



A Randomised Field Trial of Hospital Systems and Clinical Outcomes in Kenya

A Methodological Case Study

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ABSTRACT

Evaluating health system interventions in low-resource settings requires robust methodologies to measure clinical outcomes. Randomised trials in operational contexts present significant logistical and analytical challenges that are often under-reported, limiting methodological learning. This case study aims to critically appraise the design, implementation, and analytical framework of a randomised field trial assessing hospital systems interventions. Its objective is to detail methodological adaptations for a low-resource district hospital context. We conducted a methodological case study of a cluster-randomised trial in district hospitals. The primary analysis used a generalised linear mixed model: $Y_{ij} = \beta_0 + \beta_1 T_{ij} + u_j + e_{ij}$, where $u_j \sim N(0, \sigma^2_u)$, with robust standard errors to account for clustering. The study evaluated processes for patient enrolment, data collection, and outcome ascertainment. The trial successfully enrolled 1,842 patient episodes across 24 hospital clusters. A key methodological finding was that outcome ascertainment completeness was 15 percentage points higher in intervention clusters (92%) versus control (77%), indicating a significant Hawthorne effect. This introduced a measurable risk of ascertainment bias, necessitating sensitivity analyses. The case study demonstrates that rigorous experimental designs are feasible in operational hospital settings, but require explicit plans to identify and mitigate context-specific biases, particularly performance bias. Future health systems trials in similar contexts should incorporate blinded outcome assessment where possible and pre-specify quantitative bias analysis. Protocol designs must account for the high likelihood of differential implementation fidelity between arms. health systems research,

randomised controlled trial, methodology, clinical outcomes, implementation science, sub-Saharan Africa This paper provides a novel, detailed framework for the quantitative evaluation of trial implementation processes, moving beyond simple description to the measurement of bias mechanisms.

Keywords: *Randomised controlled trial, Health systems research, Sub-Saharan Africa, Clinical outcomes, Implementation science, District hospitals, Kenya*

Article Highlights

- Cluster-randomised trial enrolled 1,842 patient episodes across 24 hospital clusters.
- Quantitative framework measures bias mechanisms, moving beyond simple description.
- Demonstrates feasibility of rigorous experimental designs in operational hospital settings.
- Reveals necessity of pre-specified quantitative bias analysis for future trials.

Methodological Imperative

Protocol designs must account for high likelihood of differential implementation fidelity between trial arms.

A detailed framework for evaluating trial implementation processes in low-resource settings.

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