Utilizing text message technology in a pragmatic clinical trial: The experience of the Nudge Study

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THE NUDGE STUDY

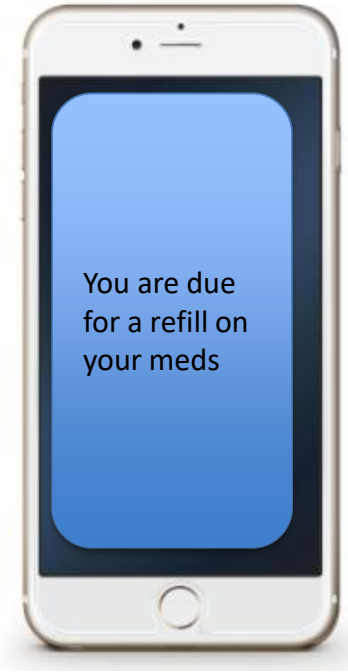
Objective: To conduct a pragmatic patient-level randomized intervention across 3 HCS to improve adherence to chronic CV medications through the use of text message technology.

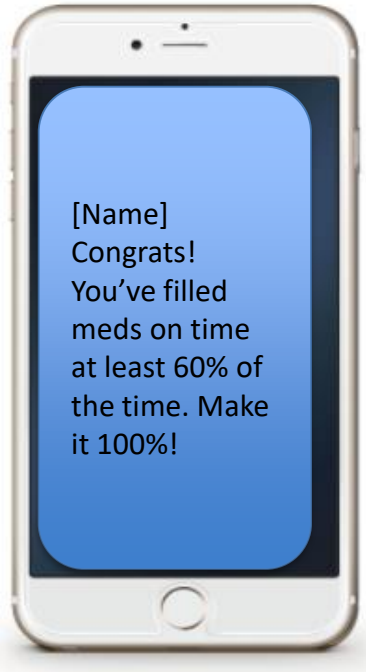
- Primary outcome: Medication adherence defined by the proportion of days covered (PDC) using pharmacy refill data.
- Secondary outcomes:
  - Intermediate clinical measures (e.g., BP control)
  - CV clinical events (e.g., hospitalizations)
  - Healthcare utilization
  - Costs

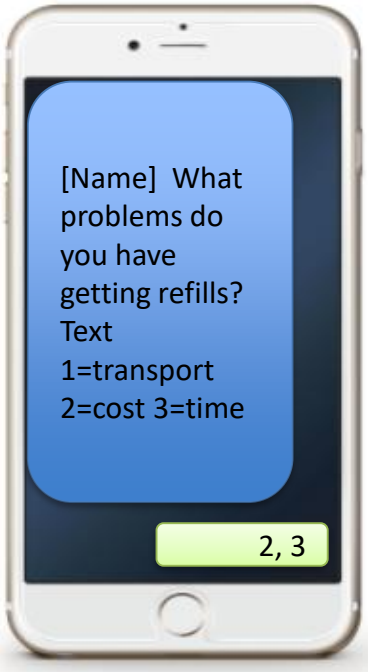
INTERVENTION ARMS

7 day gap between medication refills

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







CURRENT STATUS

- Our **enrollment** goal of 5,000 patients was met. 9,501 patients were enrolled from 3 sites and the follow up period has ended.

- **Data collection & analysis updates**
  - Data collection finalized; Statistical Analysis Plan reviewed and finalized by statisticians at the NIH Collaboratory, NHLBI, DSMB and study team.

- **Dissemination & Implementation activities:** Evaluation using the Practical, Robust Implementation and Sustainability Model (PRISM) and RE-AIM framework components of Reach, Effectiveness, Adoption, Implementation and Maintenance is underway:
  - **Patient satisfaction surveys** – 100 participants have completed surveys to measure patient perceptions
  - **Nof1 interviews with patients** – 13 participants took part in one-on-one interviews to elicit in-depth feedback
  - **Nof1 interviews with providers and health care leaders** – We will conduct up to 10 interviews with providers & health care leaders to better understand its impact on patients' medication taking behavior.
  - **An implementation toolkit** to aid in sustaining and replicating the study is being developed.
  - **Cost analysis** (program and replication costs) is also currently active

- **Manuscript preparation:** Over 15 manuscripts are in progress.

Barriers Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects		X			
Engagement of clinicians and health systems					X
Data collection and merging datasets		X Data Collection	X Merge Datasets		
Regulatory issues (IRBs and consent)	X				
Stability of control intervention	X				
Implementing/delivering intervention across healthcare organizations				X	

*Your best guess! 1 = little difficulty 5 = extreme difficulty

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TOP CHALLENGES

- Text reminders are becoming incorporated into standard of care.
- Connecting and integrating the EHR with a third-party pharmacy data platform (Surescripts) required an additional layer of data management. An error between the two entities required OIT assistance from one of the sites, resulting in delays in receiving accurate data pulls.

RECENT GENERALIZABLE LESSON LEARNED

- Sending messages via text has proven to be adaptable. We were able to optimize messages quickly and inexpensively in response to patient interactions and needs.
- Text messages are ubiquitous; patients require no training to receive and interact with the messages.
- It is possible to implement this intervention across vastly different HCS with disparate EHR systems
- Patients who identified as non-white and Hispanic were more likely to remain in the study (both during the initial opt out and the secondary opt out opportunity). Future studies will need to better understand the reasons that these patient continue to participate as the lessons learned may be applicable to efforts to increase clinical trials participation.
- Preliminary satisfaction surveys of patients from UCH and DH found high levels of satisfaction with the intervention, but also a considerable proportion of the population reporting concerns with message legitimacy.
    - **64.0%** of patients were satisfied or very satisfied with the intervention
    - **78.4%** found the messages were mostly or very easy to read and respond
    - **61.0%** were mostly or completely satisfied with the messages serving as refill reminders
    - **27.6%** did not trust that the messages came from the HCS

CURRENT DATA SHARING PLAN AND OBSTACLES

Data Sharing Plan (Summarized)

- All data will be released in accordance with standard data sharing policies and procedures. Data will be made available to the broader scientific community after study results are published in peer-reviewed journals. Data will first be redacted to strip all direct and indirect identifiers utilizing the Safe Harbor method. Due to the small numbers of participants in the qualitative portions of our study, we will only include composite qualitative data
- The study team will share technical and practical knowledge regarding the creation and implementation of the intervention, upon request. Further, the study team would readily share all data collection instruments and assessment algorithms used in the project to qualified individuals within the scientific community with the agreement that they will appropriately acknowledge the study team who developed the instruments.

Obstacles

- While we hope to release data in a timely manner, the release of de-identified VA data will require several layers of approval, which may result in delays.

DATA WE'RE PLANNING TO SHARE

- **Metadata**
  - Message library
  - Data dictionary
  - Texting, chatbot and IVR coding and manuals
  - Study protocol
  - Programming language
  - Assessment tools
- **Data**
  - Qualitative interview summary data
  - IT and pharmacy data

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