Rapid qualitative methods to inform implementation of a community paramedicine multi-site pragmatic randomized clinical trial

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BACKGROUND

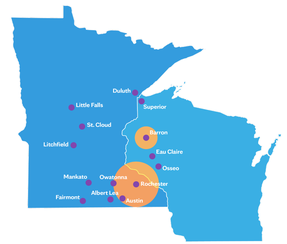
Practice-embedded pragmatic trials aim to generate timely evidence for translation. While balancing rigor and speed, researchers must also ensure that procedures are feasible, minimize practice burden, and maintain real-world conditions.

This research was conducted in the pre-implementation period of a trial assessing effectiveness and implementation of a community paramedic (CP) program to shorten or prevent emergency department (ED) visits or hospitalizations in adults being treated in the pre-hospital (home, clinic), ED, or hospital setting. The aim was to identify facilitators and barriers to implementation and refine workflows, ensuring feasible program and study conduct.

SETTING

Two Mayo Clinic Ambulance service areas that consist of very rural, rural, and urban communities.

- 40-mile radius of Mayo Clinic (Rochester, MN)
- 20-mile radius of a Mayo Clinic Health System site (Barron, WI)



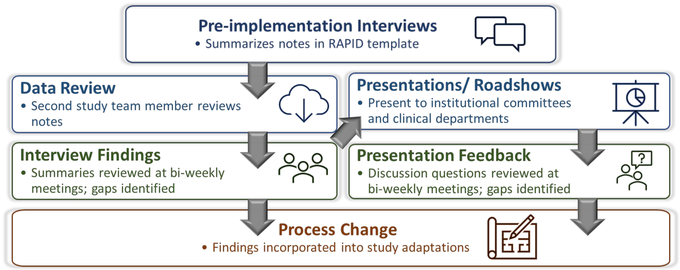
PRE-IMPLEMENTATION METHODS

Recruitment: The study team identified individuals in roles likely to be involved in or impacted by the trial and invited them to participate.

Data collection: Semi-structured interviews were conducted virtually and audio recorded for analysis. The study team also presented trial information to key stakeholder groups to increase awareness and solicit questions and concerns.

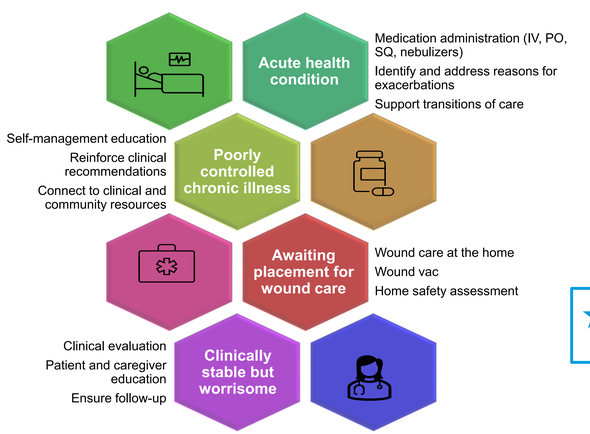
Data analysis: Interview recordings were reviewed by two team members and summarized in Rapid Assessment Procedure (RAP) sheets[1] organized by constructs related to implementation determinants. Presentation questions were tracked. The study team met biweekly to debrief findings and identify necessary actions, including trial adaptations to increase feasibility and acceptability.

FIGURE 1. Analysis procedures



Adapted from https://www.rapidresearchandevaluation.com/research

INTERVENTION + PRAGMATIC TRIAL



Intervention: The Care Anywhere with Community Paramedics (CACP) program for patients with intermediate acuity health needs who already are, or may be referred to, the ED or hospital for the receipt of services not typically available in the ambulatory setting.

Design: Pragmatic, two-group parallel, 1:1 randomized clinical trial of CACP vs. usual care among adults 18 years or older.

Study procedure: Randomization of 240 patients with intermediate acuity who present to the clinic, ED, or hospital.

Study aims:

★1) Identify potential facilitators and barriers to implementation and refine workflows in pre-implementation phase.

2) Evaluate CACP effectiveness, compared to usual care, as well as RE-AIM implementation outcomes.

3) Assess patient, CP, and clinician acceptability, satisfaction and perceived sustainability.

RESULTS

- Thirty individuals participated in interviews between December 2021 and April 2022, including referring clinicians (n=15), administrators/clinical leaders (n=5), individuals in related service lines, e.g., lab and pharmacy (n=5), and community paramedicine team members (n=5). The mean duration was 31 minutes (range 19, 59).
- The study team presented the study to and held discussions with 17 institutional committees and clinical departments.

TABLE 1. Examples of pre-implementation findings and related actions taken

Need/Issue Identified	Action Taken
1) Lack of CP program awareness	Curated “roadshow” presentations to raise awareness and address questions
2) Vagueness of program parameters	Created brochures, slideshows, and CP website for access to trial information
3) Access to inpatient medications	Work with pharmacy to create “wholesale pharmacy” to supply CP trucks
4) Clear and defined referral process	Referral process designed as an order set and communicated
5) Fear of misuse of CPs as providers	Graphical layout of CP scope of practice; further defined program parameters
6) Interest of other referring providers	Met separately with them to discuss study/enrollment flow
7) Difficult to refer patients “after hours”	Identified other timeframes to enroll patients
8) Remote consenting (i.e., technology issues)	Added access to phone and digital consent and ways to involve others

FIGURE 2. Community paramedic care

Community paramedics deliver care in community settings, including homes, hotels, and community day centers.

CONCLUSIONS

- In the 3 months pre-implementation, the team was able to identify and resolve key areas of concern.
- While resource intensive, rapid methods of engagement, data collection, and analysis provide timely feedback and inform changes to bolster feasibility and stakeholder relationships.

REFERENCES

[1] RREAL Rapid Research Evaluation and Appraisal Lab. (2020). https://www.rapidresearchandevaluation.com/

ACKNOWLEDGEMENTS

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