eRegQual analysis

Chris Rose, Norwegian Institute of Public Health (30 Jun 2020)

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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 logistic regression to estimate the relative odds of success for each of the process outcomes under the treatment versus control conditions. For outcomes measured at multiple time points, we modelled clustering within each pregnancy using random-effects, and computed cluster-robust standard errors to account for the cluster-randomized design. For outcomes measured at only one time point within each pregnancy, we accounted for the cluster-randomized design using random effects. No data were missing for these analyses.

We adjusted for the stratification variable (CHMP 2015) and the variables used to constrain randomization (Li 2017) as fixed effects in all analyses, using individual- rather than cluster-level measurements where possible. 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). We masked the treatment allocation from the statistician during analysis.

# Results

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| Table 1. Successful attendance | | | | | | |
|  | Odds Ratio | Robust |  |  |  |  |
| y |  | Std. Err. | z | P>|z| | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| F | 1.18 | 0.13 | 1.46 | 0.15 | 0.95 | 1.47 |
| primiparous |  |  |  |  |  |  |
| Primiparous | 0.96 | 0.06 | -0.64 | 0.53 | 0.85 | 1.08 |
| \_cons | 0.43 | 0.08 | -4.31 | 0.00 | 0.29 | 0.63 |
| /lnsig2u | 0.61 | 0.08 |  |  | 0.45 | 0.76 |
| sigma\_u | 1.35 | 0.05 |  |  | 1.25 | 1.46 |
| rho | 0.36 | 0.02 |  |  | 0.32 | 0.39 |

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| Table 2. Successful hypertension | | | | | | |
|  | Odds Ratio | Robust |  |  |  |  |
| y |  | Std. Err. | z | P>|z| | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| J | 0.60 | 0.07 | -4.24 | 0.00 | 0.48 | 0.76 |
| primiparous |  |  |  |  |  |  |
| Primiparous | 1.02 | 0.11 | 0.16 | 0.87 | 0.83 | 1.25 |
| \_cons | 30.86 | 7.28 | 14.54 | 0.00 | 19.44 | 48.99 |
| /lnsig2u | -0.17 | 0.26 |  |  | -0.68 | 0.34 |
| sigma\_u | 0.92 | 0.12 |  |  | 0.71 | 1.19 |
| rho | 0.20 | 0.04 |  |  | 0.13 | 0.30 |

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| Table 3. Successful diabetes | | | | | | |
|  | Odds Ratio | Robust |  |  |  |  |
| y |  | Std. Err. | z | P>|z| | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| L | 1.46 | 0.18 | 3.13 | 0.00 | 1.15 | 1.85 |
| primiparous |  |  |  |  |  |  |
| Primiparous | 1.06 | 0.05 | 1.20 | 0.23 | 0.96 | 1.17 |
| \_cons | 0.15 | 0.03 | -10.31 | 0.00 | 0.11 | 0.22 |
| /lnsig2u | -14.34 | . |  |  | . | . |
| sigma\_u | 0.00 | . |  |  | . | . |
| rho | 0.00 | . |  |  | . | . |

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| Table 4. Successful malpresentation | | | | | | |
| y | Odds Ratio | Std. Err. | z | P>|z| | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| B | 1.42 | 0.31 | 1.61 | 0.11 | 0.93 | 2.18 |
| primiparous |  |  |  |  |  |  |
| Primiparous | 1.48 | 0.23 | 2.56 | 0.01 | 1.10 | 1.99 |
| \_cons | 0.86 | 0.33 | -0.40 | 0.69 | 0.41 | 1.82 |
| /lnsig2u | -0.28 | 0.24 |  |  | -0.75 | 0.19 |
| sigma\_u | 0.87 | 0.10 |  |  | 0.69 | 1.10 |
| rho | 0.19 | 0.04 |  |  | 0.13 | 0.27 |

# References

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