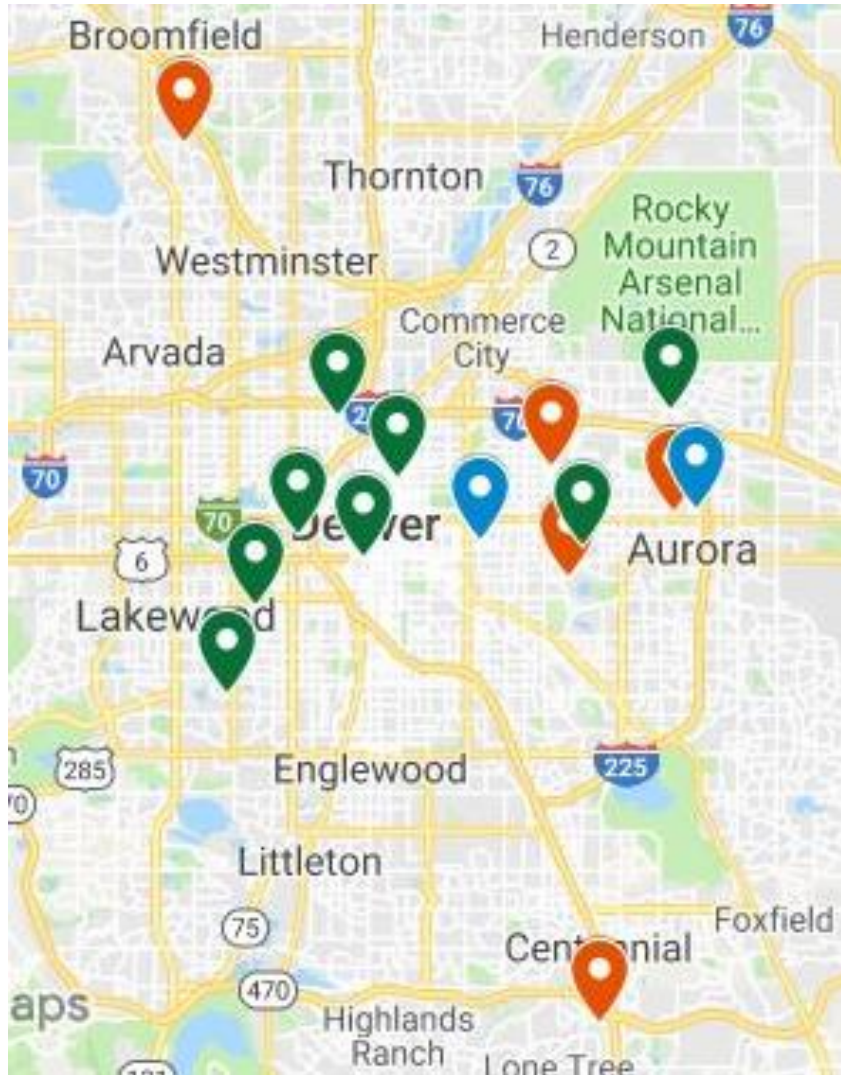
# Nudge Aims for Year 1 (UG3 phase)


- **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

## Nudge

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# Patients with cardiovascular conditions will be included

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

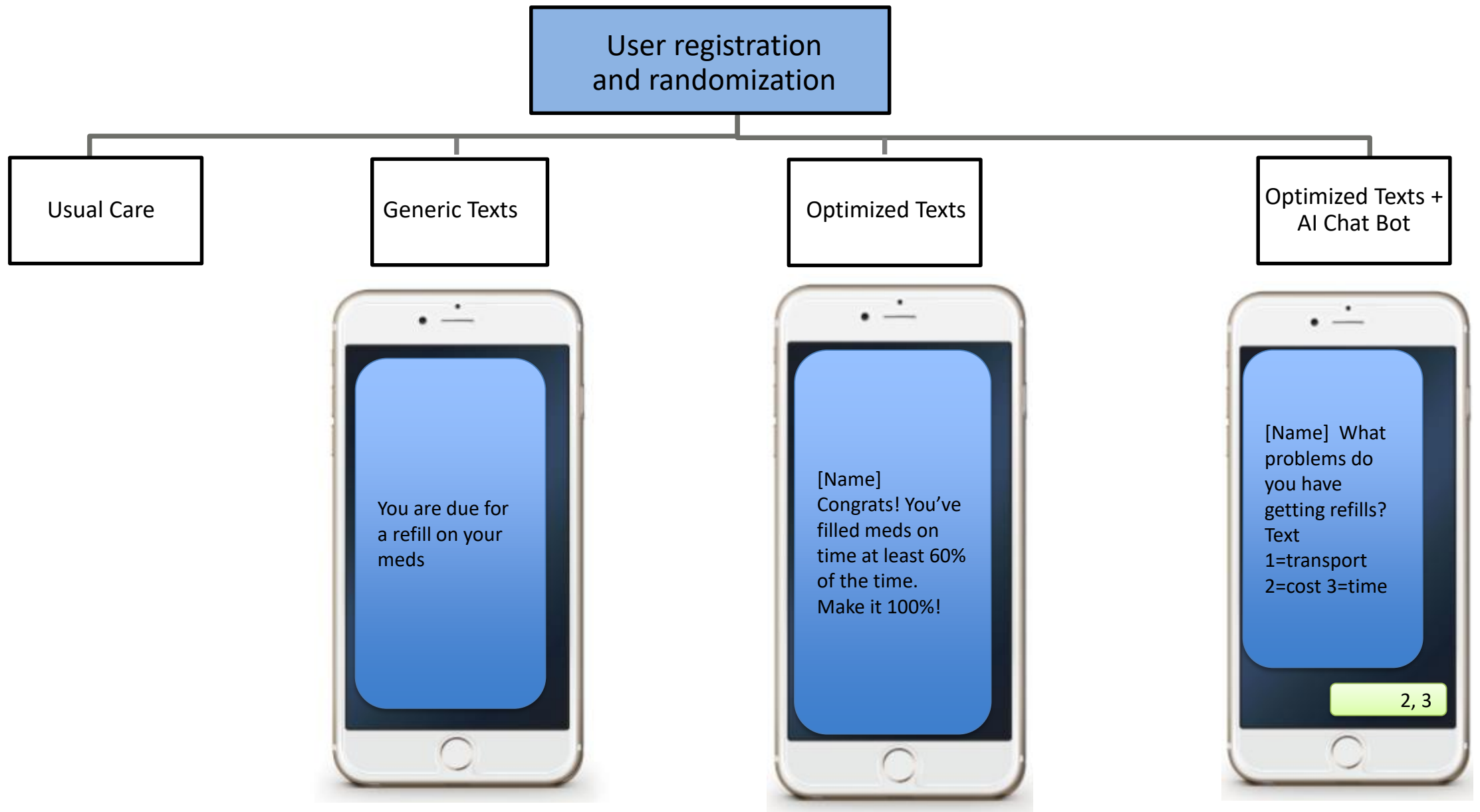
Condition	Classes of medications
Hypertension	Beta-blockers (B-blockers), Calcium Channel Blocker (CCB), Angiotensin converting enzyme inhibitors (ACEi), Angiotensin Receptor Blockers (ARB), Thiazide diuretic
Hyperlipidemia	HMG CoA reductase inhibitor (Statins)
Diabetes	Alpha-glucosidase inhibitors, 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



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# Intervention arms for the proposed pragmatic trial





**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

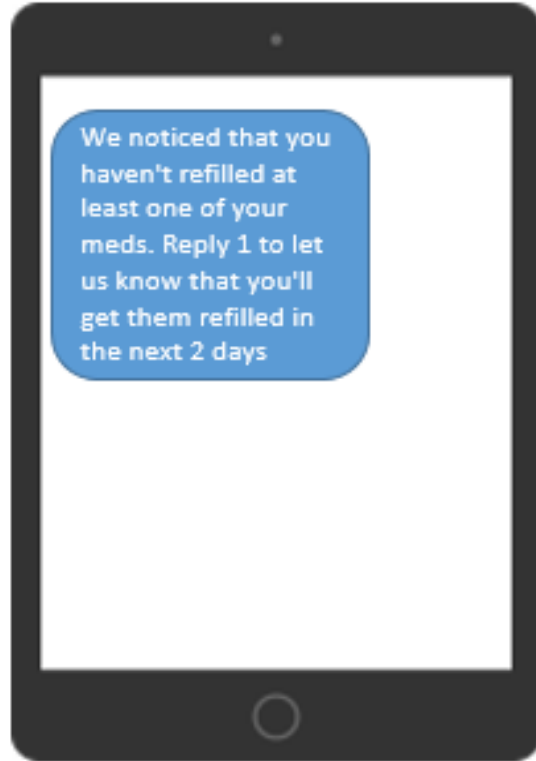
- Using an N of 1 study design, we have interviewed 31 persons across three systems to get their feedback on message design and content

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Day 1 continued...

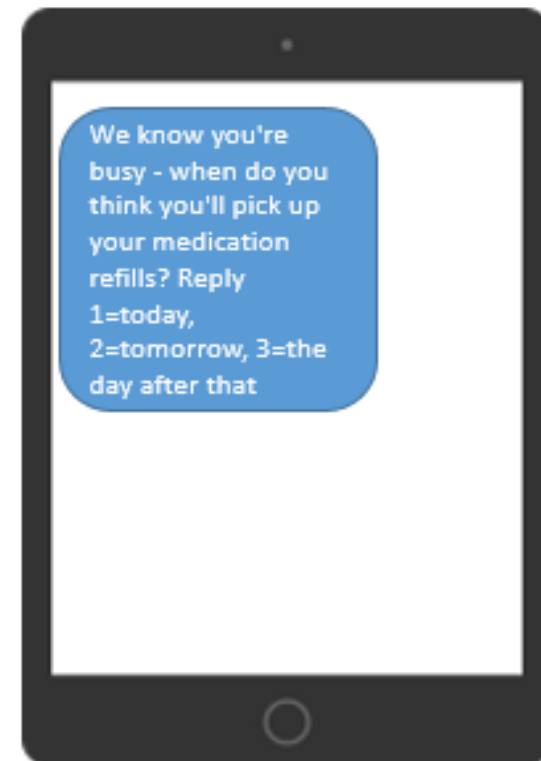
## SCREEN 2



A



B

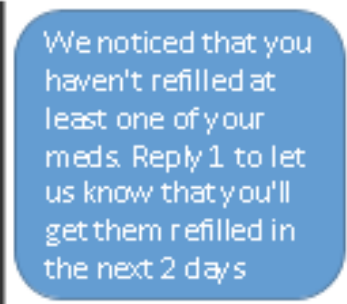
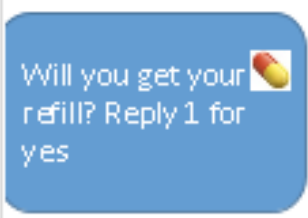
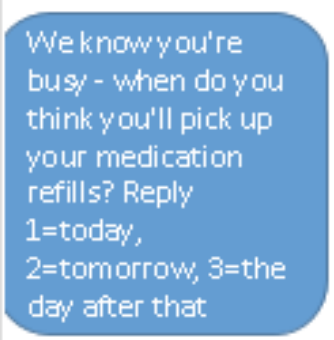


C

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	<b>Screen2</b>		
	<b>A</b>	<b>B</b>	<b>C</b>
<b>Offensive</b>			
<b>Don't Understand</b>			
<b>Don't Like</b>			2
<b>TOTAL NEGATIVE (SUM of first 3 variables)</b>	0	0	2
<b>Positive Response</b>	1	1	
<b>Other suggestions or feedback for specific messages</b>		UCH116 "Positive simple quick reminder"	UCH116-"big brother like"



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# N of 1 interviews

## Progress & Findings

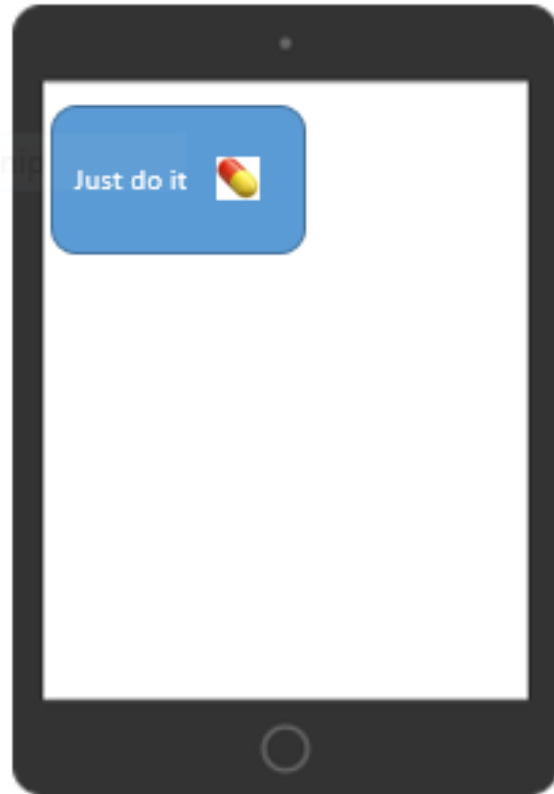
- “I like that the messages put the ownership on self.”
- “I like the ones that relate to a hospital stay. I’ve been in the hospital and once you have done that you will want to avoid it in the future. It’s good motivation for me to stay out of the hospital.”
- “The message validates my feelings that 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.”



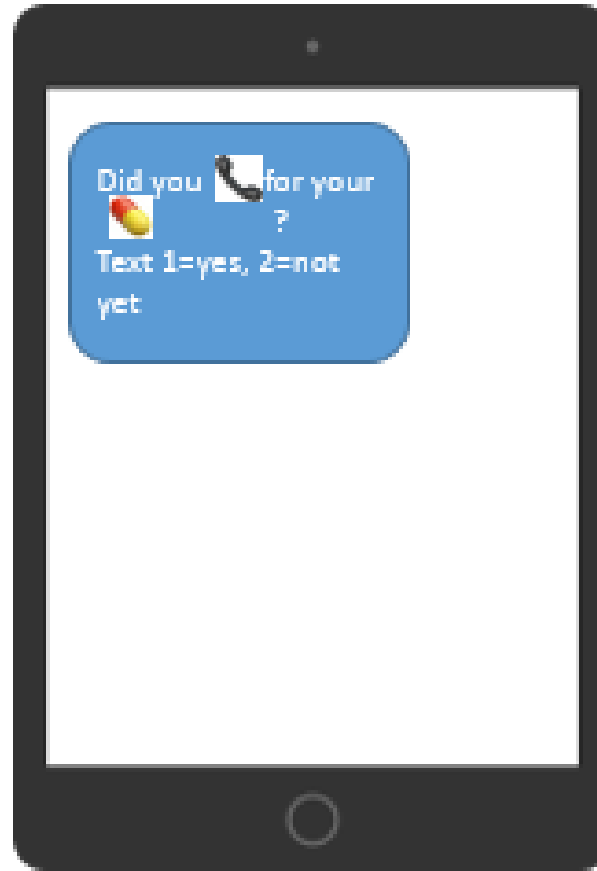
# N of 1 interviews

## Progress & Findings

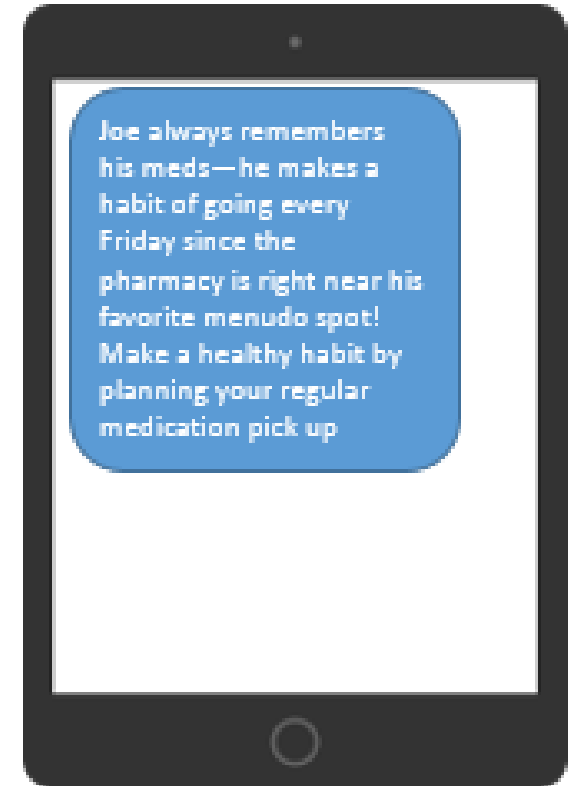
Examples of messages that received negative feedback



B



C

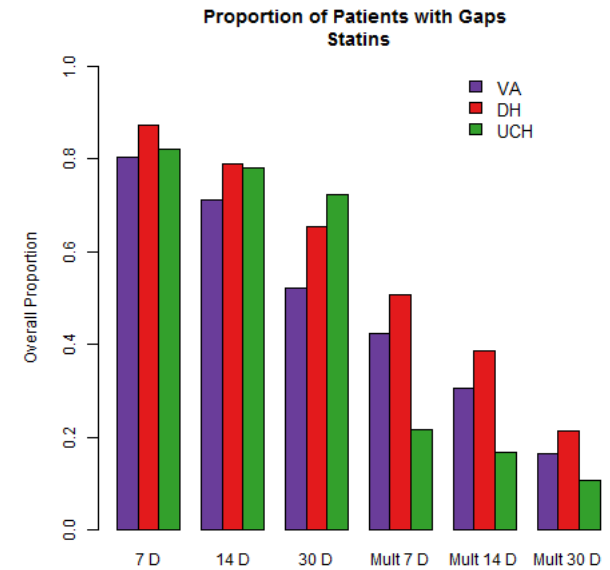
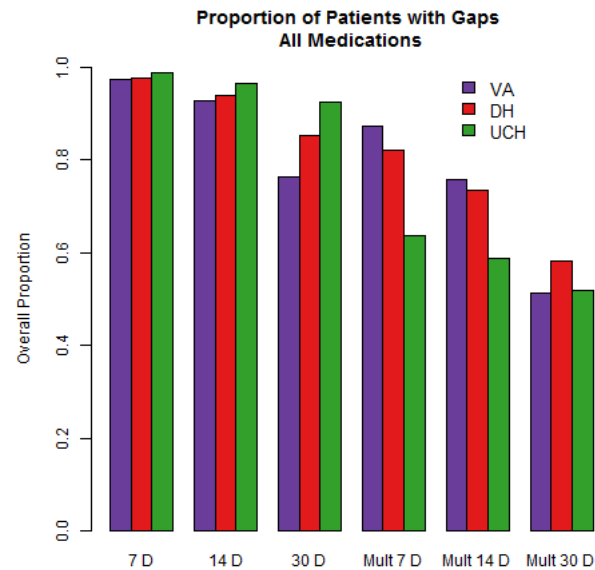
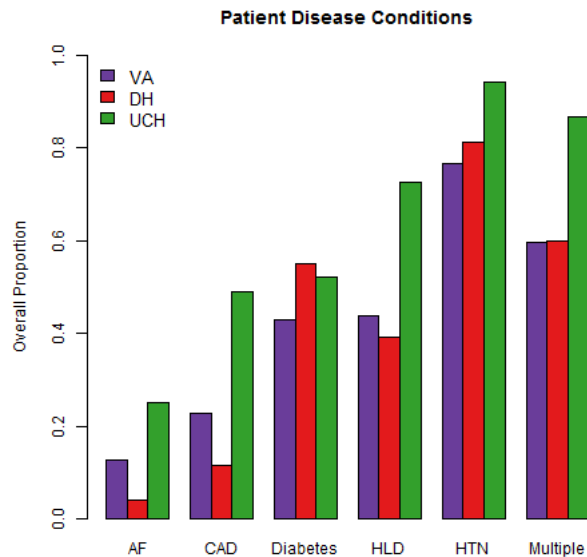


C

# 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



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### **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
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	<b>Patients that opted-out</b>	<b>Packets returned by USPS</b>
<b>UCHealth</b>	22 (11.0%)	6 (3.0%)
<b>Denver Health</b>	12 (6.0%)	3 (1.5%)
<b>Denver VA</b>	36 (18.0%)	0
<b>Total</b>	<b>70 (11.7%)</b>	<b>9 (1.5%)</b>



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## **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).



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# Initial findings from feasibility and usability

Date	Time	Location	Response	Study Arm	Notes
1/7/18	12:04 PM	UCH	STOP	Generic messages	
1/7/18	12:08 PM	UCH	DONE	Generic messages	
1/7/18	12:01 PM	DH	DONE	Generic messages	
1/7/18	12:01 PM	DH	Español	Optimized	JW opted out of <u>DH Pilot Optimized Arm</u> and opted into <u>DH Pilot Optimized Spanish Arm</u>
1/7/18	12:01 PM	VA	DONE	Generic Messages	
1/7/18	12:01 PM	VA	DONE	Chatbot Messages	
1/7/18	1:40 PM	UCH	STOP	Chatbot Messages	
1/7/18	4:20	UCH	STOP	Chatbot Messages	Patient first responded "Help, which meds didn't I get refills for?" then replied STOP
1/7/18	12:27	DH	Español	Chatbot Messages	JW opted out of <u>DH Pilot Chatbot Arm</u> and opted into <u>DH Pilot Chatbot Spanish Arm</u>
1/7/18	12:52	DH	Español	Chatbot Messages	JW opted out of <u>DH Pilot Chatbot Arm</u> and opted into <u>DH Pilot Chatbot Spanish Arm</u>
1/7/18	2:13 PM	VA	DONE	Chatbot Messages	

Body	MMS	Campaign	Received	Actions
2		DH_Chatbot_Pilot Row: #2 This is ...rom the ...	Today at 11:05AM MST	✗ ★ 📧
1		DH_Chatbot_Pilot Row: #2 This is ...rom the ...	1/9/2019 3:46PM MST	✗ ★ 📧
4		DH_Chatbot_Pilot Row: #2 This is ...rom the ...	1/9/2019 3:45PM MST	✗ ★ 📧
Done		DH_Nudge_Generic_Pilot Row: #2 This is ...roject a...	1/9/2019 2:23PM MST	✗ ★ 📧
Dont know what it is		DH_Nudge_Generic_Pilot Row: #2 This is ...roject a...	1/9/2019 2:06PM MST	✗ ★ 📧
Ya lo hice		DH_Chatbot_Pilot_Spanish Row: #2 Este es ... Nudge d...	1/9/2019 2:06PM MST	✗ ★ 📧
1		DH_Optimize...lot_Spanish Row: #1 Este es ... Nudge d...	1/7/2019 3:07PM MST	✗ ★ 📧
Español		DH_Chatbot_Pilot Row: #1 This is ...rom the ...	1/7/2019 12:52PM MST	✗ ★ 📧
Español. Po. favor		DH_Chatbot_Pilot Row: #1 This is ...rom the ...	1/7/2019 12:27PM MST	✗ ★ 📧
Done		DH_Nudge_Generic_Pilot Row: #1 This is ...rom the ...	1/7/2019 12:01PM MST	🗨️ ★ 📧
Español		DH_Optimized_Pilot Row: #1 This is ...rom the ...	1/7/2019 12:01PM MST	✗ ★ 📧

# 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



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# 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?

