Infection Control Cluster Randomized Control Trials and Healthcare Facility Participation: A Need for Readiness Assessment

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1. Introduction

- Readiness assessments for healthcare organization participation in cluster randomized control trials (CRCTs) have not been developed.
- CRCTs have been important for increasing the evidence base for infection control[1].
- This study describes complex factors that can impact participation in an ongoing multi-site infection control CRCT within the VA healthcare system and the process of assessing such factors.

2. Methods

- A survey of 10 inpatient acute care patient units within five VA healthcare facilities was conducted to assess study participation eligibility and feasibility.
- With study delays, we began conducting readiness evaluations through email communications and conference calls.
- Content analysis [2] of conference call minutes [3] and email communications was performed using a matrix of domains from the Consolidated Framework for Implementation Research (CFIR)[4] to capture factors impacting feasibility.

3. Results

The first unit launched data collection in March 2022. As of September 2022, 5/10 units across 3/5 are participating in the CRCT. While the survey successfully captured eligibility metrics such as unit type, number of beds, infection rates, and infection control practices; conference calls and emails were more effective than the survey at detecting determinants of readiness for feasible study participation.

Barriers and Facilitators to Clinical Site Readiness & CRCT Feasibility: Content Themes

Relative Priority
- COVID-19

"Apologies but there is just too much going on with the [omicron] surge and planning."

Available Resources
- Staff (unit & research)
- Time

"No, all of our current coordinators are swamped with COVID studies and I'm not sure what next year will bring (in terms of COVID)."

Outer setting
- IRB requirements & approval delays

Inner Setting
- Fast-paced clinical environment

Complexity
- Nurses need to assess patient eligibility

"Nursing staff are easy to talk to; very willing to help; just takes a long time to wait for them to finish what they are doing"

Compatibility
- Unit process for tracking patient flow
- Baseline gloving practices on units
- Policies regarding who can collect specimens

Process: Planning, Executing, & Engaging
- Identifying study champions
- Involving unit staff in tailoring study procedures to unit workflow

"Refining process of identifying eligible patients and collecting specimens; working with nurses and MSAs to do so"

Adaptability
- Extent to which study procedures could be tailored

4. Conclusions

- Organizational readiness can delay or impede important infection control CRCTs.
- This study exemplifies the complexity of healthcare organizations' participation in clinical studies that may not be addressed in existing readiness tools or assessments.
- The emergence of the COVID-19 pandemic amplified the importance of identifying a wide range of contextual factors that need to be captured in ongoing assessments for readiness.
- An essential first step in developing organizational readiness tools and assessments is to identify and define readiness constructs in complex changing healthcare settings.
- Next steps include developing and testing such a tool and applying identified facilitators to the remainder of the CRCT.

5. References

[1]O'Hara, L.M., Blanco, N., Leekha, S., Stafford, K., Slobogean, G.P., Ludeman, E., Harris, A.D. Design, implementation, and analysis considerations for cluster-randomized trials in infection control and hospital epidemiology: A systematic review. *Infection Control & Hospital Epidemiology,* **40,** 686-692.

[2] Vaismoradi, M., Turunen, H., Bondas, T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nursing & Health Sciences* **15,** 398-405 (2013).

[3]Bowen, GA. Document analysis as a Qualitative Research Method. *Qualitative Research Journal,* **9,** 2, 27-40 (2009).

[4]Kirk, M.A., Kelley, C., Yankey, N. *et al.* A systematic review of the use of the Consolidated Framework for Implementation Research. *Implementation Sci* **11**, 72 (2015). https://doi.org/10.1186/s13012-016-0437-z

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