Involving Clinic Staff in a Large Randomized Control Trial: Balancing Study Goals with Maintaining Positive Relationships with Clinics

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INTRODUCTION

Previous studies have shown :

- High incidence of medical errors in primary care.
- More errors happen with elderly patients.
- One of the most serious hazards in primary care is INFORMATION CHAOS, leading to poor situational awareness and high mental workload.

We conducted a randomized control trial (RCT) in 4 clinics in the Wisconsin Research & Education Network (WREN) titled Situational Awareness Facilitating Excellent Care of the Elderly, or SAFE-C.

Purpose: To test the hypothesis that a human factors engineering intervention designed to increase situation awareness about a primary care elderly visit would increase physician situation awareness, reduce mental workload, and improve patient outcomes.

METHODS

4 Clinics
PCP/Nurse teams per clinic
Patients per physician per week

Recruitment:

3/4 participating clinics were recruited from a group of "full-support" clinics. These are WREN clinics that have an annual contract with WREN to subsidize a portion of the salary of a nurse or medical assistant (MA) to serve as a liaison to WREN, providing infrastructure to support participation in research projects.

Study Intervention:

Pre-visit Chart Review
- Nurse/MA completes chart review and fills in information on "Patient Overview Document" (POD)

Pre-visit Patient Phone Call
- Nurse/MA makes patient phone call to collect and fill in remaining data on POD

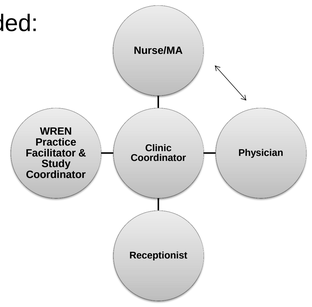
Day of Visit Huddle & Guide
- PCP and Nurse/MA complete "huddle" to review POD
- PCP uses POD during visit to help direct care

Measures:

Physician: Pre- and post-visit surveys
Visit : POD
Number & type of problems addressed per visit
Billing data
Patient: Post-visit survey

METHODS, cont.

The **Clinic Coordinator** served as the central hub within each clinic. Their duties included:



- Checking the 4 physician schedules 2 weeks in advance to identify patients >65
- Utilizing the REDCap Research Electronic Data Capture database to manage patient enrollment
- Running a randomization program to select study subjects - 16 per week
- Assigning a study ID number
- Directing the receptionist to call patient subjects to confirm visit appointment
- Getting study packet to Nurse/MA, and filling in for them during time-off
- Monitoring completeness of intervention & data collection
- Obtaining billing data and clinic notes from each study visit
- Maintaining integrity of study packets
- Troubleshooting problems in clinic

All randomization, patient enrollment, data collection and performance of the intervention occurred at the clinic and was conducted by the clinic team.

RESULTS

Recruitment: Successfully recruited and retained all 4 clinics and 16 PCPs

Enrollment:

Phase	Expected Duration	Actual Duration	Number Enrolled	% of Goal
Pre-Intervention	3 months	6-9 months	755	99%
Intervention	6 months	10-13 months	1514	98.6%

Challenges:

Communication: Both written instructions and regular in-person, telephone, and e-mail communication were crucial. Not all clinic staff had email access or used e-mail regularly; some had computers, but no internet access.

IRB: 18 months were spent in discussion with the IRB regarding study procedures for patient enrollment and consent. The study was deemed minimal risk and did not require patient consent to deliver the intervention, but due to privacy concerns, the clinic staff needed to perform the identification and enrollment of patients, as well as complete Human Subjects training.

Technology: Due to each clinic having its own billing system, EHR, and scheduling software, different processes had be developed to obtain data.

Timeline: The study duration was much longer than planned. Physician absences from clinic were underappreciated, such as vacation time, hospital duties, leave of absences. Clinic needs (rightly) took priority over study needs at times. Clinic physicians and staff used their clinical judgment to skip over study patients who were too ill, and sometimes the schedule was so hectic that study patients were missed.

CONCLUSIONS

- Conducting a large RCT within and across four primary care practices posed many challenges.
- PBRNs considering RCTs need to plan for adequate financial and personnel support for clinic personnel involved with the study.
- Pre-existing financial relationships with full-support clinics expedited recruitment and helped retain practices, and the use of clinic personnel as on-site study coordinators made it possible to meet enrollment goals.
- SAFE-C was very ambitious, and we underestimated the time needed for the study and the extent of clinic staff involvement required.
- The dedication of the physicians and staff at each of the 4 clinics, and the leadership of the Clinic Coordinators played a large role in the successful completion of SAFE-C.
- WREN and the SAFE-C Study Team worked well together and supported in clinics by providing:
  - Frequent communication
    - Relationship building and support for clinic coordinators
    - Feedback loop on study procedures
    - Daily availability for troubleshooting & problem solving
  - Extensive training and reference materials
  - REDCap: This easy to use, internet accessible software was critical
  - On-site check-ins
  - CHOCOLATE
- **There is a limit to how much you can ask clinics to do and how long you can keep them engaged for one project. PBRNs need to find a balance between meeting study goals and maintaining positive relationships with clinics.**
- **The study provided many lessons learned for conducting a large scale project with multiple phases and data collection points with busy staff at primary care practices within a PBRN.**

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