

Multi Data Management Systems in a Cluster Randomized Trial in Poor Resource Setting: The Pneumococcal Vaccine Schedules Trial

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Abstract : A randomized controlled trial is the 'gold standard' for evaluating the efficacy of an intervention. Large-scale, cluster-randomized trials are expensive and difficult to conduct, though. To guarantee the validity and generalizability of findings, high-quality, dependable, and accurate data management systems are necessary. Robust data management systems are crucial for optimizing and validating the quality, accuracy, and dependability of trial data. To the best of author knowledge, few studies have examined innovative multi-data management strategies while conducting extensive cluster-randomized trials in poor resource settings. Regarding the difficulties of data gathering in clinical trials in low-resource areas, there is a scarcity of literature on this subject, which may raise concerns. Effective data management systems and implementation goals should be part of trial procedures. Publicizing the creative clinical data management techniques used in clinical trials should boost public confidence in the study's conclusions and encourage further replication. In the ongoing Pneumococcal Vaccine Schedule study in rural Gambia, this report details the development and deployment of multi-data management systems and methodologies. We implemented six different data management, synchronization, and reporting systems using Microsoft Access, RedCap, SQL, Visual Basic, Ruby, and ASP.NET. Additionally, data synchronization tools were developed to integrate data from these systems into the central server for reporting systems. Clinician, lab, and field data validation systems and methodologies are the main topics of this report. Our process development efforts across all domains were driven by the complexity of research project data collected in real-time data, online reporting, data synchronization, and ways for cleaning and verifying data.

Keywords : data management, data collection, data cleaning, cluster-randomized trial

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