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Participating in a Multisite Study Exploring Operational Failures Encountered by Frontline Nurses

Lessons Learned

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This article describes our experience participating in a multisite collaborative study involving frontline nurses and operational failures (OFs). We encountered a range of challenges conducting the study as proposed by the study's coordinating center (CC), which hindered our ability to meet our goals and objectives. We identified 3 general areas in which our expectations and actual experience diverged: 1) research resources, design, and methods; 2) CC communications and deliverables; and 3) influencing organizational change. Nurse executives considering collaborative research or assessing methods to engage clinical nurses in organizational improvements will benefit from our experience.

In fall 2013, a research institute dedicated to the study of healthcare improvement science widely distributed a call for hospitals to join a multisite collaborative study. Participation was based on a "pay-to-play" model; hospitals paid a fee to join the collaborative and participate in the study. In return they would benefit from the expertise and research tools of the institute. In addition, participating organizations were to receive organization-specific as well as aggregated data reports across all participating institutions. This particular study examined a methodology involving RNs in the detection and recording of operational failures (OFs) using a tool that the study sponsor had developed and previously vetted.

Operational failures are defined as instances where a worker does not have the supplies, equipment, information, or people needed to complete work tasks.[1] Operational failures stem from a variety of causes, may be classified into many categories, and their consequences range from minor inconveniences to catastrophes.[1,2] They are more common when work is complex.[1] Hospitals are complex systems[3] within which nurses experience OFs repeatedly throughout their shifts. This results in interruptions in their work leading to decreased efficiency and an increased risk of medical error.[1,4,5] An alternate work procedure, known as a work-around,[1] is often devised to get the job done. Evaluating work-arounds provides valuable information for prioritizing and fashioning organizational improvement initiatives.[4] Although OFs are frequently the focus of study within the hospital quality improvement context, their complex nature often makes them a challenging problem to address.

The underlying assumption of the collaborative study was that direct involvement of RNs in the observation and recording of OFs would help to engage them in institutional problem solving. RNs

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serving as stakeholders in organizational learning is a key component of Magnet® designation. Expanding opportunities for nurses to conduct research focusing on improvement of practice environments and health systems is an Institute of Medicine (IOM) 2010 recommendation.[6] Thus, the values inherent in the stated study goals were also shared by Magnet and IOM. The opportunity of participating in a multisite study is attractive to nurse executives who are committed to providing research experience for clinical nurses, particularly those institutions with few resources to conduct research on their own. Multisite collaborative studies offer a compelling solution to gather much-needed data to address institutional needs and priorities. This specific study had many interesting elements: collaboration with a nationally recognized group and the ability to study a clinically meaningful question about system defects at the point of care. Our organization had previously developed a Lean Six Sigma program and conducted several learning lines on clinical units. These Lean events provided both a structure and a process for nurse managers to bring the voice of clinical nurses to the problem-identification and problem-solving table. Although many problems at the point of care were identified and addressed through Lean methods, we were interested in trying a different methodology of engaging RNs in problem identification. In addition, having access to aggregated data from many other participating sites would allow us to establish benchmarks and best practices on which to gauge the success of in-house initiatives in the future. These potential outcomes prompted our participation.

Thus the chief nursing officer of this inner city, 3-time Magnet-designated academic medical center responded affirmatively to the call. A reasonable brief application was required as well as payment of fee. Once accepted, a contract between the coordinating center (CC) and our institution was finalized. The contract allowed individual sites to publish and present data from their individual site-specific report. Although not required by the CC, our legal department stipulated that a data use agreement be executed before study initiation to ensure that our organization owned its own data and thus had primary control of our data. Later, when we examined the utility of the data provided in our site-specific report, this provision proved to be quite important.

Our overall expectations for participating in the collaborative study were not met. This article examines some of the challenges and obstacles we encountered. First, we provide a brief overview of the study eligibility requirements, goals, and objectives. Next, we describe the study procedures and time lines. We then examine the divergences between our expectations, as described in the study protocol and other materials, and what we experienced. The challenges we encountered can be categorized into 3 general areas: 1) research resources, design, and methods; 2) CC communications; and 3) influencing organizational change. We conclude with implications for nurse executives.

Study Eligibility Requirements, Goals, and Objectives

The multisite collaborative study focused on acute care hospitals. Prospective hospitals had to have been in operation for at least 1 year and had to identify 3 medical surgical (M/S) units with an average length of stay from 0 to 6 days to participate. There were 10 hospitals in the study cohort consisting of teaching/nonteaching and Magnet-/non-Magnet–designated sites. Each site was to recruit and enroll 20 RNs from each unit. The national study goals, as outlined in the protocol, were to (*a*) inform improvement initiatives at participating institutions and (*b*) explore the relationship of OFs, organizational culture, and nurses' perceptions of their practice environment. Study objectives included assisting sites with the: 1) collection of robust OF data; 2) production of reports on OF characteristics and their relationship to nursing practice environment (NPE); and 3) development and execution of action plans to address identified OFs.

Study Procedures and Time Lines

Study Team, Subject Recruitment, and Communications

The multisite collaborative study protocol provided participating sites with basic guidelines and recommendations for the recruitment, written informed consent, and data collection and management procedures. The protocol described the processes and procedures for transfer of on-site data to the CC, which would then perform data quality control, analysis, and production of summary reports for sites. It recommended that each site assemble a research team including a site principal investigator (PI), study coordinator (SC), and volunteer research assistants (RAs) to manage the various activities of the study, including data entry into the CC electronic database. The protocol required institutional review board (IRB) approval at each site. A supplemental handbook provided guidelines for IRB submission, protocol implementation, data entry, and offered sample e-mails for RN recruitment and other miscellaneous information.

The CC established the study time line, with specific dates from recruitment to completion of data

quality control, before the study launch. All sites were expected to meet the timetable. The CC scheduled periodic webinars and phone conferences with site PIs to share information and assess progress being made at each site. A project coordinator at the CC was available for communications outside of scheduled calls.

Data Collection Activities

After a 21-day recruitment phase, a 34-day period was devoted to data collection using 2 CC-designated tools. The 1st tool was an "index card" designed to fit into the RNs pocket. Six global OF categories were listed: (*a*) equipment/supplies, (*b*) physical unit/layout, (*c*) information/communication, (*d*) staffing/training, (*e*) medication, and (*f*) other. Registered nurses were instructed to write a brief OF description under the corresponding category on the card then indicate the frequency of its occurrence with a hash mark each day. The flip side of the card instructed RNs to consider "disruptions in ability to execute prescribed task" and provided some examples of what fit under each category. Each RN was given 10 cards to complete in the span of 20 days.

The 2nd tool was a survey packet that included multiple validated scales and instruments to assess organizational and work environment factors such as teamwork, NPE, quality improvement activities, perceptions of safety and quality of care, and job satisfaction. Registered nurses had 2 weeks to complete the survey packet. Confidentiality of RN participants was achieved by the assignment of an identification code to all data collection tools. Research assistants would visit each unit to collect the cards and surveys daily. Research assistants were then to enter the data into the electronic data portal. Once all data were entered, the CC performed quality control review. These processes, from recruitment through CC data quality control, were to be completed within 70 days. The CC would then analyze the data from all sites. Site-specific and aggregated reports would then be issued by the CC, after which they would assist sites in designing improvement initiatives.

Challenges Encountered at Our Site

Almost immediately, variations in what was expected emerged. Some hospitals obtained IRB approval more quickly than others and CC decided to stagger sites into 2 cohorts with the 2nd cohort beginning 21 days after the 1st. Only after the 2nd cohort finished data collection, 91 days after the 1st cohort started, would the CC analyze the data from all sites. The decision to create 2 cohorts was followed by additional alterations to the time line for other reasons, which led to delays in data quality control processes and aggregated analysis of data across sites. This was a harbinger of things to come. Our site-specific summary report was received 3 months after we submitted our data to the CC. Table 1 provides a summary of findings from our site-specific report.

Research Resources, Design, and Methods

There were several areas where our experiences differed from the descriptions in the CC protocol. In the area of research resources, design, and methods, these divergences affected the study team, as well as the participating RNs. The study team struggled with allocating adequate staff time at each study phase, specifically when recruiting/consenting RNs in the clinical arena and entering paper and paper data into the electronic portal. Registered nurses experienced confusion and a wide range of challenges using the index card tool to record OF data, although these difficulties were not apparent until after the data collection period when we met with unit nurses to discuss study findings. Table 2A provides a summary of some key differences between what was expected and what we experienced at our site with regard to research resources, design, and methods.

CC Communications and Deliverables

The CC scheduled periodic conference calls among the participating sites to provide updates and answer questions. A CC project coordinator served as the 1st contact for questions or problems encountered by sites, relaying more serious questions to co-PIs and directors of the CC. There was little opportunity to hear about experiences at other sites. It was difficult to discern whether others were experiencing some of the same challenges we were. Furthermore, the written materials provided by the CC were insufficient, particularly with regard to the training of RNs about the index cards and data collection procedures. This led to variations in how RNs completed the tool, which only became apparent after our reanalysis of our site data. In short, the CC did not foster a learning environment among the participating sites nor was there sensitivity to the working environment of RNs, which would impact their ability to be effective data collectors.

As a result of the alterations in the time line noted, expected deliverables from the CC, that is, site-specific and aggregate site reports, were significantly delayed. Analysis of the correlation between OFs and NPE was discussed on a phone call but not addressed in the CC issued reports. Creating 2 cohorts suggested that some sites struggled with aspects of the study. Initially obtaining IRB approval was a factor but later delays in the issuance of the aggregated report, which was received 9 months after our submission of site

Table 1. Descriptive Summary of Our Site Specific Report

Data Collection Activities	
Number of RNs recruited	60
Number of RN submitted index cards	52
Total number of index cards obtained	269
Average index cards submitted per RN	5.2
Index cards compliance rate[a]	60.3%
Survey response rate[b]	96%
Total number of operational failure reports	1427
Average operational failures reported per shift	5.3
Percentage of OFs by Category	**%**
Equipment/supplies	27.5
Physical unit/layout	11.1
Information/communication	12.5
Staffing/training	10.4
Medication	22.3
Other	16.2

[a]Percentage of cards completed up to the maximum permissible amount (10 cards) given the number of shifts the RN worked during the study.
[b]Percentage that completed both index cards and surveys.

data, indicated that other issues were present. The reason for the delay was not explained to the sites. Whatever the cause, the delays stymied our ability to progress according to plan. We finally decided to act on our site-specific report alone, leading us down the path of conducting our own reanalysis of our data. This revealed a range of data inconsistencies and confounding variables that would not have otherwise been known. Table 2B provides a comparison between what was expected and what we experienced at our site with regard to CC communications and deliverables.

Influencing Organizational Change

Ultimately, the goal of the multisite collaborative study was to provide data to develop and implement action plans to address OFs identified by the RNs. In addition, we were interested in comparing our data to other sites to benchmark our performance and to have opportunities to share best practices with colleagues. These goals were not achieved for a variety of reason. The delays were 1 factor but insufficiency of the data was a serious impediment to our ability to rally support among leadership for an action plan. After a "deep dive" into our data, we were able to isolate 1 specific and actionable OF from within the "missing equipment" category that was common across all the units. That specific issue, however, represented a

Table 2. Illustrations of Challenges Encountered At Our Site

A. Research Resources, Design and Methods
Allocation of resources
Required additional resources to meet requirements of the protocol, particularly recruiting and interacting with RNs during data collection
Unanticipated reanalysis of site data and meetings with stakeholders to discuss findings
Data collection
RNs were unclear about proper data collection protocols; additional training information and instructions were required (learned after completion of study)
B. Coordinating Center Communications and Deliverables
Effectiveness of communications
CC has recommended communications with RNs and others did not align well with institutional processes and practices
Little opportunity to share experiences with other sites and to discuss best practices
Insufficient occasions to speak with CC professionals about emerging issues and challenges
Timeliness and utility of data
Site-specific report delayed 3 mo (after submission of our data to CC)
Aggregate report delayed 9 mo (at which time we had already concluded our analysis)
OF data provided in site-specific report was categorized in 6 general categories; too global to generate action plan without additional data analysis
Additional in-house analysis revealed that CC conducted data manipulations, which revealed data collection inconsistencies, which had not been shared with sites
OF and survey data were not correlated in the CC report
C. Influencing Organizational Change
Data in aggregated report revealed differences among sites in terms of size, patient demographics and other characteristics making it of little use of benchmarking
In an effort to identify an actionable finding, we reanalyzed our site data. Within the equipment/supply global category we drilled down to the largest subcategory common to all units. The problem most frequently cited reflected only a small proportion of all identified OFs.
The CC did not support formulation of action plans
Urgency to "solve the problem" was diminished by delays

small fraction of the total OFs identified, which was not deemed serious enough for resource-intensive action. More importantly, given our reservations about the entire process, we were reluctant to overstate our case with leaders. Ultimately, we presented our findings to nursing leadership. However, because of the inordinately long time line and insufficient confidence in the data, we were unable to secure resources to address the issue. In hindsight, we recognized that having a member of Nursing Leadership on the research team may have provided additional insights and leverage to influence change. Table 2C provides a comparison between what was expected and what we experienced at our site with regard to influencing organizational change.

Implications for Nurse Executives

Participation in multisite research collaborations may provide institutions, particularly those with minimal research resources, the ability to participate in a diverse, national study.[7-10] In an era of scorecards and benchmarks, the possibility of sharing and comparing data across sites is compelling and valuable. However, there are hidden challenges that may reduce the likelihood of achieving the desired outcomes.

Our experience, although disappointing in many ways, elucidates some important lessons to consider when deciding to participate in a multisite collaborative study, especially academic-clinical practice partnerships. There were positive aspects to our involvement in the research collaboration, particularly with regard to developing an established site research team, which included 3 RN volunteers. This demonstrated that RNs in our setting, under defined parameters, can be effective research team members. We have subsequently replicated this approach with other internal studies. In addition, the frontline RNs who participated in the study, although poorly prepared for their task, were genuinely interested in solving OFs identified on their units. When we met with unit nurses to discuss our study findings, they provided valuable insights on the topic.

To some extent the less successful aspects of the multisite collaborative study stemmed from differences in academic research centers and clinical practice settings. The study's research design, recruitment processes, and data collection activities reflected an academic mindset rather than that of the hospital's fast-paced, outcome-oriented, data-driven decision-making environment[11] where effective communications across services and disciplines are imperative. Hospitals, especially academic medical centers, also encourage learning environments where colleagues work together to solve problems and avoid making the same mistake twice. Unanticipated delays, poorly designed reports, and less than robust results require post hoc debriefing and plans for improvement. In short, the mismatch between study and site required more in-kind contributions of resources on our end than was originally anticipated (beyond the participation fee) and, more importantly, failed to produce meaningful results.

Going forward we identified several recommendations for institutions to consider when joining a multisite collaborative study:

- Obtain a data-use agreement providing access to your institution's data. This turned out to be a critical provision in our contract with the CC. Our ability to do a deep dive of the data not only allowed us to get more granular view of our data for identifying OFs but also revealed many recoding and other data decisions made by the CC, which sites were not made aware of.
- Conduct a literature review on the topic of the research before deciding to participate in the study. We examined the literature after we completed the project, learning afterward that there is minimal consensus among researchers as to best approaches for collecting data from practicing RNs.
- Learn more about the other participating sites. Our cohort represented a diverse group of hospitals, Magnet/non-Magnet, rural/urban, and suchlike. This can produce interesting comparative data for research purposes but may not include enough clusters of same-type hospitals for developing meaningful benchmarks.
- Engage leadership from the start. Our nursing leadership was aware of our participation in the multi-site collaborative study but there was no single individual who served as its champion. Perhaps with more involvement of leadership we could have anticipated some of the barriers we encountered and struggled to resolve. More importantly, an influential champion may have assisted in crafting a more compelling argument to invest in solving our identified OF.
- Speak with the multisite collaborative study PI to get a firm idea of how much support, consultation, and communication to expect from the coordinating body. As mentioned, the conference calls and webinars did not result in a sense of community among the participating sites. We were not routinely informed about which OFs were found at other sites, for example, or if any sites were successful at launching action plans. Though a CC research coordinator was helpful and available, we had few opportunities to discuss our concerns and challenges with the national PI or research director.

Multisite "pay-to-play" research collaborative studies can be valuable to hospitals and other practice settings that share common objectives and concerns. Our interest in studying OFs, and our desire to assess alternative methodologies to include RN input in problem solving and improvement, motivated us to participate in such a collaborative. Our experience had limited success in providing the data we sought but provided a unique opportunity for us to assess our RNs ability (and enthusiasm) to conduct research on OFs that impact their practices. Hospitals and sites that have limited resources for conducting research can benefit from collaborative arrangements, particularly those seeking Magnet status. Nurse executives should balance the potential benefits of collaborative research with the potential disadvantages of such an arrangement, particularly with respect to devoting sufficient resources to meet project requirements, managing deadlines (and oftentimes delays), and maintaining communications between CC, study team, and nursing leadership at your institution. With these elements in place, multisite collaborative studies can produce results that will influence organizational change and meet organizational expectations.

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