eRegQual analysis - Time and motion study analysis

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# Introduction

This document presents analyses for the time and motion component of the eRegQual trial.

# Methods

Times (durations) are non-negative and their distributions are often positively skewed (e.g., there are many consultations of “typical” duration, but some are much longer). Further, we anticipated that the intervention is likely to have a multiplicative rather than additive effect. We therefore analyzed times on the log scale. We used mixed-effects linear regression to estimate relative differences in time used on health information management, client consultation, and client care, comparing treatment to control. We adjusted for the stratification variable (CHMP 2015) and the variables used to constrain randomization (cluster size and lab availability; Li 2016) as fixed effects. We also adjusted for the possible effect of whether a visit was a booking visit because we anticipated these visits would be longer than subsequent visits. We modelled the cluster-randomized design as a random effect, and adjusted confidence intervals for clustering of measurements of time within observers.

Similarly, we used mixed-effects linear regression to estimate time used finding, reading, and writing files using paper or the eRegistry. This analysis was identical to the previous one, with the exceptions that activity (finding, reading, etc.) was modelled as a fixed effect and clustering of activities within consultations within clinic was modelled using nested random effects. Note that it was necessary to retain treatment allocation as a fixed effect because while participants in the control arm could not use the eRegistry, those in the treatment arm could use computer- and paper-based methods.

We exponentiated to obtain estimates of relative differences in time used, and computed predictive margins of mean time spent finding, reading, and writing files. We report uncertainty on estimates and predictions using 95% confidence intervals. We followed the intention-to-treat principle for all analyses: participants were analyzed in the arms to which they were randomized, and all participants were included in the analyses. No data were missing. Statistical analyses were performed using Stata 16 (StataCorp LLC, College Station, Texas, USA). The statistician was not involved in data collection and was blinded to treatment allocation for the analyses of relative differences in time used on health information management, client consultation, and client care. It was not possible to blind the statistician to treatment allocation for the analyses of time used finding, reading, and writing files because the treatment allocation was obvious. Protocol deviations are documented in Appendix 1.

# Results

## Health information management, client consultation, and care

The following tables present comparisons of time used on health information management, client consultation, and care.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Table 1. HIM time per consultation (mins) | | | | | | |
|  | Rel. Time | Std. Err.\* | z\* | P>|z|\* | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| B | 0.70 | 0.09 | -4.21 | 0.00 | 0.59 | 0.82 |
| \* The standard error, z-score, and P-value are from the analysis performed on the log scale. | | | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Table 2. Consultation time (mins) | | | | | | |
|  | Rel. Time | Std. Err.\* | z\* | P>|z|\* | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| B | 0.87 | 0.12 | -1.17 | 0.24 | 0.69 | 1.10 |
| \* The standard error, z-score, and P-value are from the analysis performed on the log scale. | | | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Table 3. Client care time within consultation (mins) | | | | | | |
|  | Rel. Time | Std. Err.\* | z\* | P>|z|\* | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| B | 0.87 | 0.16 | -0.88 | 0.38 | 0.64 | 1.18 |
| \* The standard error, z-score, and P-value are from the analysis performed on the log scale. | | | | | | |

## Activities

The following table shows relative differences in time used finding, reading, and writing in the treatment versus control conditions. Values greater than unity corresponding to more use of time in the treatment condition.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Table 4. Comparison of relative times used finding, reading, and writing files | | | | | | |
|  | Rel. Time | Std. Err. | z | P>|z| | [95% Conf. Interval] | |
| Finding | 5.06 | 2.13 | 2.38 | 0.02 | 0.89 | 9.23 |
| Reading | 2.41 | 1.19 | 2.03 | 0.04 | 0.08 | 4.74 |
| Writing | 2.33 | 0.56 | 4.16 | 0.00 | 1.23 | 3.43 |

The following table shows predictions of mean times used finding, reading, and writing files per consultation. Estimates are expressed in minutes.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Table 5. Predictions of mean times used finding, reading, and writing files per consultation (mins) | | | | | | |
|  |  | Delta-method |  |  |  |  |
|  | Margin | Std. Err. | z | P>|z| | [95% Conf. Interval] | |
| activity |  |  |  |  |  |  |
| Finding files (eRegistry) | 1.46 | 0.32 | 4.53 | 0.00 | 0.83 | 2.10 |
| Finding files (paper) | 0.29 | 0.06 | 4.52 | 0.00 | 0.16 | 0.41 |
| Reading files (eRegistry) | 1.16 | 0.34 | 3.42 | 0.00 | 0.50 | 1.83 |
| Reading files (paper) | 0.48 | 0.11 | 4.25 | 0.00 | 0.26 | 0.71 |
| Writing files (eRegistry) | 6.73 | 1.82 | 3.69 | 0.00 | 3.16 | 10.30 |
| Writing files (paper) | 2.89 | 0.21 | 13.51 | 0.00 | 2.47 | 3.31 |

# References

Committee for Medicinal Products for Human Use (CHMP) (2015). Guideline on adjustment for baseline covariates in clinical trials. London: European Medicines Agency.

Li, F., Lokhnygina, Y., Murray, D. M., Heagerty, P. J., & DeLong, E. R. (2016). An evaluation of constrained randomization for the design and analysis of group‐randomized trials. Statistics in Medicine, 35(10), 1565-1579.

# Appendix 1 — Protocol Deviations

We did not plan to model relative times via transformation to the log scale. Nor did we plan to adjust for observer but chose to do so as it is plausible that systematic differences may exist between observers. We did not plan in detail how time used finding, reading, or writing files would be analyzed.

# Appendix 2 — Full Regression Results

## Comparisons of time used

The following tables show the full regression results. Note that time was modelled on the log scale and the full estimation results have not been exponentiated.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Table 6. HIM time per consultation (mins) | | | | | | |
|  |  | Robust |  |  |  |  |
| him\_time | Coef. | Std. Err. | z | P>|z| | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| B | -0.36 | 0.09 | -4.21 | 0.00 | -0.53 | -0.19 |
|  |  |  |  |  |  |  |
| strat\_var |  |  |  |  |  |  |
| Ramallah | -0.21 | 0.71 | -0.30 | 0.76 | -1.60 | 1.18 |
| Nablus | -0.31 | 0.86 | -0.36 | 0.72 | -1.99 | 1.37 |
| Salfit | -0.32 | 0.70 | -0.46 | 0.65 | -1.69 | 1.05 |
| Jenin | -0.45 | 0.72 | -0.62 | 0.53 | -1.87 | 0.97 |
|  |  |  |  |  |  |  |
| cluster\_size | -3.58 | 1.85 | -1.94 | 0.05 | -7.20 | 0.04 |
|  |  |  |  |  |  |  |
| lab\_available |  |  |  |  |  |  |
| Lab | -0.02 | 0.12 | -0.13 | 0.90 | -0.25 | 0.22 |
|  |  |  |  |  |  |  |
| bookingvisit |  |  |  |  |  |  |
| Booking visit | 0.77 | 0.13 | 6.15 | 0.00 | 0.53 | 1.02 |
| \_cons | 2.78 | 0.62 | 4.48 | 0.00 | 1.56 | 4.00 |
| Data were analyzed on the log scale. Estimates have not been exponentiated. | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- |
| Table 7. Consultation time (mins) | | | | | | |
|  |  | Robust |  |  |  |  |
| consult\_time | Coef. | Std. Err. | z | P>|z| | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| B | -0.14 | 0.12 | -1.17 | 0.24 | -0.37 | 0.09 |
|  |  |  |  |  |  |  |
| strat\_var |  |  |  |  |  |  |
| Ramallah | 0.70 | 0.16 | 4.37 | 0.00 | 0.39 | 1.01 |
| Nablus | 0.29 | 0.35 | 0.83 | 0.41 | -0.40 | 0.97 |
| Salfit | 0.35 | 0.10 | 3.54 | 0.00 | 0.15 | 0.54 |
| Jenin | 0.30 | 0.16 | 1.85 | 0.06 | -0.02 | 0.63 |
|  |  |  |  |  |  |  |
| cluster\_size | -1.96 | 1.70 | -1.16 | 0.25 | -5.29 | 1.37 |
|  |  |  |  |  |  |  |
| lab\_available |  |  |  |  |  |  |
| Lab | 0.02 | 0.14 | 0.17 | 0.87 | -0.25 | 0.29 |
|  |  |  |  |  |  |  |
| bookingvisit |  |  |  |  |  |  |
| Booking visit | 0.82 | 0.10 | 8.41 | 0.00 | 0.63 | 1.01 |
| \_cons | 2.27 | 0.12 | 18.71 | 0.00 | 2.03 | 2.51 |
| Data were analyzed on the log scale. Estimates have not been exponentiated. | | | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Table 8. Client care time within consultation (mins) | | | | | | |
|  |  | Robust |  |  |  |  |
| care\_time | Coef. | Std. Err. | z | P>|z| | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| B | -0.14 | 0.16 | -0.88 | 0.38 | -0.45 | 0.17 |
|  |  |  |  |  |  |  |
| strat\_var |  |  |  |  |  |  |
| Ramallah | 1.70 | 0.21 | 8.02 | 0.00 | 1.29 | 2.12 |
| Nablus | 0.93 | 0.36 | 2.58 | 0.01 | 0.22 | 1.63 |
| Salfit | 0.86 | 0.19 | 4.54 | 0.00 | 0.49 | 1.23 |
| Jenin | 0.95 | 0.21 | 4.43 | 0.00 | 0.53 | 1.37 |
|  |  |  |  |  |  |  |
| cluster\_size | -2.28 | 2.94 | -0.78 | 0.44 | -8.04 | 3.47 |
|  |  |  |  |  |  |  |
| lab\_available |  |  |  |  |  |  |
| Lab | 0.14 | 0.12 | 1.13 | 0.26 | -0.10 | 0.37 |
|  |  |  |  |  |  |  |
| bookingvisit |  |  |  |  |  |  |
| Booking visit | 0.58 | 0.15 | 3.82 | 0.00 | 0.28 | 0.88 |
| \_cons | 0.61 | 0.42 | 1.46 | 0.14 | -0.21 | 1.43 |
| Data were analyzed on the log scale. Estimates have not been exponentiated. | | | | | | |

## Estimates of time used finding, reading, and writing files

The following tables shows the full regression result for the analysis of time used on each activity. Note that time was modelled on the log scale and the full estimation results have not been exponentiated.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Table 9. Time used (mins) | | | | | | |
|  |  | Robust |  |  |  |  |
| time | Coef. | Std. Err. | z | P>|z| | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| B | -1.29 | 0.30 | -4.25 | 0.00 | -1.89 | -0.70 |
|  |  |  |  |  |  |  |
| activity |  |  |  |  |  |  |
| Finding files (paper) | -1.62 | 0.42 | -3.85 | 0.00 | -2.45 | -0.80 |
| Reading files (eRegistry) | -0.23 | 0.08 | -3.04 | 0.00 | -0.38 | -0.08 |
| Reading files (paper) | -1.11 | 0.43 | -2.56 | 0.01 | -1.96 | -0.26 |
| Writing files (eRegistry) | 1.53 | 0.13 | 11.83 | 0.00 | 1.27 | 1.78 |
| Writing files (paper) | 0.68 | 0.21 | 3.19 | 0.00 | 0.26 | 1.10 |
|  |  |  |  |  |  |  |
| strat\_var |  |  |  |  |  |  |
| Ramallah | 0.57 | 0.24 | 2.34 | 0.02 | 0.09 | 1.04 |
| Nablus | 0.10 | 0.06 | 1.58 | 0.11 | -0.02 | 0.22 |
| Salfit | 0.01 | 0.20 | 0.05 | 0.96 | -0.39 | 0.41 |
| Jenin | -0.06 | 0.21 | -0.27 | 0.78 | -0.48 | 0.36 |
|  |  |  |  |  |  |  |
| cluster\_size | -4.75 | 1.54 | -3.08 | 0.00 | -7.78 | -1.73 |
|  |  |  |  |  |  |  |
| lab\_available |  |  |  |  |  |  |
| Lab | -0.01 | 0.11 | -0.09 | 0.93 | -0.22 | 0.20 |
|  |  |  |  |  |  |  |
| bookingvisit |  |  |  |  |  |  |
| Booking visit | 0.55 | 0.09 | 6.03 | 0.00 | 0.37 | 0.73 |
| \_cons | 1.33 | 0.31 | 4.25 | 0.00 | 0.72 | 1.94 |
| Data were analyzed on the log scale. Estimates have not been exponentiated. | | | | | | |