PERSONALIZED PATIENT DATA AND BEHAVIORAL NUDGES TO IMPROVE ADHERENCE TO CHRONIC CARDIOVASCULAR MEDICATIONS

The Nudge Project: Overview and Status

PIs: Mike Ho, MD, PhD & Sheana Bull, PhD, MPH
Adherence is low-hanging fruit: “Medications don’t work if you don’t take them.”

- Up to 50% of patients do not take their cardiovascular medications as prescribed, leading to increased mortality, adverse events such as heart attacks, and healthcare costs (e.g. MI-FREEE data).
- Previous attempts to improve adherence are costly, time-consuming, and have demonstrated inconsistent benefit.
Leverage principles of behavioral economics to nudge people to do the right thing

- A “Nudge” is the idea that a strategic reminder can help people adopt healthy behaviors.
  - Nobel prize winning economists (e.g. Dan Kahneman and Richard Thayler) have shown this can work to improve nutrition, physical activity and other behaviors.

- Because patients almost universally use cell phones, we can adapt the idea of a “Nudge” to the cell phone very easily.

- We aim to improve medication adherence by sending Nudges over the phone, which can specifically respond to patient needs.
Interventions to be developed and tested

User registration and randomization

Generic Texts

- You are due for a refill on your meds

Participants will receive generic messages multiple times until refill completed

Optimized Texts

- [Name] Find out secrets of people who have overcome challenges in taking meds! [URL]
- [Name] Congrats! You've filled meds on time at least 60% of the time. Make it 100%!

Participants will receive diverse optimized texts until refill completed

Optimized Texts + AI Chat Bot

- [Name] What problems do you have getting refills? Text 1=transport 2=cost 3=time
- Enter your work or home zip code—we'll give you names/hours/map to closest pharmacy
- [URL] Accepts Medicaid

Participants will receive AI chat after two optimized texts to assist in reducing specific barriers to refill
Overview of Nudge: Year 1, Aim 1

- Develop and test tools, infrastructure, and procedures needed for a proposed large, multi-center, randomized trial.
  - Develop and refine library of behavioral messages
    - N of 1 trials (n=20 from each site)
    - Stakeholder Engagement Panel (12 people total: 4 people from each of the three settings, including 2 patients, 1 pharmacist, and 1 person involved in the HCS leadership/operations).
  - Establish patient identification, eligibility, and randomization procedures across the 3 sites
Overview of Nudge: Year 1, Aim 2

- **Pilot intervention delivery** to demonstrate feasibility of and preliminary effects within 3 engaged healthcare systems.
  - *Deliver Nudge messages (via text messaging and IVR) at each site*
    - Opt-out consent
    - N=30 at each HCS
  - *Solicit feedback from patient, provider, and health system stakeholders*
  - *Develop final protocol for UH3 RCT*
Trial Patient Population

- Adult cardiovascular patients 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>

- Patients at one of three participating healthcare systems
- English or Spanish-speaking
Setting

- 8 family medicine and internal medicine clinics in the Denver Metro area
  - Denver Health
  - UCHealth
  - VA Eastern Colorado Health System
# Milestones

1. Obtain regulatory approval and contractual agreements across the 3 systems
2. Develop and refine library of behavioral messages for Nudge intervention
3. Establish patient identification, eligibility, randomization procedures across the 3 sites
4. Deliver Nudge messages (via text messaging or IVR) at each site
5. Complete data management and analytic plan
6. Develop final, NHLBI-approved study protocol for UH3 trial
7. Develop evaluation and dissemination plan
Workgroups

NIHLBI & NIH DSMB

Stakeholder Core

Administrative Core

Data & Statistics Core

Mobile Health Core

Clinical Sites
UCHealth
Denver Health
Denver VA

Implementation & Dissemination Core
## Barriers Scorecard

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Level of Difficulty</th>
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<tbody>
<tr>
<td>Enrollment and engagement of patients/subjects</td>
<td>✓</td>
</tr>
<tr>
<td>Engagement of clinicians and health systems</td>
<td>✓</td>
</tr>
<tr>
<td>Data collection and merging datasets</td>
<td>✓</td>
</tr>
<tr>
<td>Implementing/delivering intervention across healthcare organizations</td>
<td>✓</td>
</tr>
</tbody>
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**Data Science to Patient Value (D2V)**

**UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS**
Data Sharing

- **Current data plan**
  - *Data remain behind each institution’s firewall*
  - *Web-based portals*
  - *Messages are sent from a centralized team*

- **Obstacles**
  - *IRB*

- **Data Sharing**
  - *Technical and practical knowledge*
  - *Data collection instruments and assessment algorithms*
  - *Message library*
  - *Group-level data*
Data Sharing

Programmers send daily reports of new patients appropriate for study & sends daily updates when participants fill their medications.

Programmers trained by our in-house mHealth lab submit messages by logging into separate accounts on web-based platform.

Centralized Message Transmission

Separate, protected web-based portals

Denver Health
UCHealth
Denver VA
If we do the first 9 months well.. 
Phase II (UH3)

1. Conduct a pragmatic patient-level randomized intervention of "nudges" across the 3 healthcare systems to improve adherence to chronic CV medications.
   - Primary outcome: medication adherence
   - Secondary outcomes: intermediate clinical measures (e.g., BP control), CV clinical events (e.g., hospitalizations), healthcare utilization, and costs

2. Evaluate the implementation to inform local tailoring, adaptations, and modifications.
UH3 Intervention

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Usual Care

You are due for a refill on your meds

Generic messages, sent multiple times until refill completed

Diverse optimized texts, sent until refill completed

AI chat after two optimized texts, sent until refill completed
Questions?

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