

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

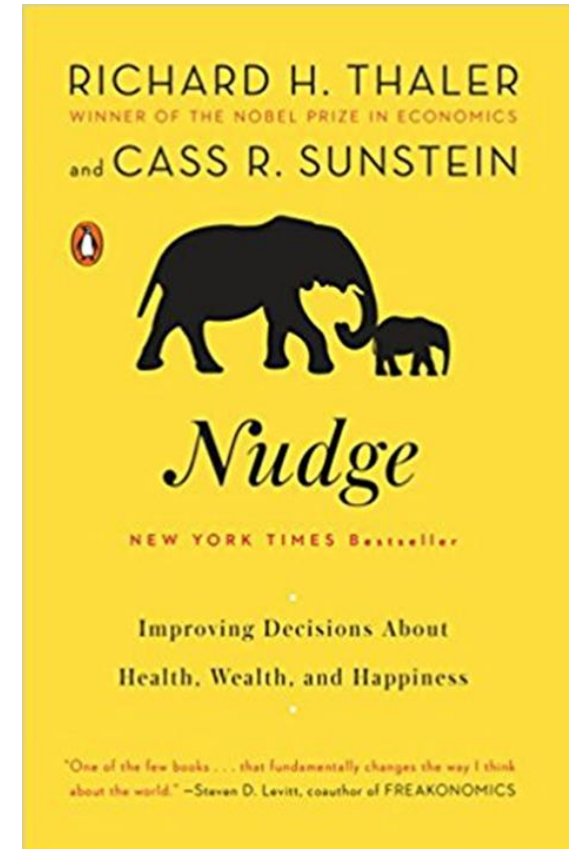
Michael Ho, MD, PhD & Sheana Bull, PhD, MPH
University of Colorado Anschutz Medical Campus
NIH Collaboratory Grand Rounds

AGENDA

- BACKGROUND
- NUDGE STUDY OVERVIEW
- PILOT YEAR FINDINGS
- CURRENT STATUS OF PRAGMATIC STUDY
- QUESTIONS

WHAT IS A NUDGE?

- A small change in choice framing or choice architecture
 - Example: “Putting the fruit at eye level counts as a nudge. Banning junk food does not.”
- Strategic reminder that can potentially help people adopt healthy behaviors
- Nobel prize winning economists have shown this can work to improve nutrition, physical activity and other behaviors



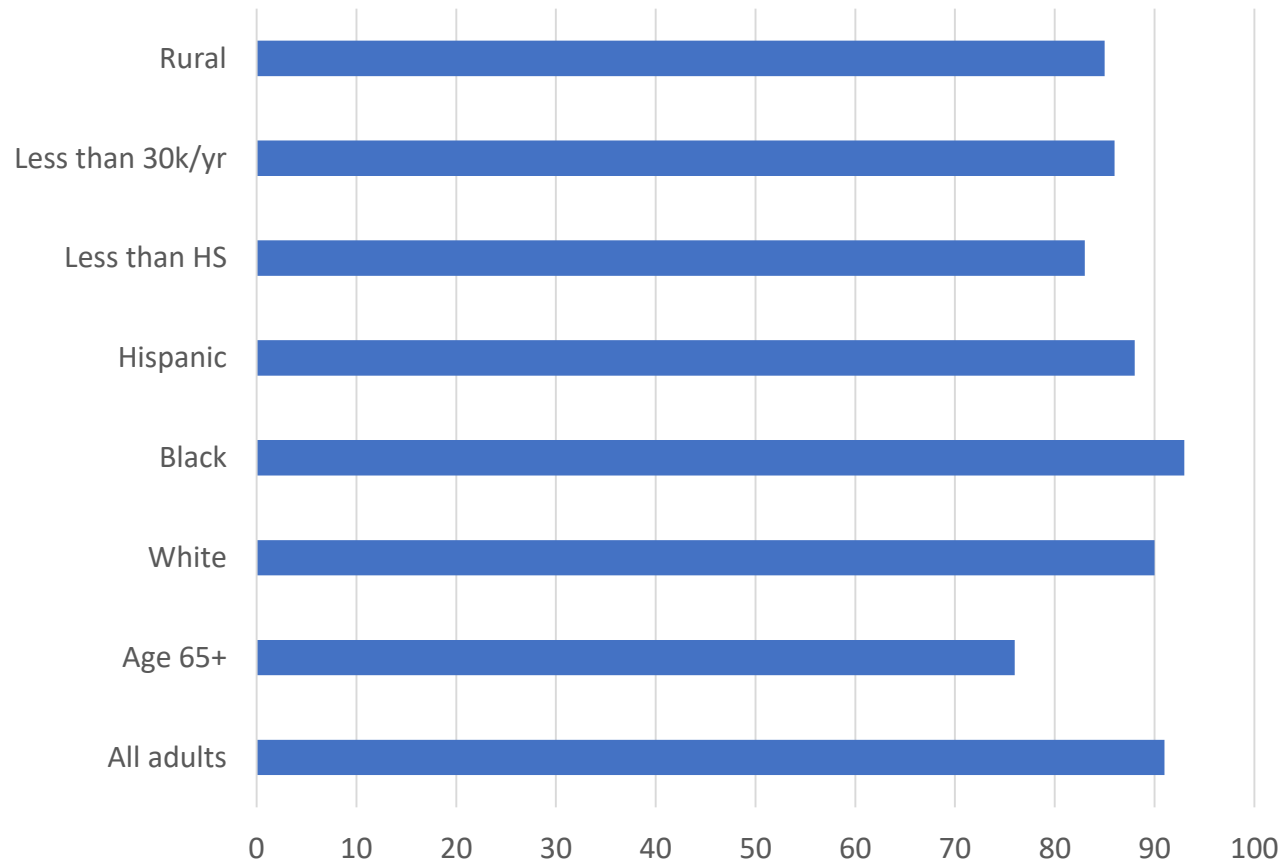
TYPES OF NUDGES EMPLOYED IN THIS STUDY

- Social Norms: Others like you are performing this behavior
 - Examples—testimonials *”People like Joseph have had success in remembering to pick up his meds by making it a habit to drive by his pharmacy on the way home from work”*
- Behavioral Commitments: Making a stated intention to take action
 - Example--*”Will you mention to a family member your intention to refill your medications today?”*
- Narrative stories: Evoking emotional connection
 - Example—*”Marta has committed to her daughter that she will stay on top of her refills so she’ll be around longer for her grandkids!”*

CELLPHONE USE IS UBIQUITOUS

<https://www.pewresearch.org/fact-tank/2013/06/06/cell-phone-ownership-hits-91-of-adults/>
<https://instantcensus.com/blog/almost-90-of-americans-have-unlimited-texting>

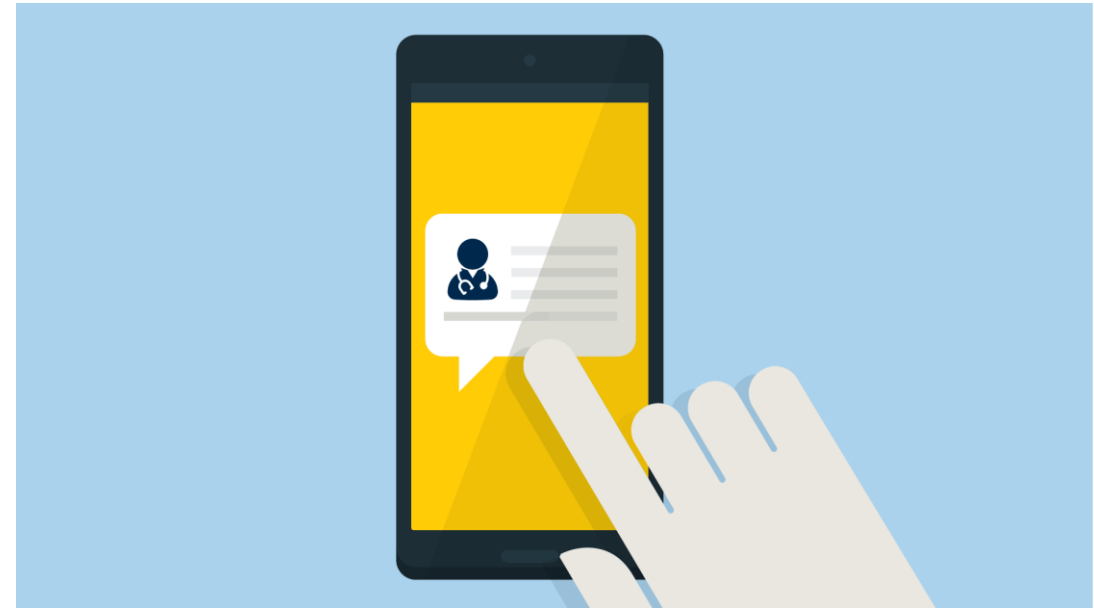
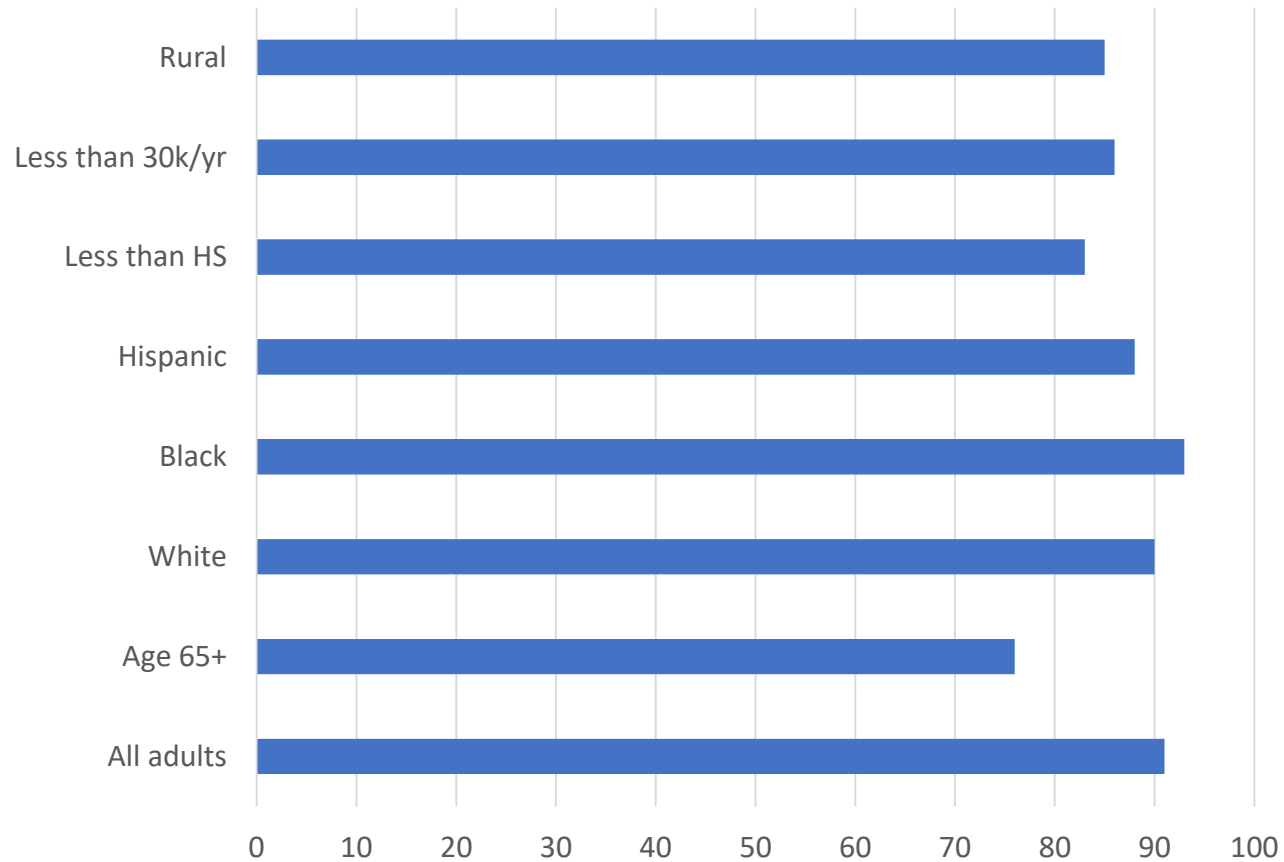
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<https://www.pewresearch.org/fact-tank/2013/06/06/cell-phone-ownership-hits-91-of-adults/>

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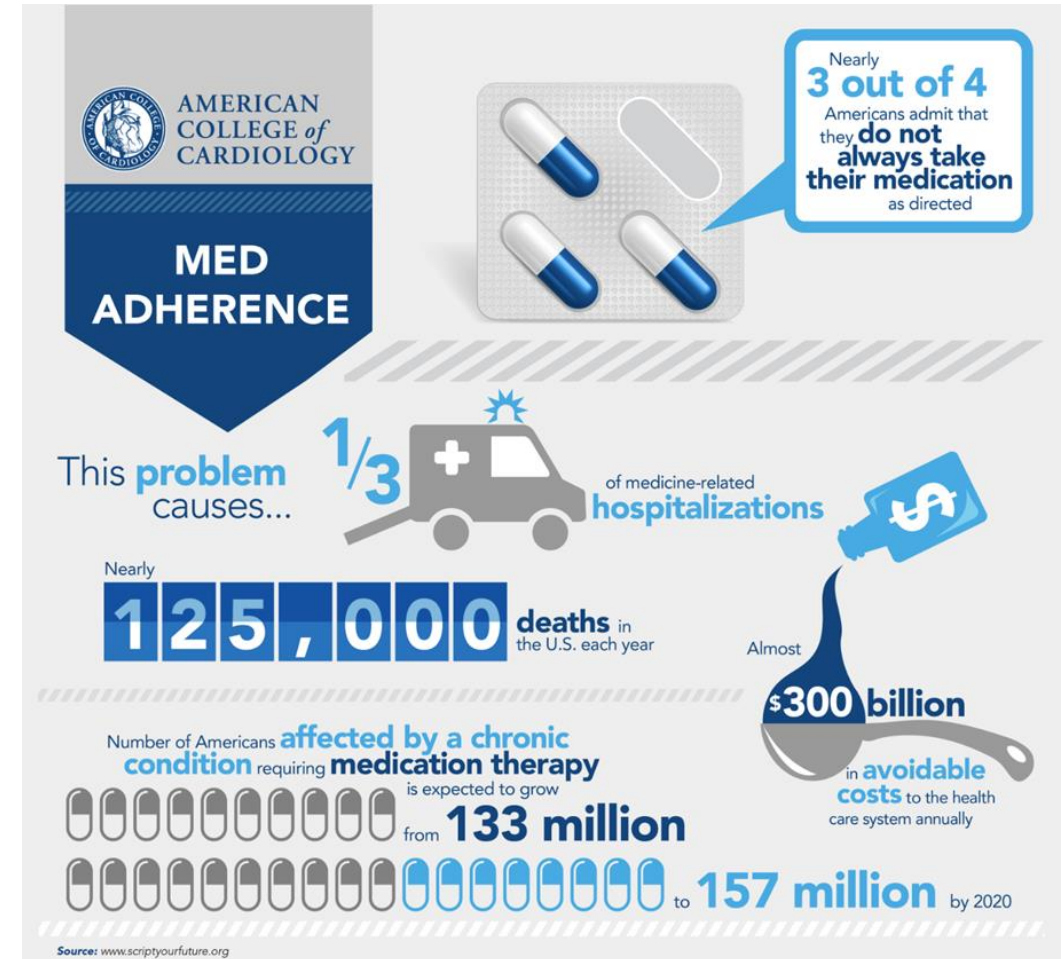
CELLPHONE USE IS UBIQUITOUS



88% of US cellphones have unlimited text messaging

MEDICATION NONADHERENCE

- Up to 50% of patients do not take their CV medications as prescribed
- Nonadherence associated with increased CV events
- Prior attempts to improve adherence are costly, time consuming and have inconsistent benefit



STUDY OBJECTIVES

- Conduct a pragmatic patient-level randomized intervention across 3 HCS to improve adherence to chronic CV medications.
 - Primary outcome: Medication adherence defined by the proportion of days covered (PDC) using pharmacy refill data.
 - Secondary outcomes:
 - Intermediate clinical measures (e.g., BP control)
 - CV clinical events (e.g., hospitalizations)
 - Healthcare utilization
 - Costs

STUDY SETTING



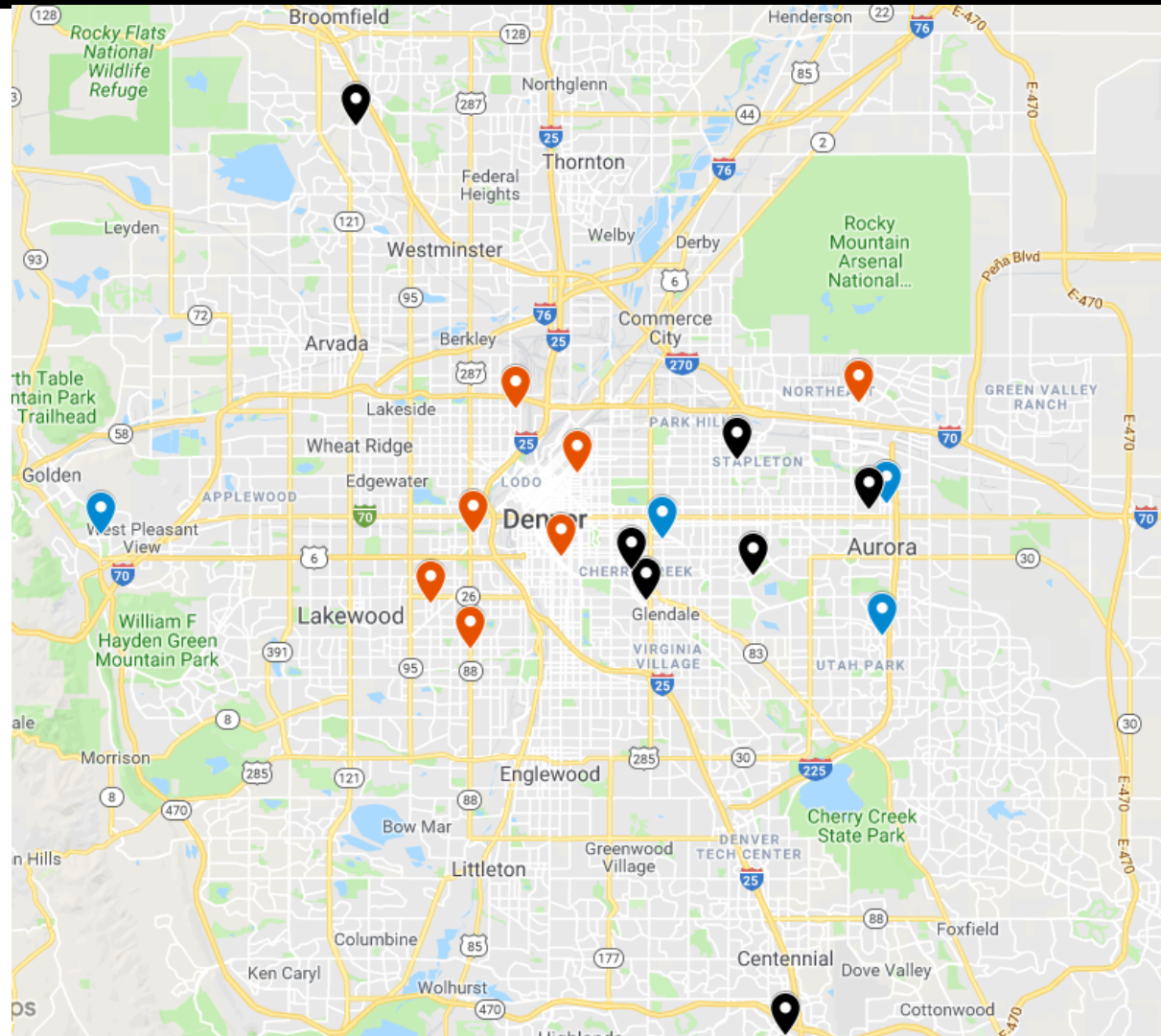
Denver Health Clinics



VA Eastern Colorado HCS Clinics



UCHealth Clinics



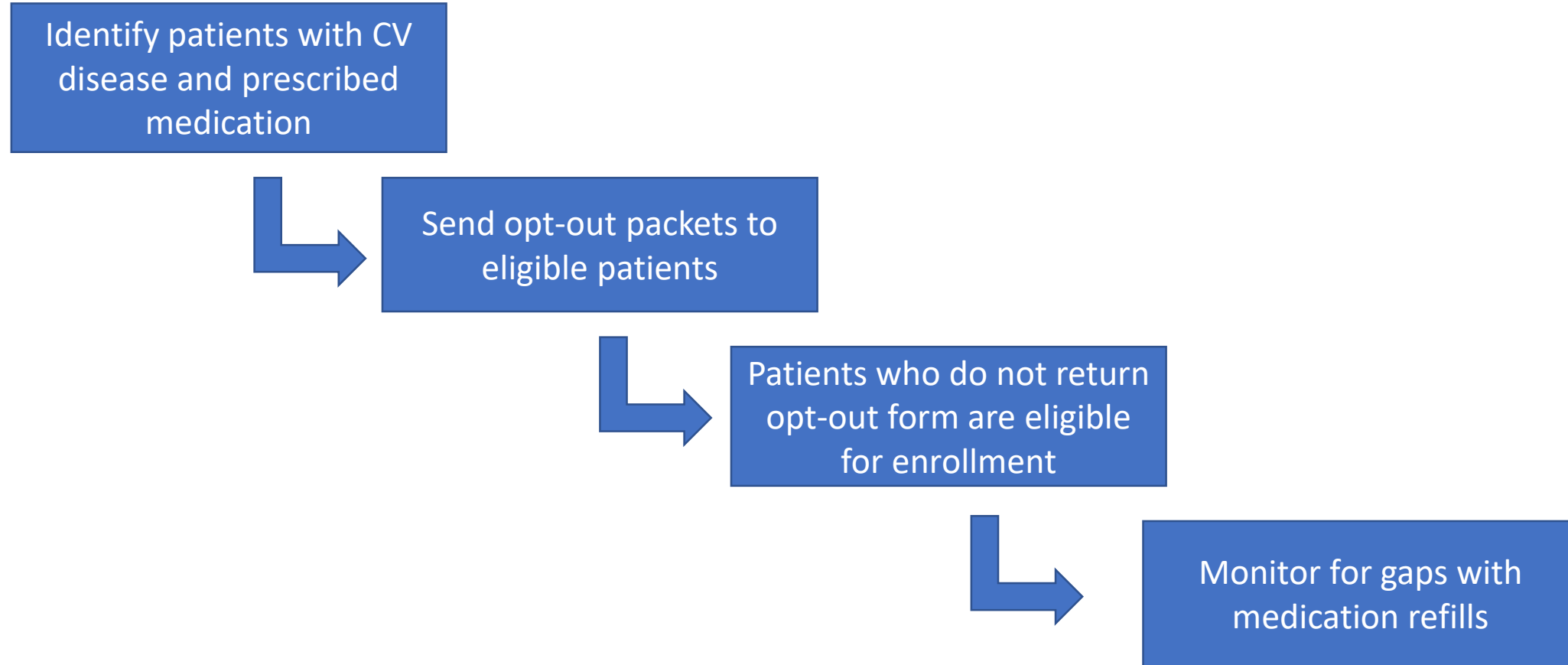
PATIENT POPULATION

- Adult patients diagnosed with ≥ 1 condition of interest and prescribed ≥ 1 medication of interest

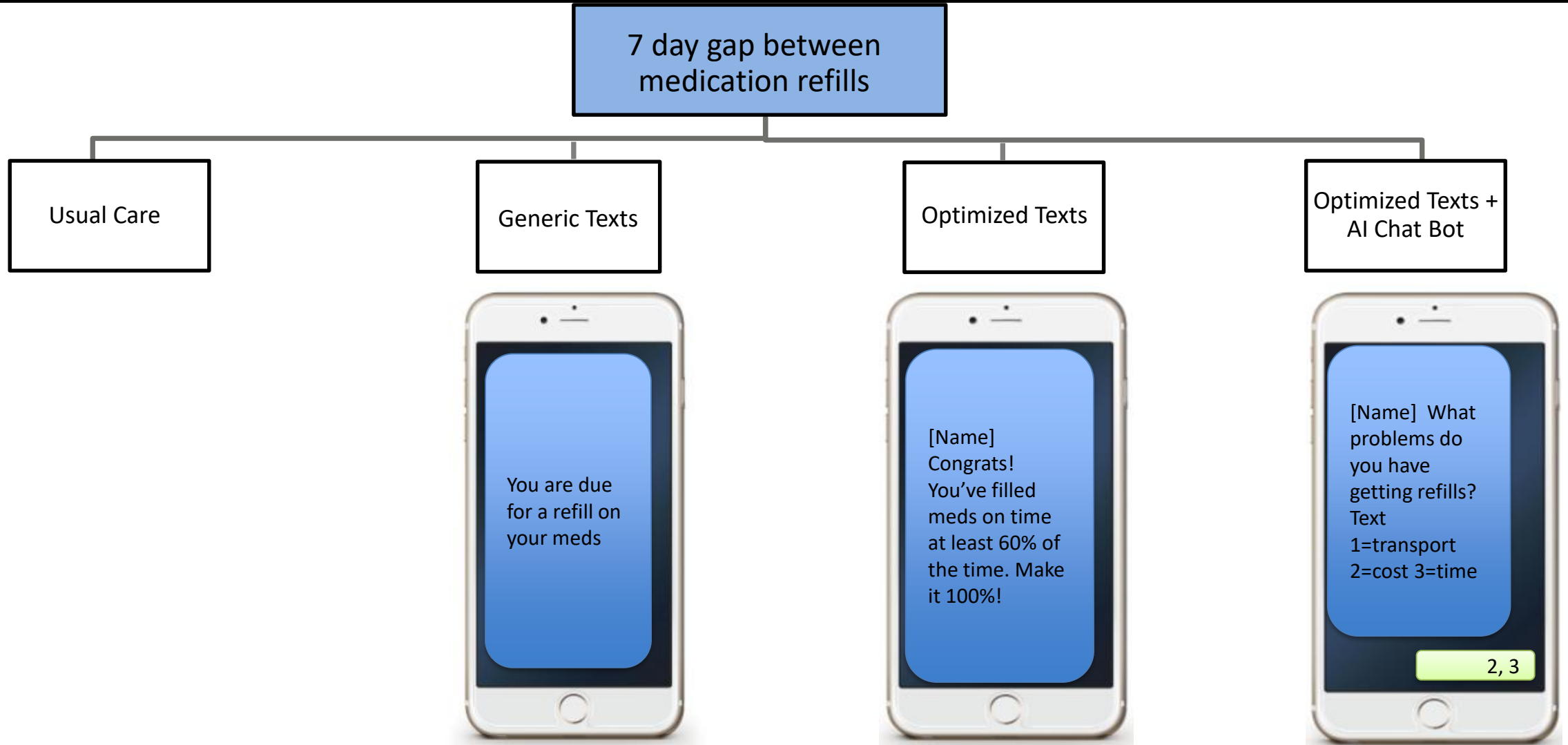
Condition	Classes of medications
Hypertension	Beta-blockers (B-blockers), Calcium Channel Blocker (CCB), Angiotensin converting enzyme inhibitors (ACEi), Angiotensin Receptor Blockers (ARB), Thiazide diuretic
Hyperlipidemia	HMG CoA reductase inhibitor (Statins)
Diabetes	Alpha-glucosidase inhibitors,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

- English or Spanish-speaking

OPT-OUT STUDY DESIGN



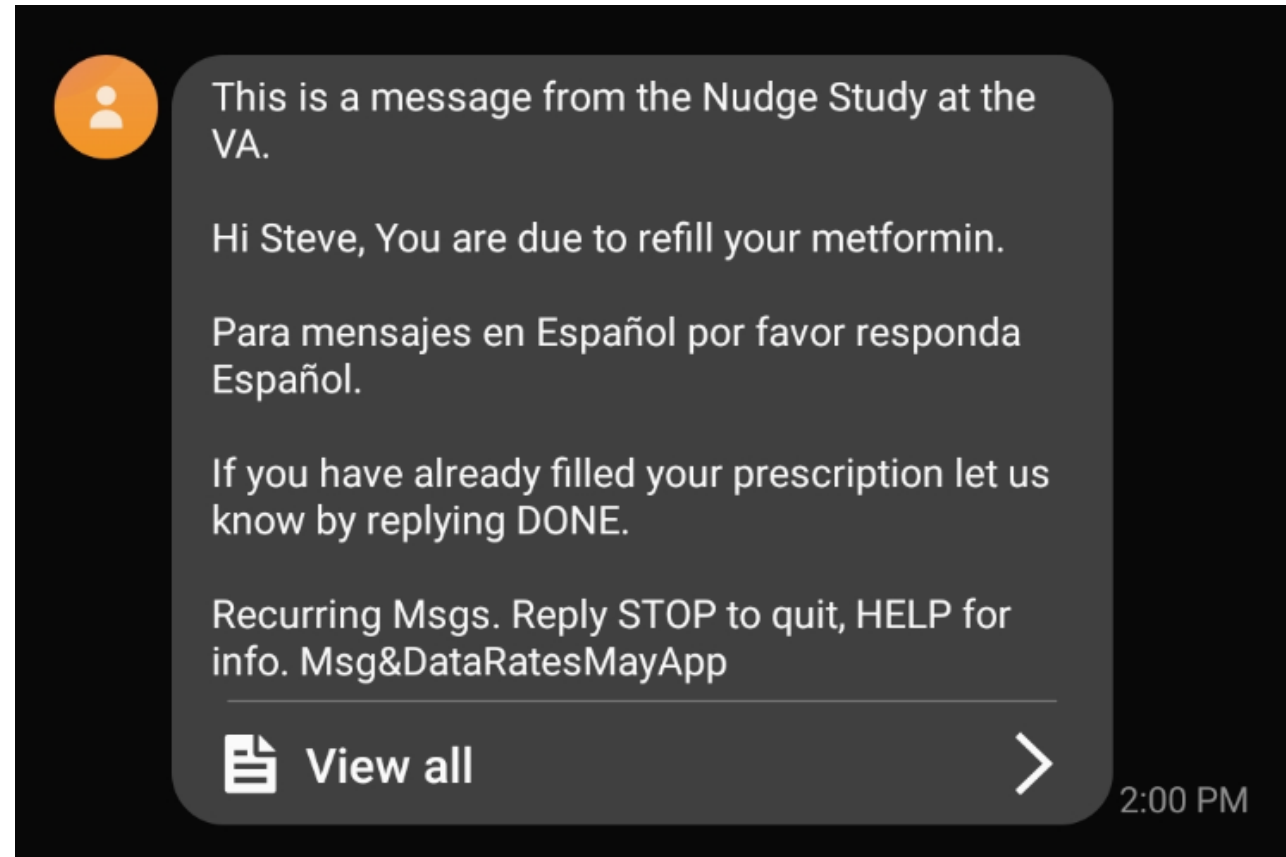
INTERVENTION ARMS



YEAR 1 OBJECTIVES

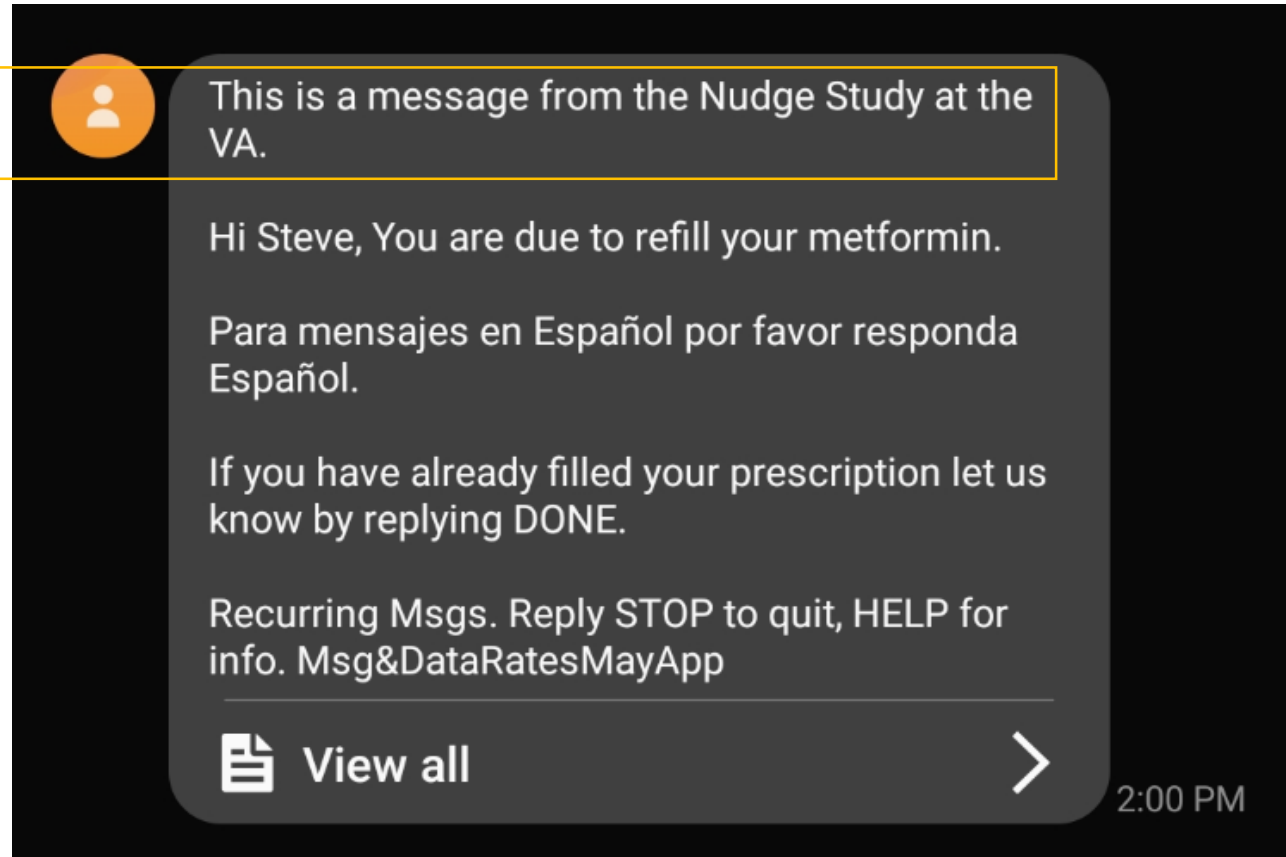
- **Aim 1:** Develop message library and chat bot content library
- **Aim 2:** Determine the potential population eligible for the intervention across the 3 HCS
- **Aim 3 :** Conduct a pilot study of the intervention

SAMPLE MESSAGES SENT



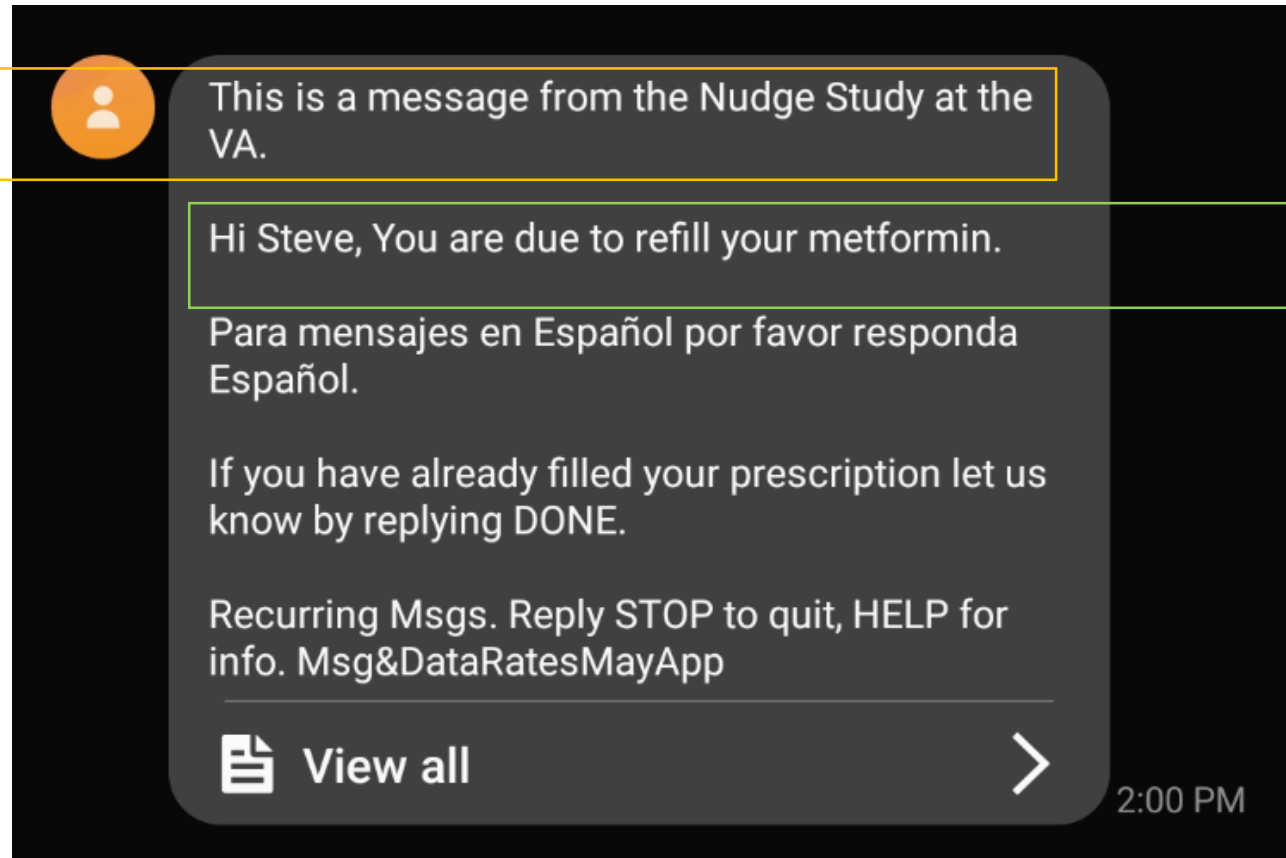
SAMPLE MESSAGES SENT

Introduction



SAMPLE MESSAGES SENT

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Generic Nudge



SAMPLE MESSAGES SENT

Introduction



This is a message from the Nudge Study at the VA.

Hi Steve, You are due to refill your metformin.

Para mensajes en Español por favor responde Español.

Temporary opt-out

If you have already filled your prescription let us know by replying DONE.

Recurring Msgs. Reply STOP to quit, HELP for info. Msg&DataRatesMayApp

 View all



2:00 PM

Generic Nudge

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Generic Nudge

Study opt-out

 View all



2:00 PM

SAMPLE MESSAGES SENT



This is a message from the Nudge Study at Denver Health.

Hi Steve,

We noticed you haven't refilled your Metformin. Reply 1= I'll get them refilled in the next 2 days. Reply 2= I'm still working on a plan to get this done

This is the 1st of 5 messages you'll receive until you can refill

11:43 AM

SAMPLE MESSAGES SENT



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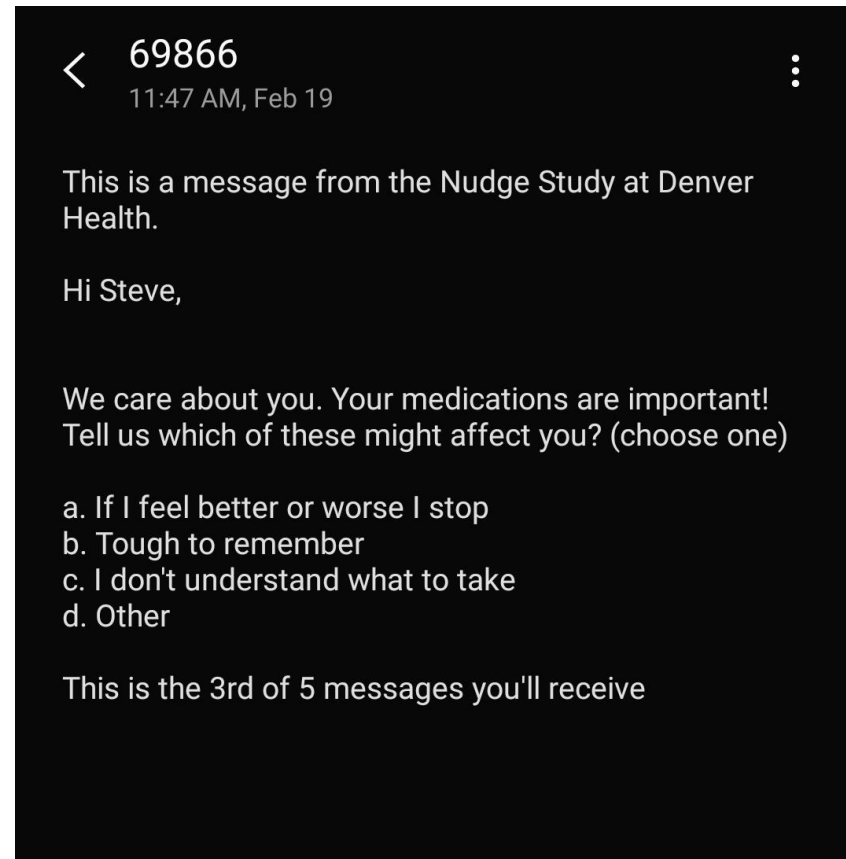
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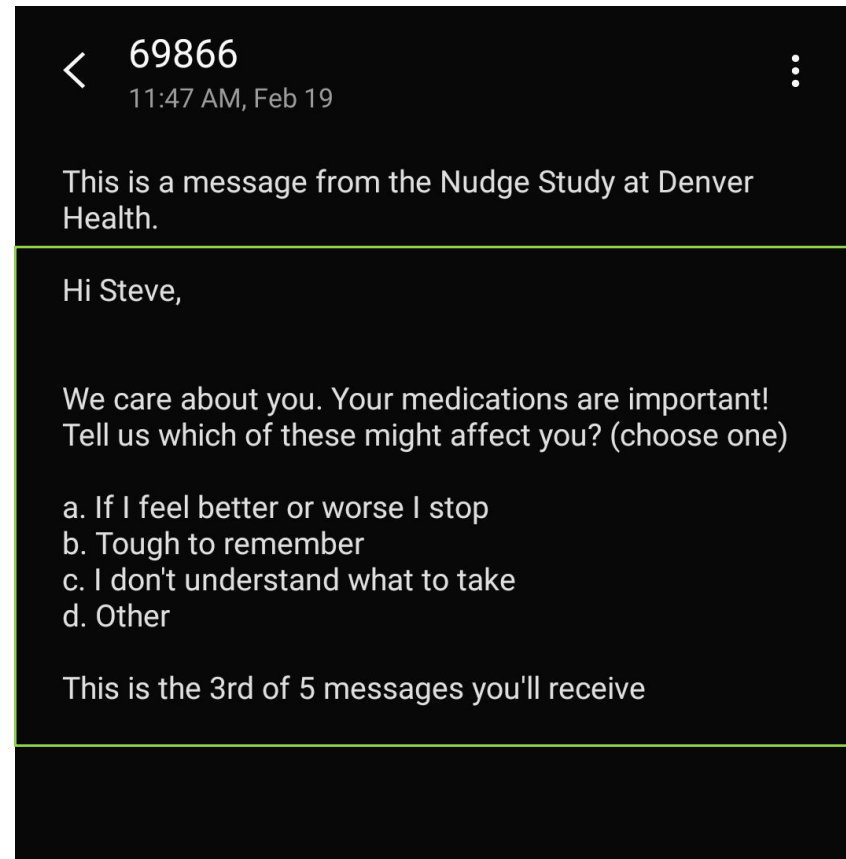
Optimized Nudge



SAMPLE MESSAGES SENT



SAMPLE MESSAGES SENT



Chatbot Nudge



PATIENT FEEDBACK ABOUT MESSAGES

- “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.”

DETERMINE THE POTENTIAL POPULATION ELIGIBLE FOR THE INTERVENTION ACROSS THE 3 HCS

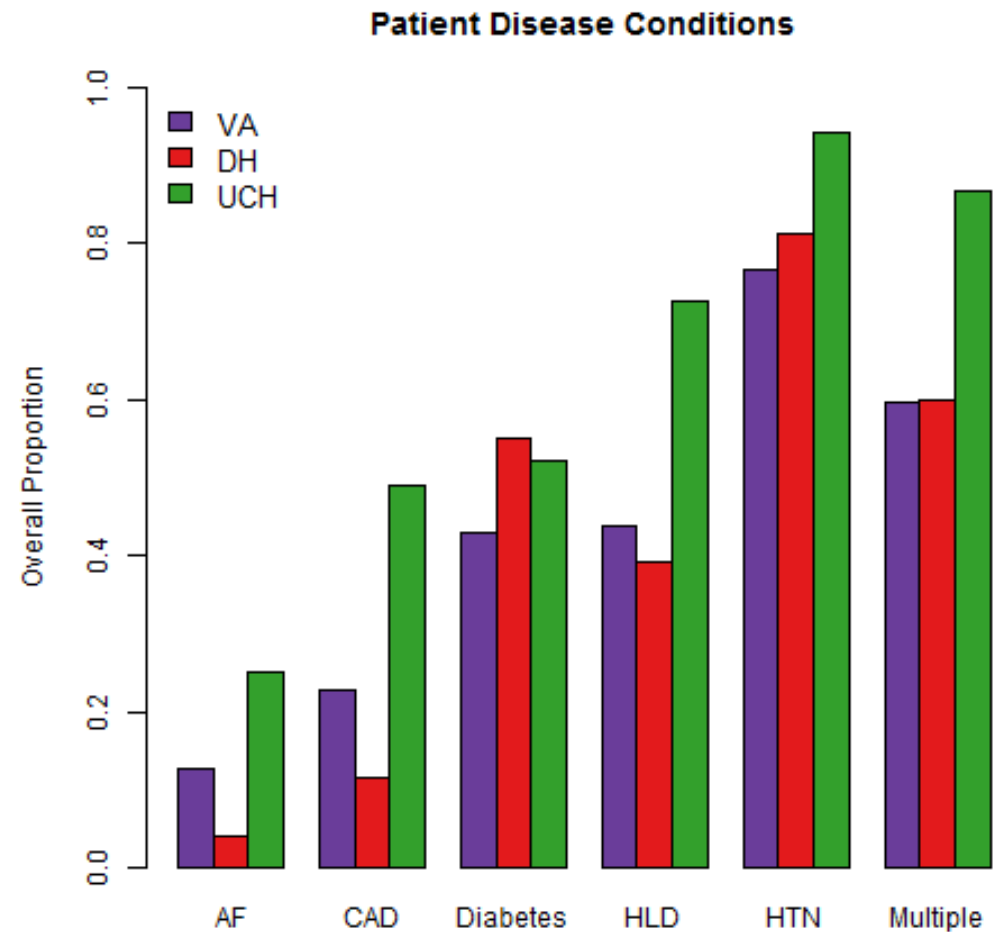
- Retrospectively identified patients who would potentially be eligible to be enrolled at each HCS

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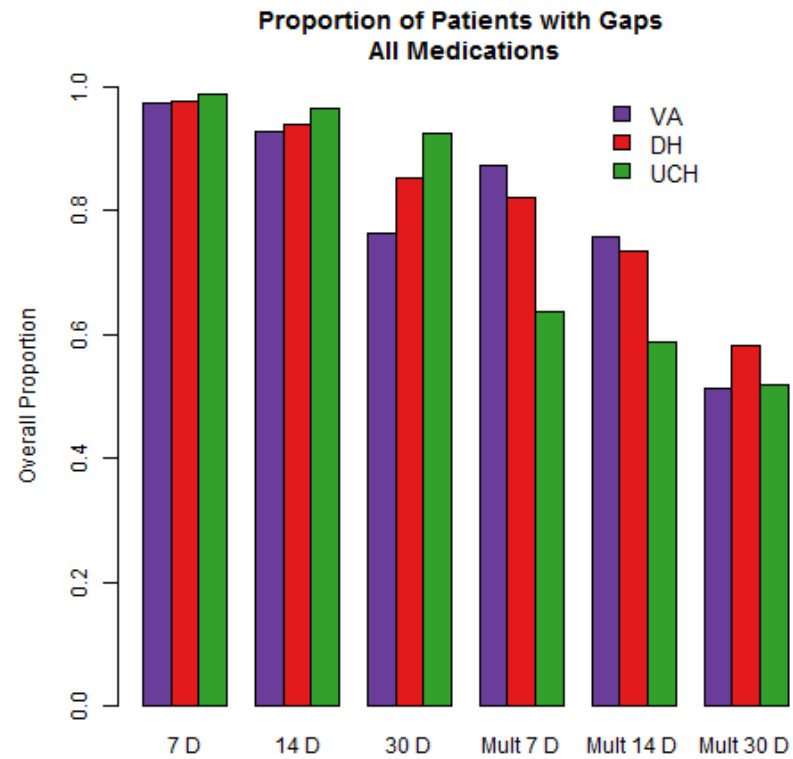
- Retrospectively identified patients who would potentially be eligible to be enrolled at each HCS
- Number of patients with at least 1 CV condition and 1 medication class prescribed
 - DH: 12,493
 - VA: 4,062
 - UCH: 1,082

DETERMINE THE POTENTIAL POPULATION ELIGIBLE FOR THE INTERVENTION ACROSS THE 3 HCS

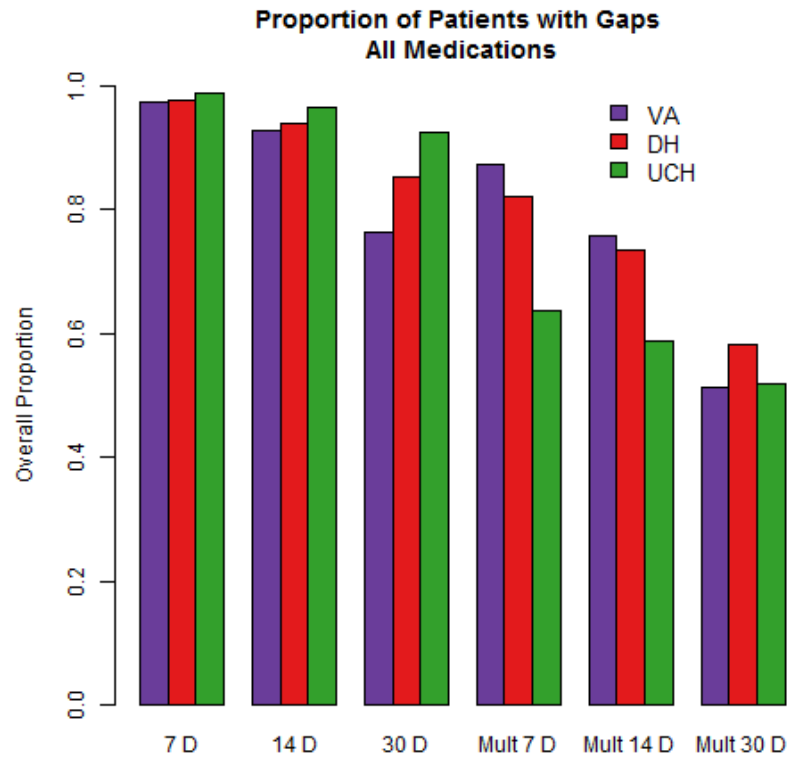
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GAPS IN MEDICATION REFILLS



GAPS IN MEDICATION REFILLS



Number of patients with a 7-day refill gap:

DH: 10,284

VA: 2,859

UCH: 821

CONDUCT A PILOT STUDY OF THE INTERVENTION

- **Opt-out packets** were sent to 400 total patients meeting inclusion criteria (200 patients per each HCS)
- Packet included an information sheet, opt-out sheet, self-addressed and stamped envelope
 - Two-week deadline to return opt-out form

CONDUCT A PILOT STUDY OF THE INTERVENTION

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	Total packets sent	Signed & returned an opt-out forms	Packets returned by USPS
Denver Health	200	13 (6.5%)	6 (3.0%)
VA	200	37 (18.5%)	0
Total	400	50 (12.5%)	6 (2.6%)



FOLLOWED PATIENTS FOR 7-DAY GAP

Characteristics of eligible patients in the pilot study

	Not Enrolled	Enrolled	p
Total N	79	207	
DEMOGRAPHICS			
Age - Mean (SD)	62.1 (10.9)	61.7 (11.9)	0.810
Male	64.6% (51)	69.1% (143)	0.481
Race			0.050
American Indian, Alaska Native	1.3% (1)	0% (0)	
Asian	0% (0)	0% (0)	
Black, African American	24.0% (19)	19.3% (40)	
Native Hawaiian, Pacific Islander	2.5% (2)	0% (0)	
White	63.3% (50)	72.5% (150)	
Multiple/Missing	3.8% (3)	2.9% (6)	
Hispanic	32.9% (26)	44.9% (93)	0.081
QUALIFYING CONDITIONS			
AF	6.3% (5)	8.7% (18)	0.631
CAD	13.9% (11)	20.3% (42)	0.238
Diabetes	38.0% (30)	58.0% (120)	0.003
Hyperlipidemia	32.9% (26)	42.5% (88)	0.177
Hypertension	87.3% (69)	78.7% (163)	0.128

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PATIENT RESPONSE TO TEXT MESSAGES

Message responses of patients assigned into intervention arms

	Arm 1	Arm 2	Arm 3	Arm 4	Total
N=	51	53	52	52	208
Responded Stop	-	1	4	4	9
Responded Done	-	12	11	9	32

DONE: Filled medication

STOP: Opt out of study

ARM 2: GENERIC TEXT

ARM 3: NUDGE TEXT

ARM 4: NUDGE TEXT + AI CHATBOT



Text Messages from Patients

- *Who is this?"*
- *"I thought my medications were up to date"*
- *"Can you tell me which medications I'm late on?"*
- *"Mas informacion no se cual medicamento" (I need more information because I do not know what medications [I need])"*
- *"No se ha cambiado los medicamentos siguen los mismos" (I haven't changed medication—I'm still taking the same ones)*
- *Yano tengo el descuento por eso no e ido a pedir me medicina (I no longer have the medication discount and haven't gone to get my medication)*

MEDICATION FILLS

Medication re-fill rates

	Arm 1	Arm 2	Arm 3	Arm 4
Total N	50	53	52	52
N Medications Gapping at Baseline - Median (IQR)	2 (1, 3)	1 (1, 3)	1 (1, 2)	2 (1, 3)
Filled at Least 1 Gapping Medication	18.0% (9)	32.1% (17)	32.7% (17)	26.9% (14)
Filled All Gapping Medications	10.0% (5)	17.0% (9)	21.2% (11)	15.4% (8)

ARM 2: GENERIC TEXT

ARM 3: NUDGE TEXT

ARM 4: NUDGE TEXT + AI CHATBOT

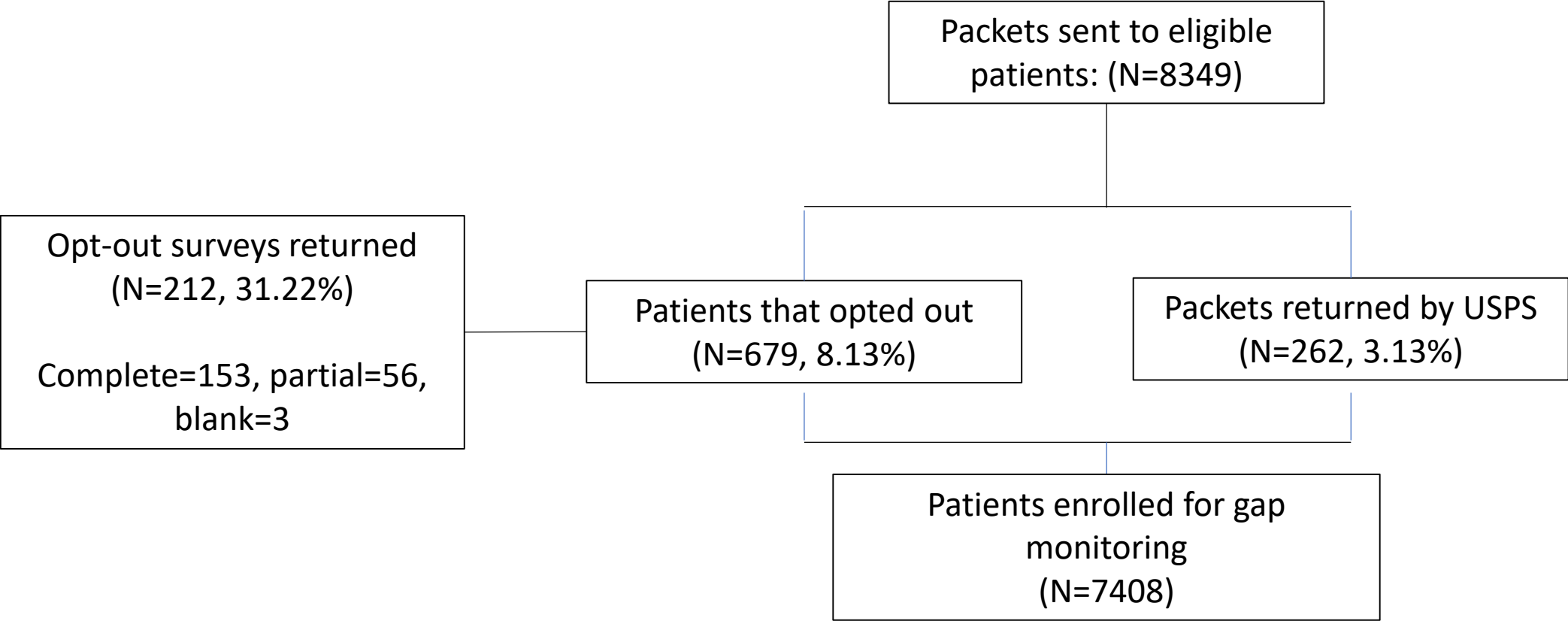


Years 2-5: PROJECTED TIMELINE

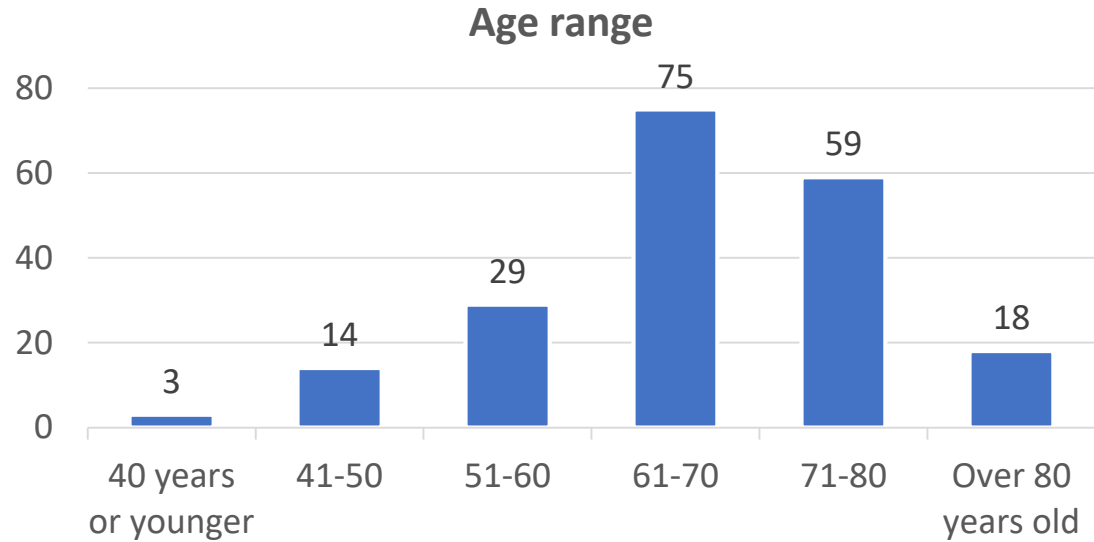
Clinic site visits		7/10/19 – 9/19/19
Patient opt-out period		9/1/19 – 9/30/19
Intervention period		10/1/19 – 6/30/21
Patient follow-up		7/1/21 – 6/30/22
Analysis & Dissemination		7/1/22 – 6/30/23



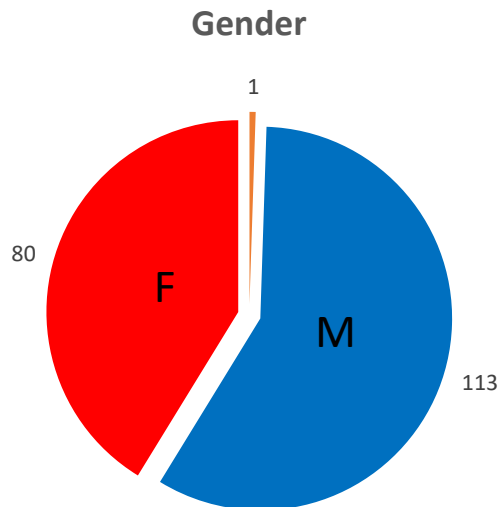
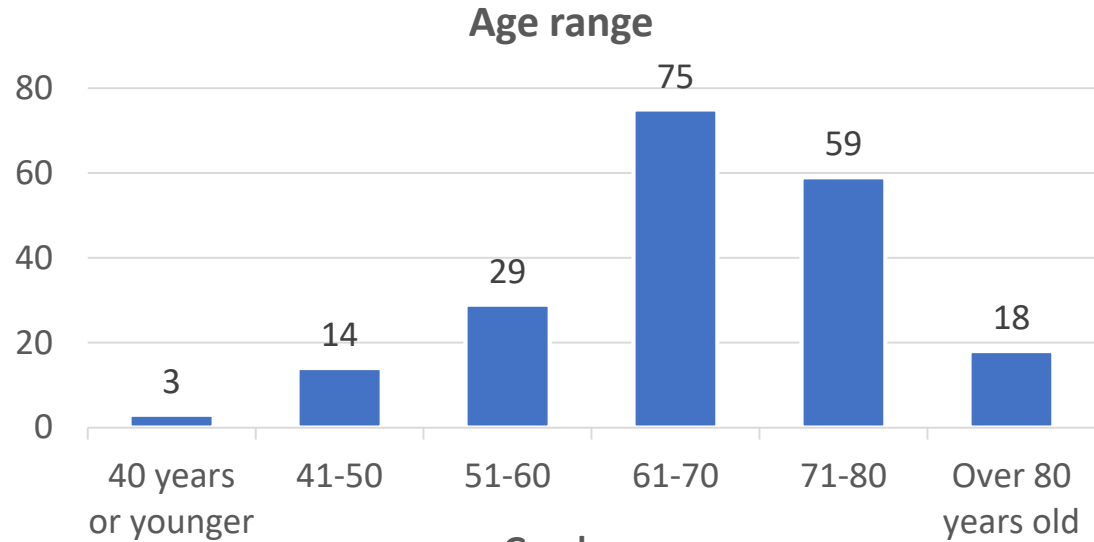
PATIENT ENROLLMENT FLOW TO DATE



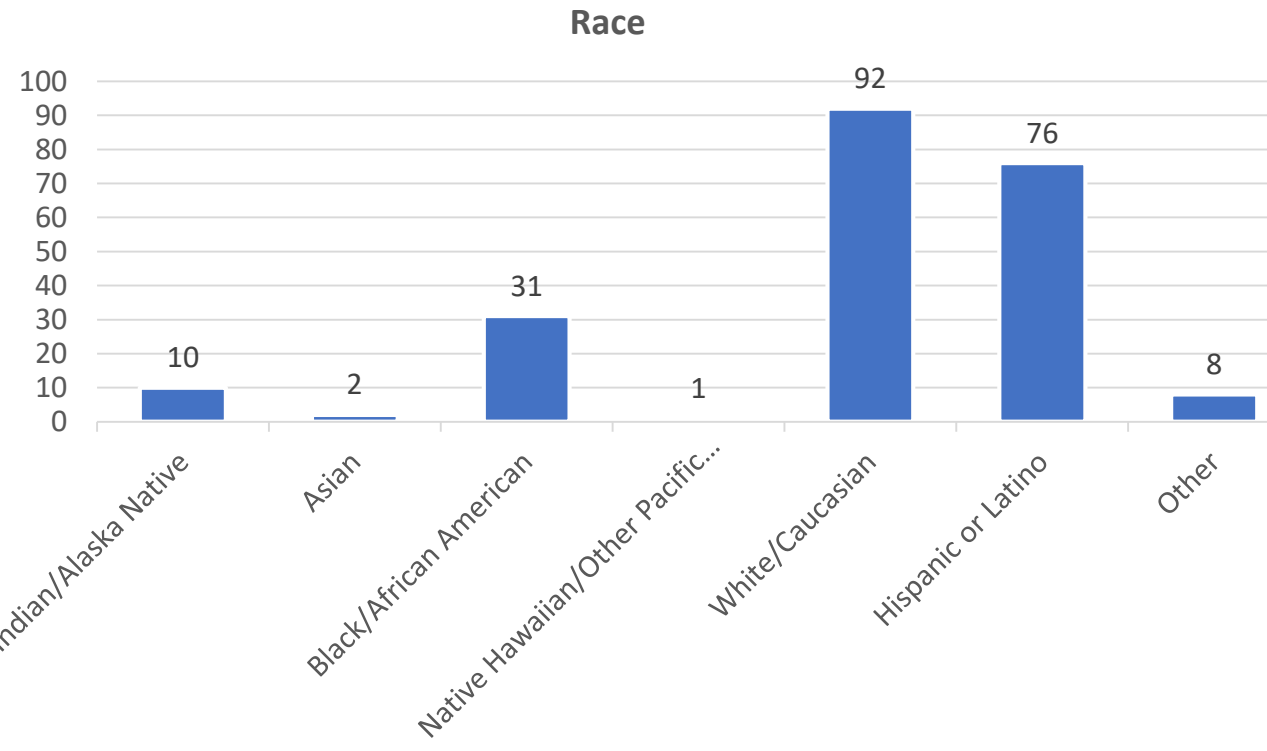
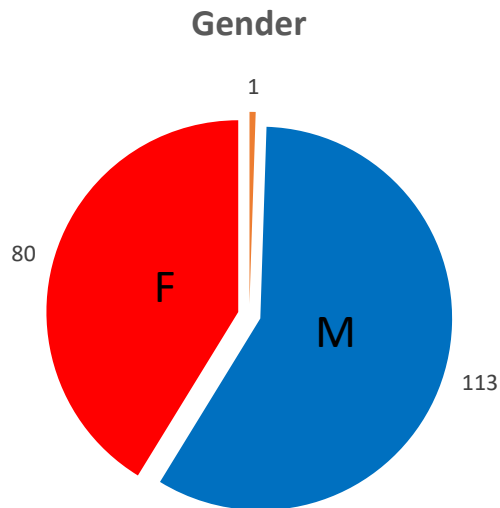
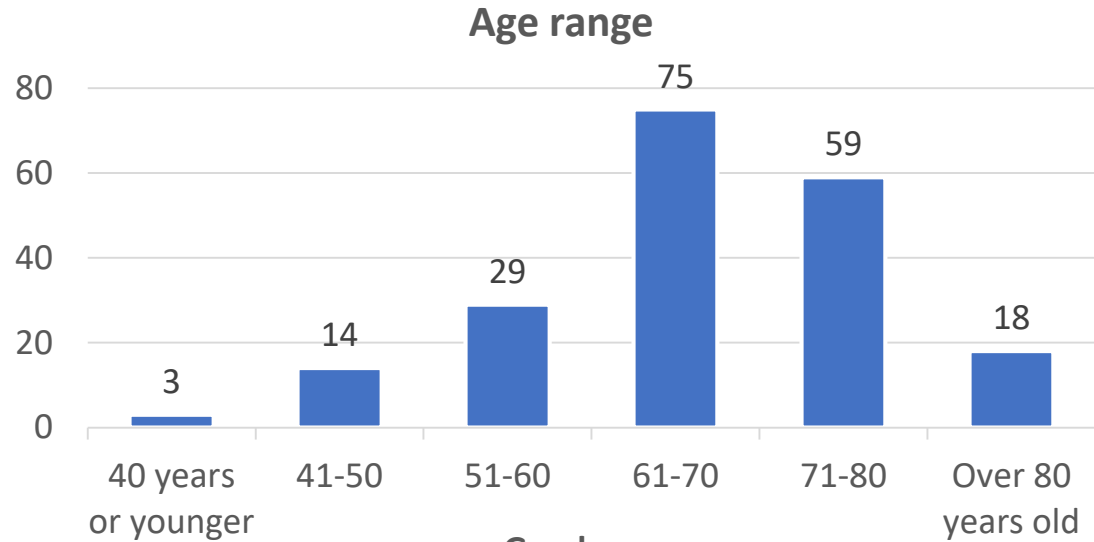
OPT-OUT PATIENTS: DEMOGRAPHICS



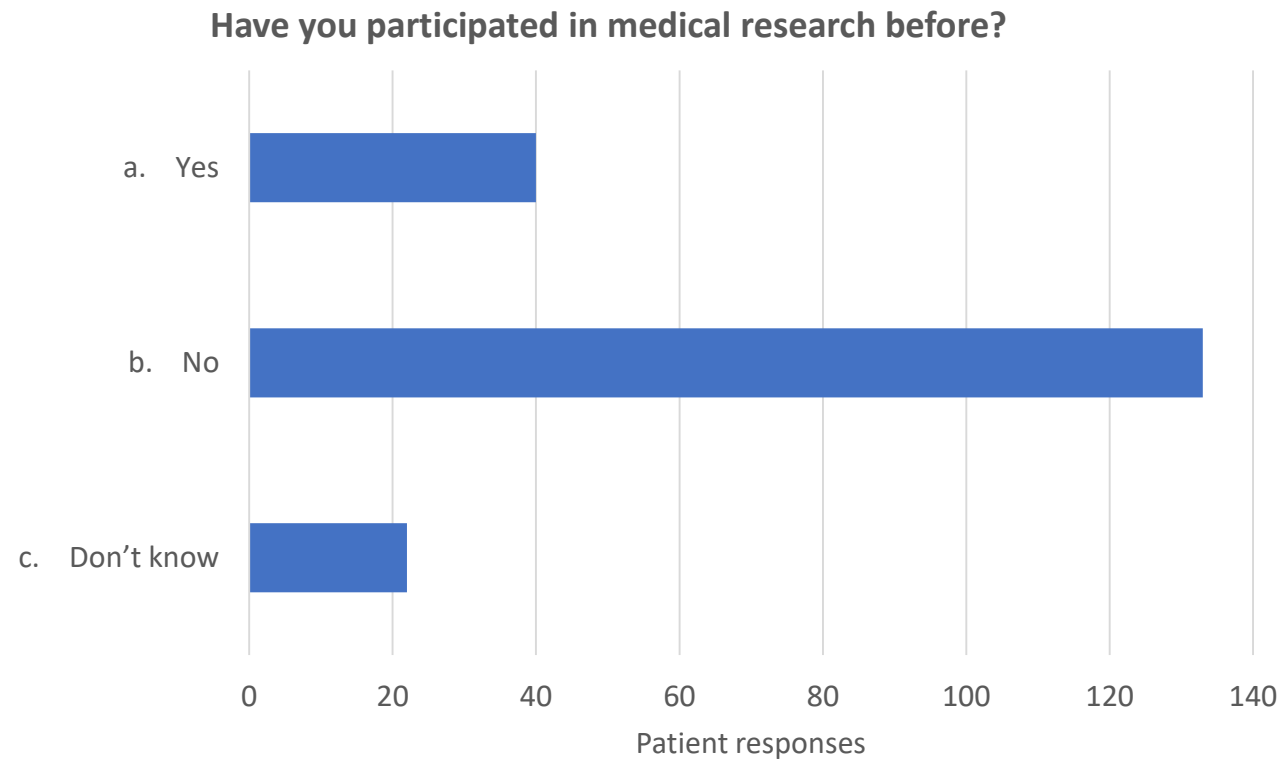
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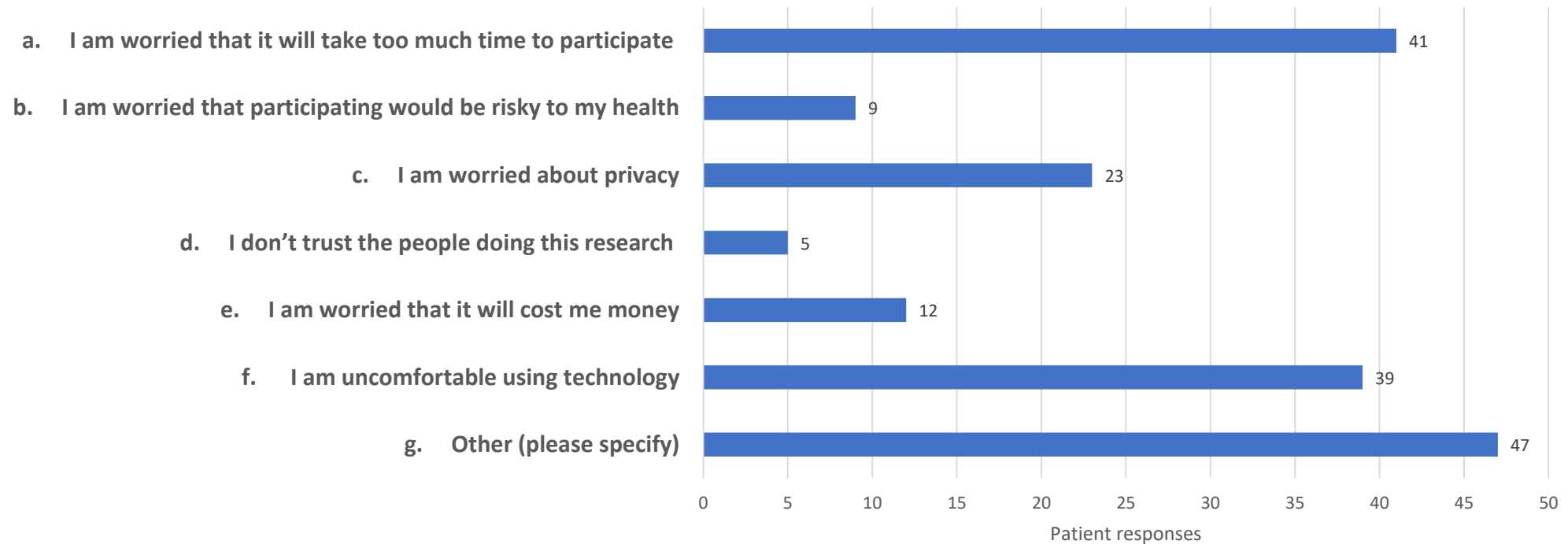


PRIOR RESEARCH EXPERIENCE



REASONS FOR OPT-OUT

Which of the following reasons contributed to your decision to opt-out of the Nudge Study?
Please circle all that apply:



Common "other" responses: "Don't need reminders" " Don't have a phone" " I do not need medications" " Don't trust people behind computers" "Don't want to participate"

TRUST IN HEALTH CARE-VA (N=68, COMPLETE=54, PARTIAL =1, BLANK=3)

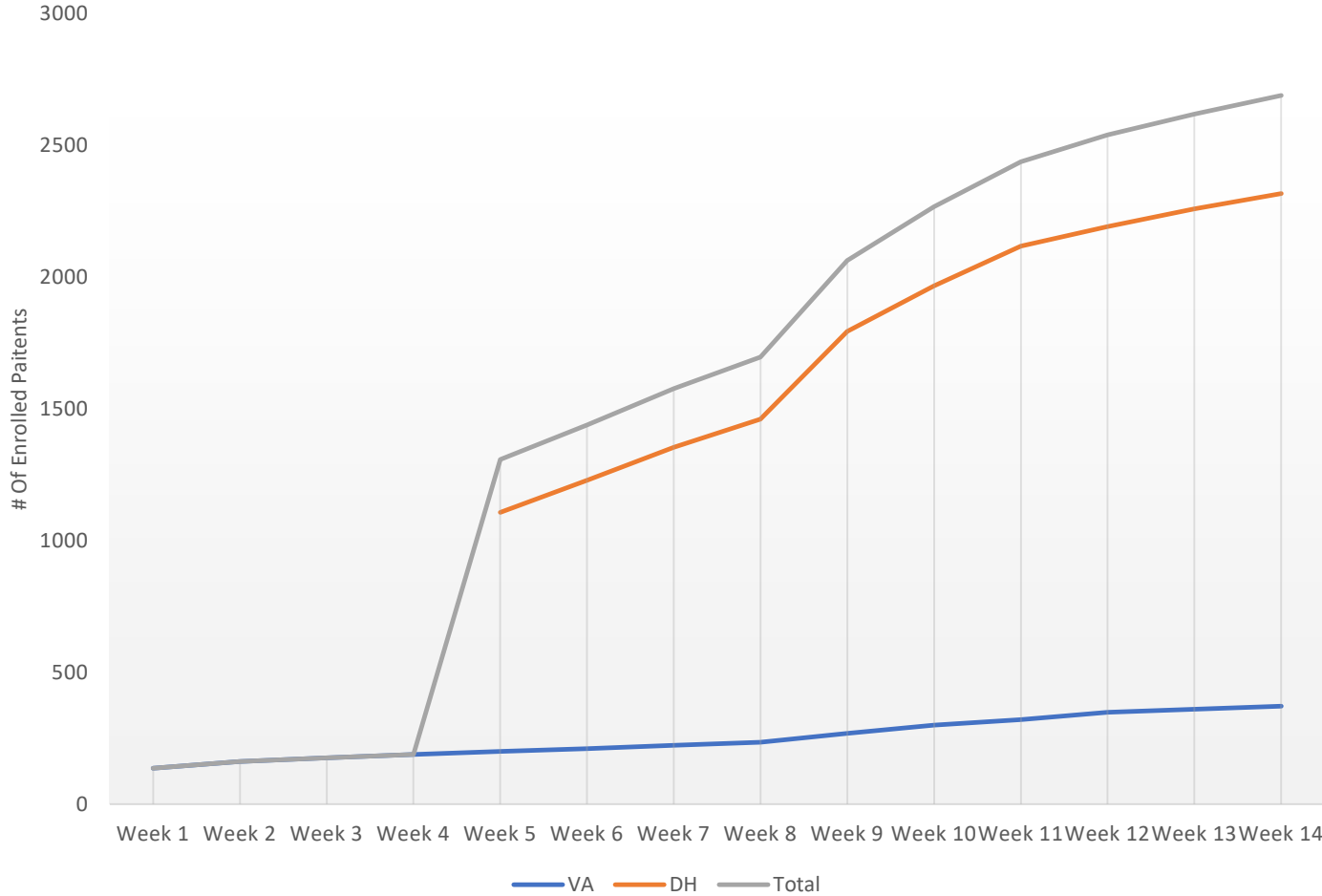
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. The VA					
The VA does its best to make patients' health better.	23	31	5	0	1
Patients receive high quality medical care from the VA.	24	26	8	0	1
The VA gives excellent medical care.	23	24	11	0	1
The VA experiments on patients without them knowing.	0	5	18	15	14
2. Research					
Doctors who do medical research care only about what is best for each patient.	13	15	21	4	1
Doctors tell their patients everything they need to know about being in a research study.	8	16	27	3	1
Medical researchers treat people like "guinea pigs."	3	4	26	12	7
I completely trust doctors who do medical research.	9	11	25	4	2
3. Doctors					
Sometimes doctors care more about what is convenient for them than about their patients' medical needs.	4	11	15	13	13
Doctors are extremely thorough and careful.	14	21	20	1	0
I completely trust doctors' decisions about which medical treatments are best.	11	17	22	3	2
A doctor would never mislead me about anything.	14	11	23	5	2
All in all, I trust doctors completely	13	18	21	3	0

TRUST IN HEALTH CARE-DHHA (N=144, COMPLETE = 99, PARTIAL 45, BLANK = 0)

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. DHHA					
DH does its best to make patients' health better.	63	43	13	2	2
Patients receive high quality medical care from DH.	62	41	17	1	2
DH gives excellent medical care.	59	41	19	0	2
DH experiments on patients without them knowing.	8	8	28	30	37
2. Research					
Doctors who do medical research care only about what is best for each patient.	34	30	43	6	5
Doctors tell their patients everything they need to know about being in a research study.	29	25	38	10	5
Medical researchers treat people like "guinea pigs."	5	9	36	27	30
I completely trust doctors who do medical research.	26	20	46	11	5
3. Doctors					
Sometimes doctors care more about what is convenient for them than about their patients' medical needs.	7	16	42	22	23
Doctors are extremely thorough and careful.	40	38	28	8	1
I completely trust doctors' decisions about which medical treatments are best.	36	37	32	7	4
A doctor would never mislead me about anything.	33	24	35	17	6
All in all, I trust doctors completely	36	35	35	9	3

ENROLLMENT BY WEEK UH3

Enrollment by Week

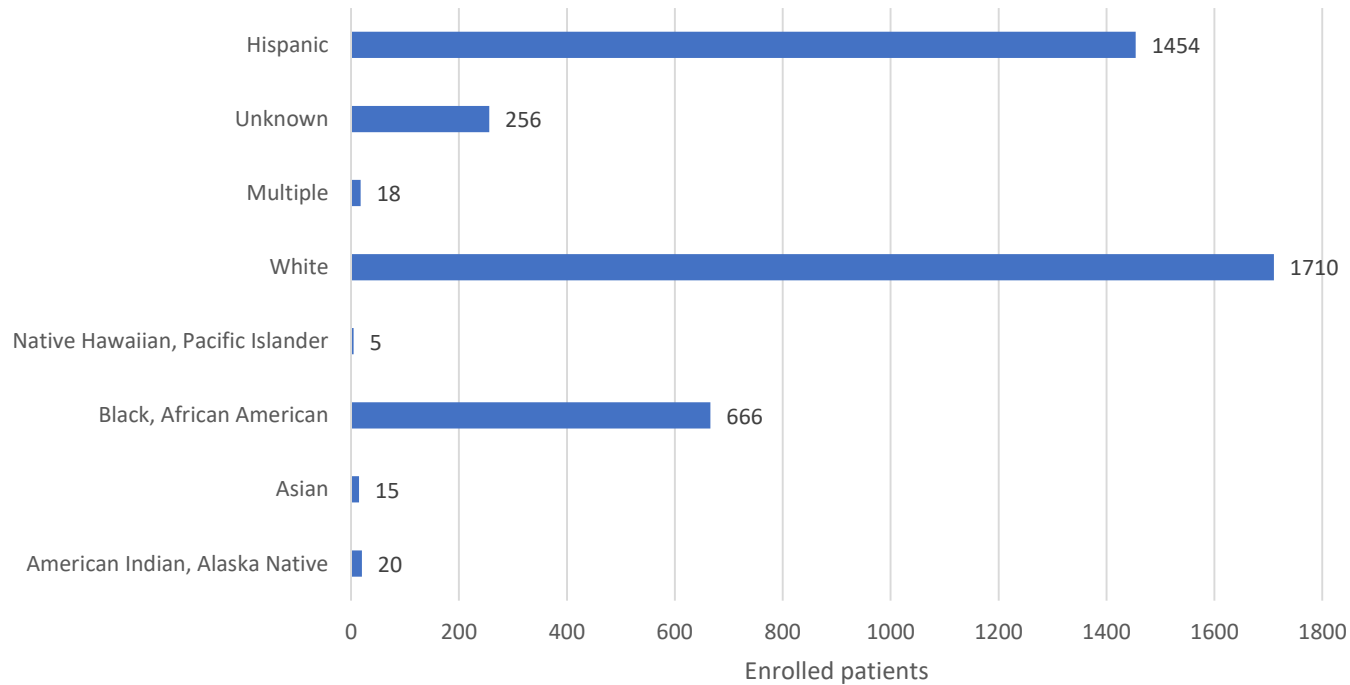


Cumulative Enrollment

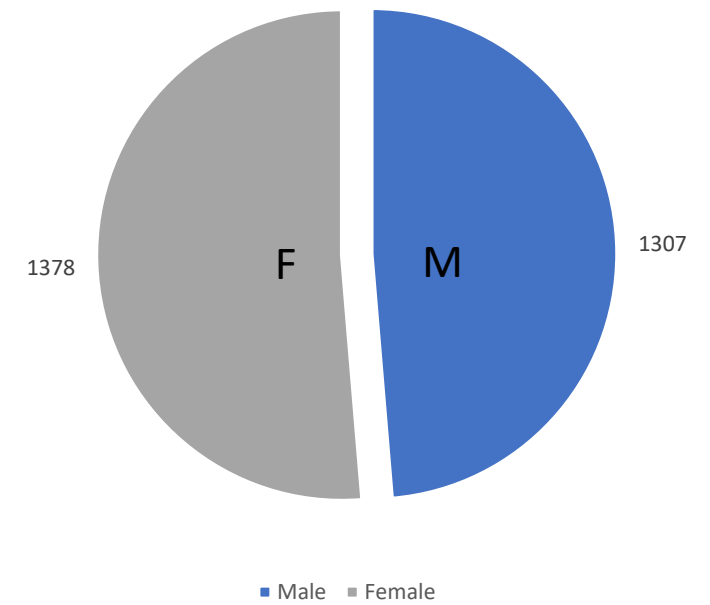
Week	VA	DH	Total
Week 1	136		136
Week 2	162		162
Week 3	176		176
Week 4	188		188
Week 5	200	1108	1308
Week 6	210	1229	1439
Week 7	223	1355	1578
Week 8	235	1462	1697
Week 9	269	1795	2064
Week 10	300	1968	2268
Week 11	321	2118	2439
Week 12	348	2193	2541
Week 13	360	2260	2620
Week 14	372	2318	2690

CURRENT ENROLLMENT: DEMOGRAPHICS

Race



Gender



CURRENT ENROLLMENT BY STUDY ARM

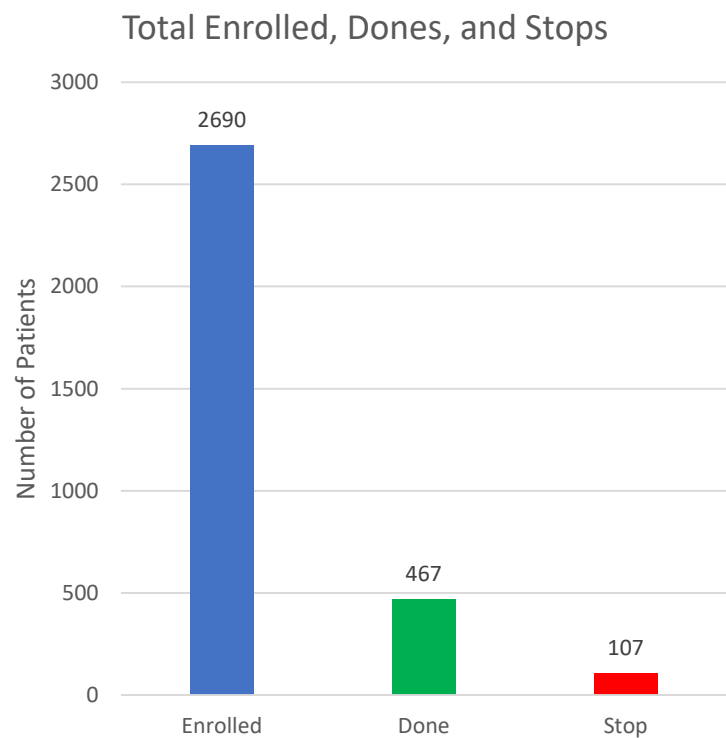
	Arm 1 (Usual Care)	Arm 2 (Generic)	Arm 3 (Optimized)	Arm 4 (Optimized + Chatbot)	Total
Enrolled					
MM	0	578	593	602	1773
IVR	0	95	80	72	247
N/A	670	0	0	0	670
Total	670	673	673	674	2690

MM: Mobile messenger (text messaging platform)

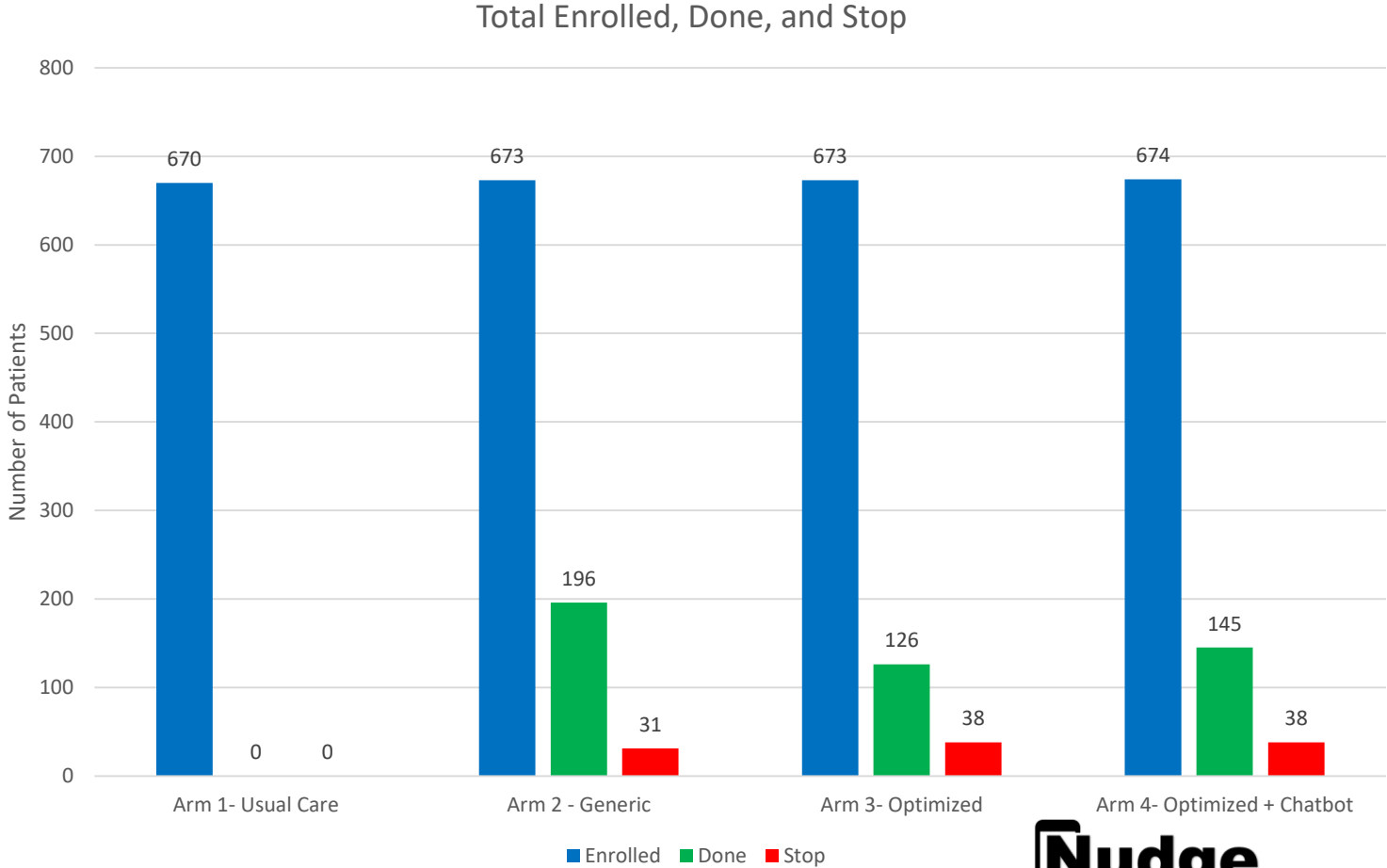
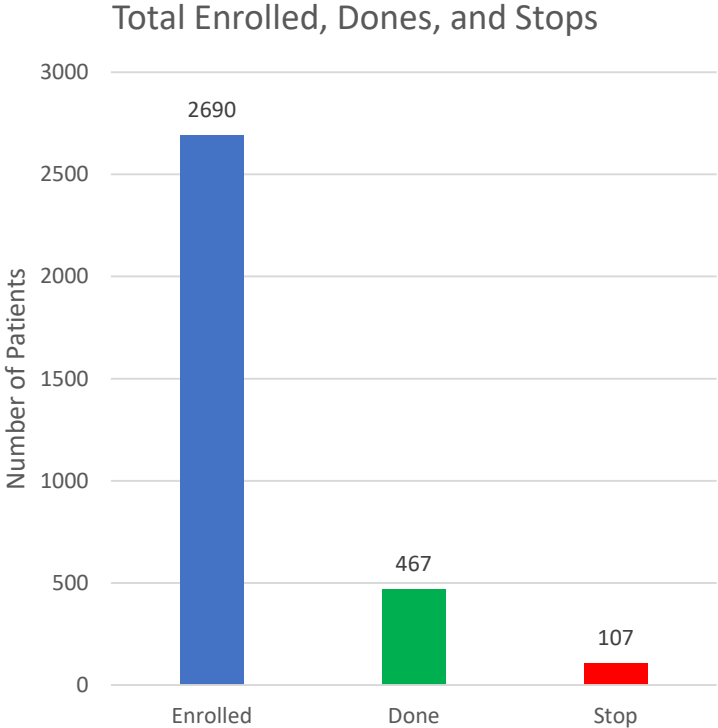
IVR: Interactive voice response (automated telephone calls)



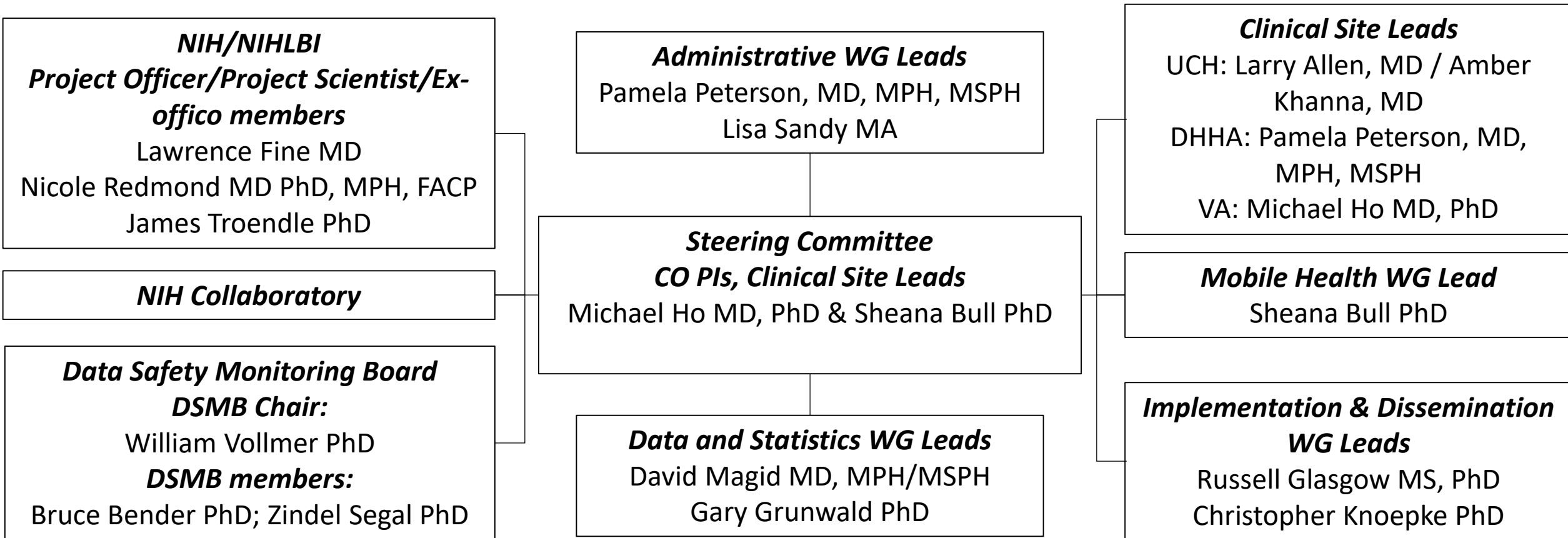
PATIENT RESPONSE TO TEXTS



PATIENT RESPONSE TO TEXTS



NUDGE STAFF



QUESTIONS?

