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Practicum Site: Patient-Centered Outcomes Research Institute

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The Missing Data Problem in Randomized Control Trials

Introduction: The Patient-Centered Outcomes Research Institute (PCORI) is an independent nonprofit organization that is a leading funder of comparative clinical effectiveness research in the United States. As a requirement of receiving funding, researchers must provide a report that demonstrates their adherence to PCORI's standards. One area of the standards is accounting for and addressing missing data. This exploratory project addresses a key question in PCORI's portfolio on how researchers are accounting for missing data in their research projects.

Methods: A study was selected if they met the criteria of being a final research report that has completed PCORI's peer review process, a Randomized Control Trial design (individual or cluster randomization), and not stopped early per the study's institution, Data Safety Monitoring Board, Institutional Review Board, PCORI, or other such institutions. 197 studies were selected. The subsequent data extraction is completed using a form designed by the Clinical Effectiveness and Decision Science team, which has gone through subsequent revisions to ensure that all aspects of missing data are being addressed per PCORI standards. Questions in the data extraction form address methodology used, statistical plans, methods for limiting missing data, and others. If a report has above 10% missing data (a general cutoff for what is considered an acceptable amount of missing data in a clinical study), the report is double-coded to ensure accuracy of answers.

Results: 197 clinical studies that meet the criteria of being a randomized control trials are being analyzed for how they account for missing data. Results presented will include analyses on what methods (or lack thereof) lead to more frequent occurrences of missing data in clinical studies.

Conclusions: This study aims to address two things: 1) how PCORI awardees can reduce amounts of missing data in their randomized control trials, and 2) an overall understanding of what contributes to large amounts of missing data in randomized control trials. Moving forward, the results will inform quality improvement for PCORI research and may add to the overall literature on addressing missing data in clinical studies.