Evaluation of AI Cost Prediction Model to Enroll Patients in Complex Care Management Program

Analysis Plan

ID: IRB-24-0848

IRB Approved 6/12/2024

NCT ID: Not yet assigned

Document Updated March 31, 2025

Primary Outcome

- Days alive and out of hospital (DAOH) at 120 days from randomization

Secondary Outcomes

- Days alive and out of hospital (DAOH) at 30 days from randomization
- Days alive and out of hospital (DAOH) at 90 days from randomization
- Days alive and out of hospital (DAOH) at 10 months from randomization
- Total healthcare expenditures at 10 months from randomization
- All-cause hospitalizations at 10 months from randomization
- All-cause emergency department visits at 10 months from randomization
- All-cause mortality at 10 months from randomization
- Ambulatory contact days out of home (days with a primary care or specialty care office visit, test, imaging, procedure, or treatment)

Exploratory Outcomes

- Cost prediction model performance over 22 months, as measured by area under the receiver operating characteristic curve. Observed healthcare expenditures for each month's control cohort will be measured over the subsequent 12 months after randomization (ie, 10 months of enrollment + 12 months of follow-up= 22 months), and compared to model-predicted healthcare expenditures. This analysis will only be conducted in the control group, as the intervention is designed to affect healthcare expenditures in the treatment group.
- Protocol fidelity over the 10 months of enrollment, measured by the proportion of patients randomized to the intervention who enroll in the complex care management program, and the proportion of patients randomized to the control who do not enroll in the complex care management program.
- Avoidable hospitalizations, defined as hospitalizations that could have been avoided through timely access to ambulatory care.
- Avoidable emergency department visits, defined as emergency department visits that could have been avoided through timely access to ambulatory care.

Analysis plan

The investigators will compare the outcomes between the intervention and control arms with Poisson regression using arm assignment as the primary model term. Regressions will control for age, sex, race/ethnicity, and each prior baseline outcome (e.g., for the DAOH-120 primary outcome, model will control for DAOH in the 120 days prior to randomization).

The randomization will be balanced on the primary outcome.

Power

The cost prediction model will identify approximately 500 patients each month, who will undergo a 1:1 randomization stratified on DAOH over the 120 days prior to randomization to either the intervention or control arms. The investigators will enroll patients for 10 months, accruing approximately 5000 patients. On an intention-to-treat basis, two groups of 2,500 patients would provide 80% power to detect an effect size of 0.08 standard deviations (SD) on our primary outcome, DAOH, assuming a two-sample t-test and a two-sided 0.05 significance level. Assuming that only 25% of intervention patients contacted actually enroll in the complex care management program, this study would be adequately powered to detect an effect size as small as 0.32 SDs on the primary outcome.