eRegQual analysis

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# Introduction

This document presents the methods used to analyze the adverse pregnancy outcome and process outcome data for the eRegQual trial and presents the corresponding results.

# Methods

We used random-effects logistic regression to estimate the relative odds of success for each of the process outcomes under the treatment versus control conditions. We modelled the clustering of multiple opportunities for success within each pregnancy using random-effects, and computed cluster-robust standard errors to account for the cluster-randomized design (i.e., clustering of pregnancies within clinics). No data were missing for these analyses.

While we randomized clusters by stratifying on district for administrative reasons, we judged prior to analysis that district may be prognostic for all outcomes, and therefore adjusted for district as a fixed effect in all analyses (CHMP 2015). Because we constrained the randomization by lab availability, clinic size (number of new enrollments), proportion of women aged >40 years, and proportion of primiparous women, we also adjusted for these prognostic variables as fixed effects using individual- rather than cluster-level data where possible (Li 2017).

We followed the intention-to-treat principle for all analyses: participants were analyzed in the arms to which they were randomized and — with the exception of the complete case analyses for the adverse pregnancy analysis — all participants were included in the analyses. We computed 95% confidence intervals and used the significance criterion P<0.05 throughout. Statistical analyses were performed using Stata 16 (StataCorp LLC, College Station, Texas, USA).

# Results

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Table 1. Successful attendance | | | | | | |
|  | Odds Ratio | Robust |  |  |  |  |
| y |  | Std. Err. | z | P>|z| | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| F | 0.29 | 0.14 | 2.13 | 0.03 | 0.02 | 0.56 |

# References

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# Appendix