Developing Clinical Ethnographic Implementation Science Methods for Rapid Assessments in Acute Care Pragmatic Clinical Trials

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Background

- The Pragmatic Clinical Trial (PCT) design has been increasingly used to assess effectiveness and implementation of evidence-based practices in real world settings.
- A central tension for implementation science and pragmatic trial combined methodologic approaches is the need to simultaneously yield insight into key implementation processes while also maintaining pragmatic trial standards that aim to minimize investigative costs per subject randomized.
- Clinical ethnographic methods derived from rapid assessment procedures (RAPICE) have been proposed as a means for productively addressing this tension.
- However, to date, these methods have not been widely used in implementation science.
- Few effectiveness-implementation hybrid trial investigations have developed methods that simultaneously address the implementation science aims of understanding uptake, adaptation and sustainability of clinical interventions while also addressing pragmatic trial constraints that aim to minimize costs per subject randomized.

Study Aims

•Introduce a methodology for collection and analysis of data that adheres to the rigor of qualitative and mixed methods yet addresses the unique demands of simultaneously conducting pragmatic clinical trials and implementation studies of evidence-based practices.
•Demonstrate the application of this method to understanding factors contributing to success or failure of implementation trial, suitability of intervention for a particular population or context, and identification of methods to be tested in subsequent clinical trials

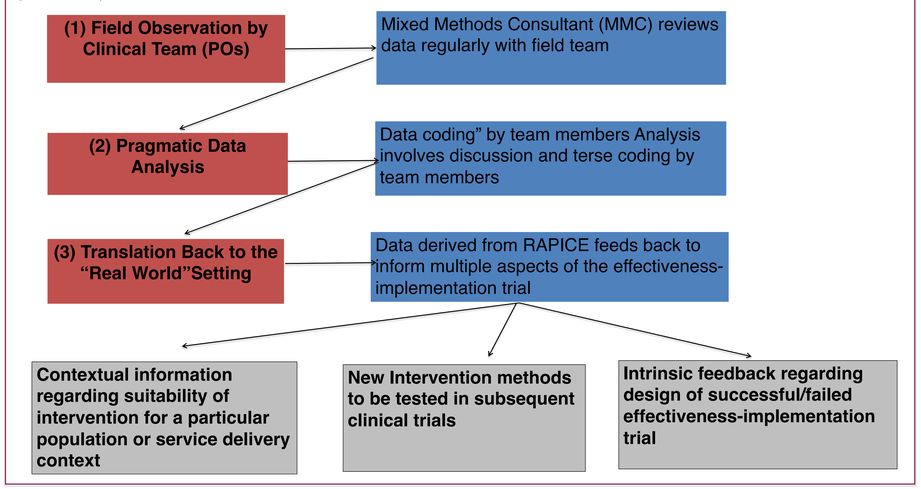
Methods (see also Table 1 and Figure 1)

- Combine previously articulated approaches
  - Rapid Assessment Procedures (Palinkas et al 2004; Palinkas 2014)
    - A) Multidisciplinary team
    - B) Multiple data sources (e.g., key informant interviews, field notes & jottings)
    - C) Iterative data collection and interpretation
    - D) Expedient data analyses that rely on both formal coding and team discussions
  - Clinical Ethnography (Zatzick et al 2011)
    - A) Clinical team engages in hundreds of hours of immersive health care system participant observation
    - B) Regular and frequent data review with expert mixed method consultant (MMC).
- Methods developed and refined during roll-out of Trauma Survivors Outcomes and Support (TSOS) effectiveness-implementation hybrid pragmatic clinical trial (Zatzick, Palinkas et al., *Implementation Science* 2016). TSOS is designed to test the delivery of high quality screening and intervention for PTSD and comorbidities across 25 United States level I trauma center sites.

Table 1. Steps to RAP-Informed Clinical Ethnography (RAPICE)

1.Participant observer (PO) conducts site visit to participating pragmatic trial clinics
2.PO participates in staff meetings, observes clinical procedures, and conducts semi-structured interviews with clinic staff.
3.PO documents site visit in the form of field notes and logs containing abbreviated transcripts of interview responses and observations.
4.PO presents field notes, logs, and any supporting material collected during the site visit to the Mixed Methods Consultant (MMC)
5.MME requires the qualitative data and queries the PO to gain more insight into the data and its context.
6.PO provides a preliminary interpretation of the meaning and significance of the data, which is organized as set of a priori and emergent themes and description of their interrelationships.
7.MMC then provides a preliminary interpretation of the meaning and significance of the data organized in the same fashion.
8.PO and MMC then identify points of convergence and divergence in the two interpretations.
9.A discussion between PO and MMC then ensues until consensus is reached regarding the meaning and significance of the data.
10.The consensus interpretation of the data is then applied to address the key study questions related to implementation.

Figure 1. Data Collection and Translation Process in RAP Informed Clinical Ethnography (RAPICE)



Results

•Monthly review of field notes and interview transcripts efficiently yielded a series of observations related to site barriers to study roll-out (e.g., challenges introduced by staff turnover, lack of site champion support for study procedures) and sustainment (lack of time and interest)
•These reviews also resulted in the identification of "an interstitial space" whereby prior implementation science methods development efforts did not adequately capture the acute care medical effectiveness-hybrid implementation context that aimed to use study findings to directly target national policy requirements
• Advantages of the RAPICE method included time efficient field observation and review procedures that constituted ideal "nimble" mixed method approaches for the pragmatic trial.
•Weaknesses included potential biases introduced by "internal" data reduction by the clinical ethnographer, as well as the potential for cursory data coding and thematic assessments.

Discussion

•Case studies have been used to identify barriers and facilitators to both pragmatic trial participation and the evidence-based PTSD screening and treatment intervention and to examine the manner in which the unique acute care context of the pragmatic trial is similar to but different from other key contexts that have informed implementation science methods to date.
• This examination resulted in the identification of "an interstitial space" whereby prior methods development efforts do not quite target study goals.
• Relevant implementation science constructs/models that could be seen to fall into this interstitial space include:

1. The effectiveness-implementation spectrum hybrid construct
2. The use of organizational culture and climate scales and organizational interventions in the current trauma surgery acute care context
3. The description of implementation stages as translated to the current effectiveness-implementation hybrid design.

Conclusions

- The integration of pragmatic trial and implementation science methodologies has great potential to advance the ultimate widespread adoption and policy relevance of clinical investigation.
- Pragmatic trials have as an inherent goal the minimization of costs per subject randomized.
- Implementation science aims to better understand the uptake, adaptation and sustainability of clinical interventions as delivered by front-line providers working in real-world health care systems such as acute care medical settings.
- Rapid assessment procedures when combined with clinical ethnographic methods (RAPICE) hold promise for the integration of implementation science and pragmatic trial approaches

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For further information

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