2019

Hybrid Effectiveness-Implementation Study to Improve Clopidogrel Adherence

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ADDENDUM TO STATISTICAL ANALYSIS PLAN

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We have made the following additions and clarifications to the original Statistical Analysis plan (described in the study protocol):

1. In addition to the intervention group of patients who were treated during the 6 month intervention period, we consider three control groups: a) patients who were treated at a site before the intervention was applied there, b) patients who were treated at a site after the intervention was ended there, and c) patients who were treated at a site that was eligible but at which the intervention was never applied. The primary hypothesis is intervention versus pre-intervention, and other comparisons are considered secondary analyses.
2. We used mixed logistic regression models for clopidogrel adherence (y/n PDC > 80%) as planned. To express results on a more interpretable risk difference scale we used standardized or average predicted value estimators (e.g. Zou, 2009; Joffe and Greenland, 1995), which compare probabilities of adherence among the groups, hypothesizing (in some cases counterfactually) that patients were in each of the four intervention/control groups. Inference was carried out using bootstrap methods and results expressed as confidence intervals for differences between groups. The same methods were used to express survival probabilities and differences in more interpretable terms (Sjolander, 2016).
3. Sensitivity analyses were carried out removing patients who received bare metal stents.

REFERENCES:

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Zou GY. Assessment of risks by predicting counterfactuals. *Statistics in Medicine* 2009; 28:3761-3781.

Sjolander A. Regression standardization with the R package stdReg. European Journal of Epidemiology 2016;31:563-574.