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Implementing Clinical Research in the High Acuity Setting of the Emergency Department

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Abstract

Introduction—Clinical research in the emergency department provides supporting evidence needed for the development of practice guidelines, such as door-to-needle and door-to-balloon times for treatment of acute coronary syndromes, and is vital to improvements in patient outcomes. The purpose of this article is to describe barriers and lessons learned in launching a multisite clinical research study of symptoms of acute coronary syndromes in the emergency department.

Methods—Participants included ED and research staff in 4 busy emergency departments in 3 states. At each step of the study launch, the principal investigator at the clinical site identified barriers that either were anticipated or experienced and discussed them with the site staff and study principal investigator to validate the issue as a barrier. Orientation sessions and ongoing communication between clinicians, research staff, and the research study team provided opportunity for adjustment of study protocols.

Results—Barriers were lack of staff engagement in research, difficulty identifying eligible patients, perception of interference in clinical care, variability in research staff education and training, patient refusals, nurses' perceptions of lack of time, undifferentiated patients, and time-sensitive quality improvement indicators necessitating acceleration in care.

Discussion—Important strategies to overcome barriers were developed, including identification and support of unit champions in emergency nursing and medicine; minor protocol modifications to improve enrollment goals; development of specific written expectations, roles, research protocols, and algorithms; and sharing successes among sites.

Keywords

Clinical research; Nursing research; Research methods; Research protocols; Emergency department; Acute coronary syndrome

Clinical research in the emergency department provides the supporting evidence needed for the development of practice guidelines such as door-to-needle and door-to-balloon times and is vital to improvements in patient outcomes.¹ Examples of other advancements in clinical care through ED research include refinement of cardiopulmonary resuscitation, pharmacologic guidelines for resuscitation, appropriate ECG analysis of ventricular fibrillation, and ST-elevation myocardial infarction (STEMI).^{2,3} Patient ED visits categorized as emergent have doubled from 8% to 16.6%, and those considered urgent have increased from 40.2% to 50.3% thus increasing acuity levels and increasing the challenge of conducting research.⁴ For instance, current standards call for rapid evaluation of patients with chest pain, with an ECG required within the first 10 minutes of arrival.²

Conducting research in the high-acuity setting of the emergency department is challenging for many reasons, including overcrowding, boarding of patients, mental health visits, provision of nonemergent care, and the need to meet quality indicators such as time to ECG for suspected myocardial infarction.³ Additionally, many quality improvement measures are publicly reported and linked to reimbursement rates, adding additional responsibilities for ED staff. Despite these obstacles, research has been recognized as providing the foundation for providing optimal patient care in the emergency department⁵ and is an expectation of the ENA.⁶ While nursing research is vital to advancing health care in the ED setting,⁷ lack of administrative and structural support has been cited as a common barrier to conducting nursing research in the emergency department.⁸ Engagement in research also is affected by lack of knowledge of the research process, lack of opportunity to participate in research, and lack of understanding of statistical analyses.^{9,10} No prior studies have documented the challenges encountered in implementing a multicenter nursing research study in the high-acuity setting of the emergency department. Therefore the purpose of this article is to describe barriers and lessons learned in launching such a study. The research being conducted is the Think Symptoms study. The main aim of the study is to examine the influence of gender on symptom characteristics during acute coronary syndromes (ACS). A novel prospective design in which symptoms are assessed on presentation to the emergency department is being used.

Methods

SAMPLE AND SETTING

Participants included ED and research staff in 4 busy emergency departments in 3 states—3 urban academic medical centers and one large referral hospital located in a rural area. Participants predominantly were female, registered nurses, and well educated. Each emergency department has a site principal investigator (PI), including 2 physicians and 2 doctorally prepared nurse researchers. Three sites have fulltime research staff employed in the emergency department who are involved in the study.

PROCEDURES

Identification of Barriers—At each step of the study launch, including preparatory work, the PI at the site identified barriers that were either anticipated or experienced and discussed them with the site staff and the study PI to validate the issue as a barrier. The initial plan was to have the Symptom Checklist completed by triage nurses, but this plan was modified early in the process because of the challenge of identifying who should be screened. In the first 6 months of data collection, we recruited many more patients who had ACS ruled out than was anticipated. To more accurately identify who was likely to be ruled in, we chose to delay the enrollment process until evidence of ischemia was available. Therefore at 2 locations the Symptom Checklist is completed by research staff who are alerted to patients

who have received orders for a troponin level check and an ECG. At another site, the Symptom Checklist is being completed by registration staff trained by the site coordinator. Research staff then determine if the patient is eligible for the study.

Think Symptoms Study—A brief background of the Think Symptoms study design and methods are presented to provide context for the methods for identification of barriers to conducting research in the emergency department. A prospective approach in which symptoms are recorded as soon after presentation to the emergency department as possible is being used in the study. The target enrollment is 800 patients admitted to the emergency department with symptoms suggestive of ACS. Participants are being recruited from 4 emergency departments in Illinois, California, and Oregon with annual visits in excess of 300,000. The primary measure is a 13-item ACS Symptom Checklist completed upon presentation to the emergency department (Figure 1). Measures of physical function, comorbidities, and clinical data are collected once the patient has provided written consent and has been admitted to a room.

Human Subjects Protection—Approval for the study was received from the sponsoring institution and the 3 other clinical sites before the study launch. A waiver of consent for the Symptom Checklist *only* was obtained from all 4 institutional review boards in order to record symptoms before the patients' enrollment in the study. The rationale for the waiver was that the research could not practicably be carried out without the waiver. The primary study aim of collecting *prospective* symptom data would not be possible without a waiver to assess symptoms while they are occurring and before providing written informed consent. Patients are approached for consent when they are stabilized. Once enrolled, participants complete a short survey and provide contact information for follow-up calls.

Presentation of Study Protocol to Triage Nurses and Research Staff—The study initially was launched at 2 sites, and an additional 2 sites were added during the following year. A formal presentation, including PowerPoint slides and handouts, was provided to all interested staff in orientation sessions. The researchers were flexible and attentive to the requests of staff in each emergency department. The type of orientation program was determined by the individual emergency departments because cultures vary by institution. The formal orientation with a PowerPoint presentation was conducted at 2 locations by the PI and co-investigator. A study protocol algorithm was developed and distributed (Figure 2). Staff had an opportunity to ask questions and provide feedback to the researchers. In one location, the PI met with the site coordinator, director of emergency medicine, and research assistant to review protocols. The site team then conducted orientation with ED staff. At the final site, the PI, clinical education nurse, and research nurse conducted a 12-hour-long informal orientation session in the ED break room. Staff attended when they were available, viewed slides, reviewed handouts, and asked questions of the research team. Booster orientation sessions were conducted on the day the study was launched.

Results

Conducting a multisite study is an arduous process. Meetings with site PIs and research staff were conducted before patient recruitment in an effort to launch successfully with as little delay as possible. Regularly scheduled monthly meetings, in person or via phone conference, were held to discuss barriers to the study and possible solutions. Phone conferences were conducted as needed. Site coordinators and research staff can reach the PI by cell phone 7 days a week, and they call whenever questions arise. Barriers to the research were identified by all ED and research staff and have been categorized in the following sections.

STAFF ENGAGEMENT IN RESEARCH

Some staff have been extremely enthusiastic about participating in the study and have self-selected to assume the role of unit champions, whereas some staff are disinterested. Support for research varies according to the culture of the institution. Despite the fact that one site is pursuing Magnet status from the American Nurses' Credentialing Center,¹¹ participation in research is not yet a priority. One site has a strong labor union, and nurses expressed resistance to participating in research. During an orientation session during change of shift, one nurse commented that research was not part of the job description. The PI and co-investigator stressed the importance of nursing research contributing to the evidence on which best practices are based. Two sites have instituted policies to encourage staff participation in the study. One site offers emergency nurses credit toward progression up the clinical ladder, and another offers release time to participate in research committees and journal clubs. These and other strategies demonstrate administrations' commitment to clinical research and aid staff in adopting the same values.

IDENTIFYING ELIGIBLE PATIENTS

The study was designed with the expectation that eligible patients would be identified by triage nurses. This process worked well in pilot testing in another institution; however, identification of eligible patients was supervised by the PI, who was present in the emergency department and collected all pilot data. When it became evident that this process would not occur in the emergency departments participating in this large study, the research team met to develop a new plan for identifying patients. Concomitantly, we tracked enrollment figures. During the first 6 months of the study, more than 300 patients were enrolled. More than 200 of these patients had ACS ruled out, exceeding our original goal of 108. The challenges associated with identifying patients at high risk for ACS accounted for the high number of patients enrolled who subsequently were ruled out. Consequently, we decided to take advantage of the fact that patients were receiving ECGs and having blood drawn to determine troponin levels within 10 minutes of arrival. Subsequently, only patients whose troponin level exceeded norm-referenced values for the institution or had ECG changes consistent with ischemia were approached for enrollment. The Symptom Checklist has been completed before an ECG has been performed and blood has been drawn for a troponin level in most cases. One site asked registration staff to complete the Symptom Checklist for stable patients because they are sent immediately to registration after evaluation in triage. Registration staff were trained by research staff in administration of the tool. This process worked well because symptoms are recorded immediately on admission and research staff then could enroll patients when they had been placed in an examining room and are comfortable.

PERCEPTION OF INTERFERENCE IN CLINICAL CARE

Some emergency nurses expressed concerns that conducting research interfered with or had the potential to interfere with the provision of patient care. This concern was particularly evident in triage nurses' resistance to completing the Symptom Checklist, even though it contained items commonly assessed during the triage and admission process. Several triage nurses in one location noted that many patients often were waiting to be evaluated and that using even a short Symptom Checklist would take time away from patient care. We could find no evidence to support the notion of interference with care in the literature. The main concern expressed by staff was that participating in the research would take them away from other patients. We emphasized to staff that compromising patient care in favor of collecting data for a research study is unethical.¹ This feedback reassured some staff that the priority of clinical care would not be compromised, but others were not convinced and declined to participate.

VARIABILITY IN RESEARCH STAFF EDUCATION AND TRAINING

Although all research staff completed mandatory ethics and Health Insurance Portability and Accountability Act training, they vary in educational preparation and experience. We received feedback that research assistants, who were not nurses, could not determine whether patients were eligible for the study based on unfamiliar items in the screening tool. Use of the tool requires clinical judgment and familiarity with the terms and concepts of heart failure, dysrhythmia, STEMI, and ACS. Some research assistants required additional training in these terms and where to find this information in the record if patients did not know their health history. Refinement of enrollment algorithms and scheduled training at monthly research meetings has helped overcome these barriers.

PATIENT REFUSAL TO PARTICIPATE

Refusal to participate in the study was a concern initially. In the first 9 months, rates were 50.4% at one site (66/131) and 30.9% (93/301) at a second site. These sites were the home institutions of the PI and co-investigator, who had frequent interactions with the study team. Data were not yet available from the other sites. Patients who refused expressed feelings of fatigue, anxiety, uncertainty, and discomfort. This issue was addressed by focusing on timing and approach to potential participants. Research assistants were trained to use a calm and friendly approach when patients were stable, more relaxed, and pain free. Every attempt was made to discuss the study when the patient was alone in his or her room with little chance of interruption. A small number of patients expressed resistance to blood draws and were enrolled without a blood sample being collected. Often patient fears were addressed successfully during quiet and empathetic discussion in private. The overall refusal rate is currently 24.8%, indicating that the strategies have been effective. Additionally, the 2 sites that launched the study later benefited from lessons learned at sites 1 and 2.

NURSES' PERCEPTIONS OF LACK OF TIME

A number of nurses responded that they did not have time to complete the Symptom Checklist or identify eligible patients because of high census, overcrowding, and/or boarding of patients. They stated that patient care in the emergency department required all of their time. In some cases, inadequate staffing was noted to be a problem. Other time constraints reported were required training, continuing education, and committee responsibilities. These barriers were beyond the control of the researchers, so we focused on assisting the research staff in enrollment activities.

UNDIFFERENTIATED PATIENTS

Enrolling patients with suspected ACS necessitates the evaluation of patients whose diagnoses remain undifferentiated and complex. For example, a sprained ankle is fairly easy to diagnose and treat based on history and physical examination, but vague symptoms such as weakness, fatigue, or indigestion make it extremely difficult to determine the problem without diagnostic testing. Identification of patients with STEMI usually is straightforward based on ECG findings, but identification of patients without STEMI and patients with unstable angina requires further diagnostic work-up, risk stratification, and clinical judgment, all of which are challenging in the ED setting. To overcome some of the initial diagnostic uncertainty and capture patients likely to rule-in for ACS early, we obtained a waiver of consent from the institutional review boards to complete the Symptom Checklist before obtaining informed consent, waited until after evidence of ischemia was available either from an ECG and/or troponin levels, gained assistance in identifying patients from unit champions, and enlisted the help of the rapid response team in one location.

QUALITY IMPROVEMENT INDICATORS

The need to meet quality indicators of care, particularly the practices that are time dependent, presents another barrier to research in the emergency department. Guideline-based care requires that patients be seen and treated more quickly for conditions such as STEMI, stroke, pneumonia, sepsis, and trauma. At the same time, fewer human and financial resources are available to accelerate triage, assessment, and diagnostic testing. For example, guidelines for the treatment of STEMI recommend a goal of 90 minutes or less for door-to-balloon time.¹² Meeting these guidelines requires many resources in order to triage, admit, and transfer patients to the cardiac catheterization laboratory as quickly as possible. Clinical care is the priority; however, once patients are seen and stabilized, they can be enrolled in research studies. It is evidence from prior studies that have resulted in the professional guidelines used in practice.

Four strategies to address each of the barriers identified were successfully undertaken and can aid other investigators conducting research in high-acuity settings. First, unit champions in nursing and medicine were identified, supported, and incentivized through promotion and release time. Second, minor modifications that did not change study aims but could improve enrollment goals, such as enlisting the cooperation of registration staff, were made based on clinician and research staff input. Third, specific written expectations, roles, research protocols, and algorithms were developed, shared with all research personnel, and reviewed periodically. Fourth, successes were shared between sites via E-mail, phone calls, and regularly scheduled meetings. Dissemination of findings within the departments also may positively affect research interest in the future. Finally, we shared collective study milestones among each site. Milestones included the number of patients screened, the number enrolled, and diagnoses. These data were graphed and shared with the entire research team via E-mail. Successful strategies to overcome barriers also were shared among sites at monthly phone conferences.

Discussion

Numerous barriers to research were noted in the launch of the Think Symptoms study. Acceleration of care such as rapid determination of troponin levels and ECGs add pressure to already busy clinicians and impedes participation in the research process. Of these barriers, lack of staff engagement and difficulty identifying eligible patients were the most critical and the most challenging. Our research team designed new approaches to identifying eligible patients by monitoring the ED admissions on the computer, arranging to be paged when patients with STEMI arrived by ambulance, and enlisting the help of unit champions to receive notice of admissions. We are supporting change in institutional policy to change role expectations and facilitate engagement of nursing staff in research. Our findings were similar to prior research, which found evidence to support the participation of nurses in clinical research when they are empowered to do so. In a study designed to describe barriers and attitudes toward safe patient handling, staff nurses willingly conducted research to improve safe patient outcomes.¹³

Many emergency nurses reported being too busy caring for patients in an overcrowded department and boarding of patients as barriers to participation in research.¹⁴ These findings also have been reported previously. Olshaker¹⁵ found that the inability to transfer patients from the emergency department to inpatient beds is the most important factor leading to overcrowding. In another study of overcrowding, patients with ACS experienced more adverse outcomes during the time of highest waiting room census (odds ratio, 3.7; 95% confidence interval, 1.3-11.0).^{15,16} Both overcrowding in the waiting room and boarding are factors that impede enrollment of patients in research studies.¹⁶ Our findings indicate that a comprehensive model of practice, including a research committee, facilitated staff

participation at one site. Larkin et al¹⁷ found that the adoption of a collaborative model of practice, including a research committee structure, improved the use of research findings in practice. Finally, the use of electronic health records (EHRs) may facilitate the conduct of clinical research in the emergency department if tools such as the ACS Symptom Checklist can be imbedded in the record. One of the benefits of the use of EHRs is use for research and standardization of documentation.¹⁸ The EHR also could be programmed to trigger an alert for the symptom checklist when a patient is triaged. There would be little redundancy because the Symptom Checklist contains symptoms already included in the nursing assessment.

Limitations

This analysis of barriers to conducting clinical research in the emergency department is limited to the implementation of one ongoing study. Although it was not an original purpose of the Think Symptoms study, it quickly became clear that evaluation of these barriers would be key to the success of the study. Therefore we added a descriptive aim to chronicle the barriers and related strategies to address them. The fact that these barriers data were not collected using formal or standardized staff surveys was a limitation. In addition, many of the barriers to conducting research described here varied across institutions and may have been the result of administrative or clinical policies and processes unrelated to this study.

Implications for Emergency Nurses

Evidence-based practice is the goal for emergency nurses. Emergency nurses can have an active role in the design, implementation, and dissemination of clinical research. Participation in clinical research has been recognized as an important area in the ED setting as part of a unit-based research team.⁹ Nurses have recognized the importance of involvement in research in improving their clinical practice and for identifying evidence-based outcomes to improve the care of their patients.

Conclusions

Initiating rigorous clinical studies in the ED setting presents unique challenges, but they can be overcome through development of clear study algorithms and communication between research personnel and ED staff. Important strategies to overcome barriers were developed, including identification and support of unit champions in emergency nursing and medicine; minor protocol modifications to improve enrollment goals; development of specific written expectations, roles, research protocols, and algorithms; and sharing successes among sites.

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Symptom	Symptom Present?		Chief Complaint (Please check only one)
	Yes	No	
1. Chest Pressure			
2. Shoulder Pain			
3. Sweating			
4. Palpitations			
5. Chest Discomfort			
6. Upper Back Pain			
7. Short of Breath			
8. Arm Pain			
9. Unusual Fatigue			
10. Nausea			
11. Lightheaded			
12. Chest Pain			
13. Indigestion			
14. Other (write in):			

FIGURE 1.
Preconsent symptom checklist.

FIGURE 2.
Study protocol. ACS, Acute coronary syndromes.