Evaluating the Efficacy of Pediatric Lipid Screening Alerts

(NCT04118348)

Statistical Analysis Plan

October 13, 2023

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Note: An earlier document included the study protocol, but this section was removed since this was redundant with an existing protocol (2022-11-10). The current document further updates an interim document to correct some data management errors and specify corrections for multiple comparisons that are more consistent with the original protocol.

As of the writing of this plan, primary and additional analyses have already been completed.

Primary Analyses

Binary logistic generalized linear mixed models (GLMMs) were used to analyze the primary outcomes – lipid screening orders and completions one week after the visit – as a function of condition, with the provider added to the model as a random effect. As the researchers were interested in the comparison between the experimental groups and the control group, as well as the relative effectiveness between the experimental groups, they conducted contrasts between all 4 groups using sets of three GLMMs with shifting reference categories. Post hoc pairwise tests were also run, adjusting for multiple comparisons using the least significant difference test. Odds ratios (ORs) were calculated, along with 95% confidence intervals (CIs); two-tailed p-values < 0.05 were used to determine statistical significance. To represent effect size, the standardized statistic, Cohen's d, was estimated using the formula $LogOddsRatio \times \sqrt{3}/\pi$ (Hasselblad & Hedges, 1995). Raw percentages and 95% CIs were also presented.

Additional Analyses

Epic Storyboard (a newly introduced method of showing information to the provider in the EHR) was introduced on November 1, 2019. As Epic Storyboard might have changed the way providers engaged with alerts, the researchers reran the models including an interaction term between the presence of Epic Storyboard (i.e., patient encounters after November 1, 2019) and the conditions.

The same kind of GLMM model as used in the primary analyses was also used to examine the effect of the experimental conditions on completions 6 months after the intervention.

To conduct pre-post comparisons, the researchers examined the records of 12,252 eligible patients with the same kind of visits 6 months prior to the study period. The four experimental conditions were compared against this pre-alert group using the same kind of GLMM used in the primary analyses. All of the contrasts were made against one group, the pre-alert group, so no adjustment was made for multiple comparisons.