Using adaptive randomized designs for the conduct of clinical research studies: NUDGE-EHR example

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Atrius Health

BACKGROUND

- Traditional randomized trials are widely considered the gold standard for evaluating the efficacy or effectiveness of interventions in health care.
- Adaptive trials incorporate changes as the study proceeds, such as modifying allocation probabilities or eliminating treatment arms that are very likely to be ineffective.
- These designs have been widely used in pre-approval drug discovery studies but have been minimally used in clinical research studies in real-world healthcare settings.

NUDGE-EHR Trial Objective:

- To determine whether designing electronic health record (EHR) tools using behavioral science principles reduces high-risk prescribing and clinical outcomes in older adults.
- To demonstrate the ability to conduct an adaptive trial in a real-world healthcare setting

METHODS

- Because there are numerous ways EHR tools could be designed using behavioral sciences, we chose to use an adaptive trial to allow the possibility of testing faster and with more efficiency.
- In October 2020, we launched NUDGE-EHR, a two-stage, 16-arm adaptive randomized pragmatic trial with a "pick the winner" design of EHR-based tools at Atrius Health **(Figure 1).**
- We completed Stage 1 in May 2021 and conducted interim analyses.
- In August 2021, we launched the second stage of the trial. Full trial results will be available in July 2022.

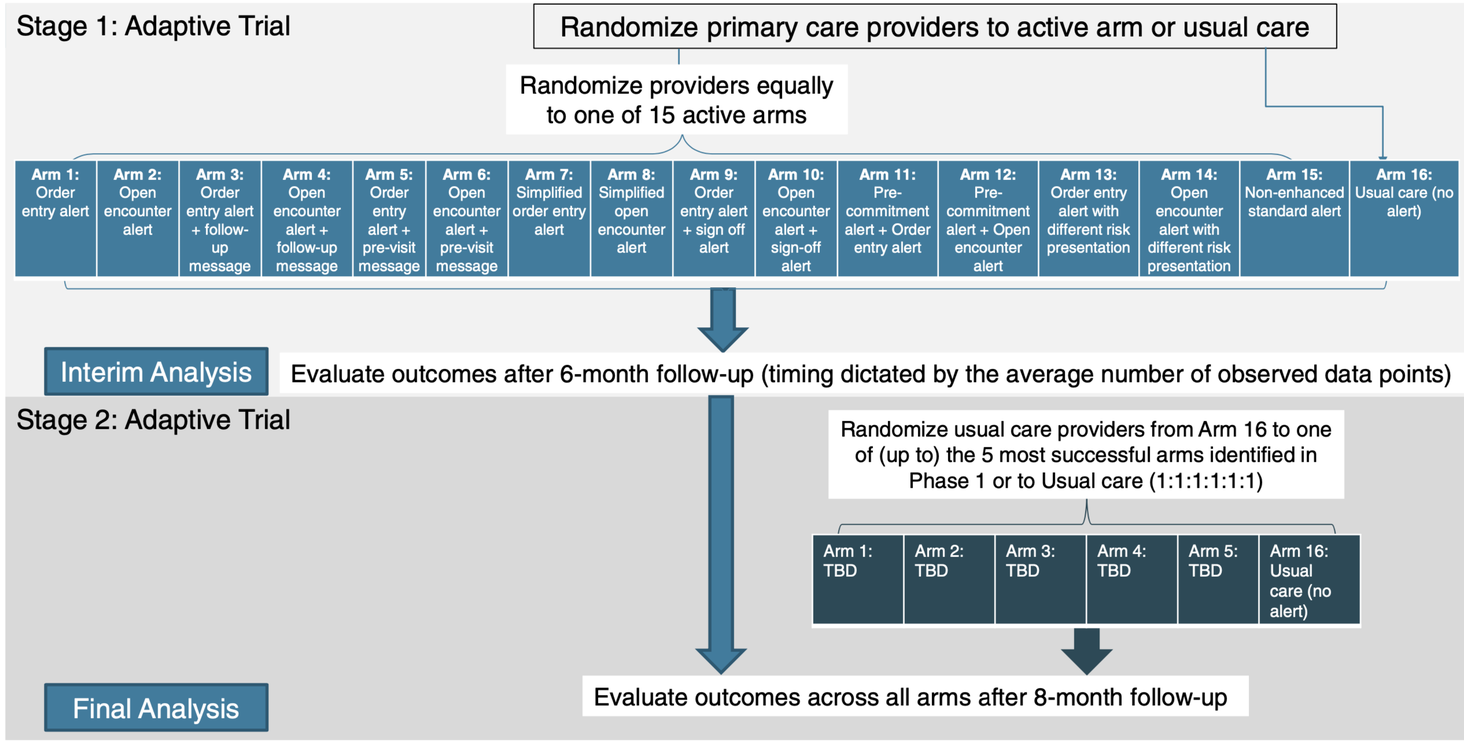

Figure 1: Overview of the adaptive trial stages of the NUDGE-EHR trial at Atrius Health

CONCLUSIONS

- NUDGE-EHR will determine the components of EHR tools that are most impactful at changing provider behavior and provide generalizable evidence both to healthcare practices about specific strategies that should be used in EHRs.
- It will also inform researchers about the practicalities of how to test different delivery strategies simultaneously using adaptive trials.

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