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Collecting Nursing Research Data 24 Hours a Day: Challenges, Lessons, and Recommendations

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Abstract

Background—Research on many routine nursing interventions requires data collection around the clock each day (24/7). Strategies for implementing and coordinating a study 24/7 are not discussed in the literature, and best practices are needed.

Objective—To identify strategies incorporated into implementing a nursing intervention trial 24/7, including key lessons learned.

Methods—Strategies to facilitate implementation of a clinical trial of a nursing intervention with patients undergoing mechanical ventilation are shared. Challenges and changes for future studies also are discussed.

Results—Adequate planning, including a detailed operations manual, guides study implementation. Staffing is the most challenging and costly part of a study but is essential to a study's success. Other important strategies include communication among the study personnel and with collaborators and direct care staff. An electronic method of recording study-related data also is essential.

Conclusions—A nursing clinical trial that requires interventions on a 24/7 basis can be done with thorough planning, staffing, and continuous quality improvement activities.

Data to generate clinical evidence to guide nursing practice are not isolated to a single point in time. Many nursing interventions are done around the clock, such as turning, suctioning, and oral care. Thus, studies to test such interventions may need to be conducted on a 24/7 basis. When these types of studies occur in the critical care setting, the complexities of the environment and nature of care create a variety of methodological challenges for the research team.^{1,2}

Confronted with such challenges, the US Marine Corps motto of “Innovate, Adapt, and Overcome”³ certainly applies to research activities. Regardless of the methodological and operational challenges associated with such an endeavor, it is essential to maintain fidelity of study interventions and data collection.⁴ Strategies for managing a study 24/7 are rarely discussed in journal articles or textbooks, and most are focused on the role of a clinical research coordinator (CRC) for sponsored clinical trials.⁵ Intervention studies at large academic health centers or those with a Clinical and Translational Science Award may have full-time staff available to support study operations. Other studies rely on the staff nurse to collect specimens and record data. Full-time staff were not available to us, and having staff nurses participate in the intervention was not acceptable, because this option had a high likelihood of affecting study fidelity.

It is essential to maintain fidelity of study interventions and data collection.

The purpose of this article is to summarize key methodological challenges and effective solutions using the example of an active 4-year project funded by the National Institutes of Health ([Clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02284178) identifier: NCT02284178) in the hope that other researchers will find it valuable.

Study Overview and Planning

Our study is a randomized trial to evaluate the effect of a scheduled, enhanced oral-care intervention to prevent aspiration and reduce ventilator-associated events. The intervention includes deep oropharyngeal suctioning every 4 hours, along with the usual oral care provided to intubated patients. We also collect samples of oral and tracheal secretions every 12 hours for analysis of outcome variables. Patients are enrolled within 24 hours of intubation and remain in the study for up to 14 days. We have just completed enrollment of 517 patients during a 3-year data collection period.

We dedicated the first 6 months to developing a detailed operations manual for the project that included steps for data collection, specimen collection and storage, training, and other study procedures (Table 1). This document provided consistent information to all research team members and served as a training manual when new members were added. Providing this information was crucial because research team members would be responsible for the oral care of all enrolled patients. Although providing oral care for all enrolled patients increased time demands and budget requirements, providing standardized usual oral care for the control group maintained the scientific rigor necessary for the project.

Research Team

The research team is critical to any project's success. The interprofessional core of our team includes experienced critical care nurses, including the principal investigator, a project director, and 2 additional full-time CRCs; a physiologist; a data manager; and research assistants. The team also includes an intensivist, a biostatistician, a physician with expertise in aspiration biomarkers, laboratory personnel, and consultants with expertise in nursing trials and the outcome measures.

The project director is responsible for all aspects of day-to-day study management and monitoring and works closely with the principal investigator. The CRCs are primarily responsible for recruitment and enrollment of patients, study implementation, and data management.^{6,7}

The project is a collaborative effort between a large university and a metropolitan hospital with level I trauma center designation. The principal investigator, data manager, and statistician are funded through the university, and the other personnel are funded via a subcontract with the hospital system.

Staffing

Providing staffing for the study has been the most challenging aspect of our operations. A 24/7 study theoretically requires 4.2 full-time equivalent research personnel to support data collection, and this estimate does not include vacation and sick-time coverage. We initially planned to staff the study with a full-time project director and several part-time research assistants. During the planning phase, we realized that 24/7 staffing would be difficult, even with many research assistants. We rebudgeted the study to hire 2 additional full-time CRCs, yielding 3.0 full-time equivalents of consistent coverage. The research assistants provided the remaining 1.2 full-time equivalents.

The part-time research assistants are experienced critical care nurses who hold staff nurse positions at the study site and work several shifts every month as study team members. We collaborated with nurse managers and the human resources department to develop a strategy for paying these individuals as having a secondary employment status. The core group of dedicated research assistants has been essential for the study to run smoothly. A potential for role confusion (ie, staff nurse vs research assistant) exists but has not occurred. Regular training and review of duties and expectations assisted in outlining specific roles.

Research staff performed the intervention every 4 hours each day. We recognized the need to schedule staff creatively to meet this requirement while containing costs. To reduce costs associated with staffing, we decided to staff the study approximately 18 h/d rather than 24 h/d. We created 6-hour shifts for the research assistants: 7 AM to 1 PM, 3 PM to 9 PM, and 11 PM to 5 AM. These shifts allow the intervention to be delivered and data to be collected every 4 hours. Although we had to be flexible with these shifts to ensure staffing, all adaptations were achieved within the context of maintaining scientific rigor.

Even with the additional CRCs, fatigue among the full-time research staff is an ongoing issue. An additional strategy we used was to suspend the study during major holidays and periods of historical low census. We coordinated enrollment to complete data collection on existing patients before the suspension. Although study suspension may affect a study's momentum, we found it essential for the well-being of the research staff.

Recommendations

We would budget for and hire a project director and 4 full-time CRCs. This model would allow more time for the project director to focus solely on study management and cover only as needed for the day-to-day data collection. Furthermore, a smaller, full-time research team dedicated to the study would lower training costs and bring improved consistency to delivering the intervention and collecting data.

A well-trained staff who deliver a study intervention is one strategy to ensure study fidelity.

Training

The principal investigator and the project director developed and demonstrated all procedures included in the operations manual before training the research staff. These elements include the sham and enhanced oral-care intervention, usual oral care, and specimen collection and labeling. The project director conducted initial training for the CRCs and research assistants in the university simulation suite. Training elements encompassed all aspects of the data collection process, including obtaining informed consent, enhanced and usual oral-care activities, data collection tools, and data entry. The most important aspect of simulated training was using mannequins to demonstrate and practice oral care and specimen collection. Members of the research team practiced these essential elements until they demonstrated consistently proper techniques for all required study skills. They indicated that use of the simulation suite greatly enhanced their preparation and confidence before interacting with patients.

An operations manual with detailed procedures and checklists is essential.

All study personnel received the detailed operations manual along with a step-by-step checklist to increase consistency in all procedures and decrease risks for errors in data collection and entry. The project director and CRCs assessed competencies in the clinical setting after the initial training to ensure ongoing fidelity of the study intervention.

A quarterly refresher training schedule for all research assistants was implemented to maintain consistency and competencies with intervention and data collection processes. Refresher activities also are focused on other aspects of the study, including specimen labeling and additional practice obtaining informed consent.

Recommendations

An operations manual with detailed procedures and checklists is essential. Initial training in a simulation setting followed by direct observation proved to be an excellent training

method. Although quarterly refresher training was included in the protocol, it was labor intensive and not consistently needed. Focused retraining at longer intervals may be adequate, depending on the study.

Initial training in a simulation setting followed by direct observation proved to be an excellent training method.

Costs

Conducting a 24/7 clinical trial demands full-time staffing, especially when all protocol activities for intervention and control groups are carried out by the research team. These staffing requirements constitute a substantial portion of any research budget. Inadequate economic resources for staffing has been identified as a common issue in nurse-led randomized controlled trials.⁸ We budgeted about \$250 000/y to cover the salary and benefits of the full-time project director, 2 CRCs, and 60 hours of coverage per week (1.5 full-time equivalents) by the research assistants.

Recommendations

We recommend using as many full-time staff as possible. Estimated costs for salaries and 25% benefits for a project director (\$90 000) and 4 full-time CRCs (\$75 000 per CRC) total \$390 000/y. This amount nears 80% of the annual budget of direct costs for a \$500 000 National Institutes of Health grant. The principal investigator must weigh the pros and cons of allocating this amount to the budget; however, we found that full-time staff members provided the best strategy for staffing. The educational level of personnel needed to deliver the intervention, obtain specimens, and record data guides the budget process. Not all studies require that an experienced registered nurse deliver the intervention and collect data.

Data Management

In our prior research, we used both paper and electronic forms to record and store data. Given the anticipated volume of data points in this study, we required a different strategy for data collection to improve accuracy, provide real-time data entry, reduce missing elements, and provide a simple way to download data. We decided to use Research Electronic Data Capture (REDCap; <https://projectREDCap.org/>) to collect and manage data for this study.⁹ REDCap is used by nearly 2000 institutions in more than 100 countries.⁹ It provides secure web access to develop and manage data collection elements. We organized our data collection tools on paper, reviewed and revised them, and then transferred them into REDCap.

Because data are collected at multiple times for each patient, we had to create coding strategies for each variable. Many data points are recorded every 4 or 12 hours; thus, we incorporated the study day (D) and military time (T) into the variable names. For example, FiO2_D1_T16 refers to the oxygen level delivered by the ventilator at 4 PM on the first day of data collection.

Initially, we entered simulated data for fictitious patients to evaluate REDCap with regard to data entry, data management (including correcting erroneous values), and data export. We found REDCap to be easy to learn, use, and edit. Furthermore, it can export data into a variety of formats suitable for statistical analysis. Our statistician can export output for analysis with SAS (SAS Institute), while others may export data into an Excel file. A particularly useful element in REDCap allows the team to quickly identify inaccurate or missing data.

REDCap has served our data collection, management, and analysis needs well throughout this project. We established read, write, and edit access, depending on the role of the study personnel who are entering data. Data editing is limited to the 5 key personnel. The research assistants have read and write access only. Laboratory staff members are blinded to all information except the laboratory values that they enter directly into REDCap.

Data integrity is always a concern, and we addressed this issue in several ways. First, initial setup of REDCap included clearly defined limits or options for many variable values. We used data validation features to prevent out-of-range values from being entered in error. We have no way of knowing how many data entry errors this prevented, but we believe this process is essential. Second, we completed data collection on several fictitious patients to test the process and system. Simulated data collection provided the research team with opportunities to identify and resolve any barriers or complexities with data entry. Third, the project director confirmed every collected value for the first few patients to ensure accuracy. Data collection or entry errors were evaluated and classified as either system related or user related. Systemic issues required minor protocol revisions and/or REDCap coding updates. User issues were addressed by the project director. Fourth, we used features within the REDCap system (eg, missing value recognition) to help identify missing data or potential outlier values. When found, these records were reviewed and updated by the project director or CRC. The project director also regularly reviewed a random subset of data for accuracy. Although these steps added to the time demands of the project director and CRCs, the rigor of correct and complete data is priceless.

Recommendations

The institutions' information technology office must be involved to set up REDCap. Information technology staff must also be available to troubleshoot software updates and other issues. Someone with expertise in setting up data fields and related logic is needed during form development and editing. The REDCap data validation features are extremely helpful in identifying missing data and outlier variables. Backup paper forms are also needed to record data during network outages, which occurred on a few occasions.

Research Team Communication

Communication among study personnel is critical, especially because our staffing model did not provide overlap in shift coverage. We developed a process to replace traditional handoff information. Timing and other data elements related to the research protocol are well documented in REDCap. However, admissions, discharges, and condition changes

associated with the 56 critical care beds within the hospital required a different communication tool. The project director, CRCs, and research assistants assigned to each shift regularly round on the units to identify and screen potential patients. We developed a password-protected screening log to facilitate this process. We color code information to note who has been screened, identify exclusions, and record other important information. The research assistant reviews the screening log at the beginning of each shift to identify which of the study units has active or potential research patients. The research assistants can communicate with one another at all times through cell phones, so any questions regarding the spreadsheet or data can be quickly addressed. We also created a custom white-board to use to identify active patients, intervention groups, and time for next intervention. The board is located in the locked study office that all study personnel share.

Data collection or entry errors were classified as either system related or user related.

Communication with the specialty laboratory that processes aspiration biomarkers also was critical. Oral and tracheal specimens are collected at baseline and every 12 hours, stored in a study freezer, and sent to the specialty laboratory for processing. Specimen labels are color coded (oral specimen, white; tracheal specimen, fluorescent yellow) and coded with the date and time, as described in the section titled Data Management. The labeling was not initially logical to the laboratory personnel, which resulted in inaccurate data entry into the REDCap database. After noting a number of missing specimen data entries, the project director and CRCs met with laboratory personnel to review the process, explain the labeling, and improve the processes for labeling and recording results. One CRC assumed the role of laboratory liaison and regularly meets with laboratory personnel. Now the laboratory personnel readily contact us to answer questions and resolve issues. Since the implementation of a modified label and face-to-face clarification, no missing specimen results have been reported, and data have been recorded accurately in REDCap.

Handoff communication strategies are needed, especially if face-to-face communication is not feasible.

Recommendations

Handoff communication strategies are needed, especially when personnel do not have the opportunity for face-to-face communication with each other. Although researchers must find what works best for them for their particular study, our color-coded screening log and whiteboard were successful for communicating key information. If the research project includes specimen processing, we recommend involving someone from the laboratory for protocol development and simulation training. Doing so will mitigate communication issues between research laboratory staff. Providing a liaison to work directly with the laboratory was another successful strategy to enhance communication.

Communication With Direct-Care Staff

Study personnel rely on the direct-care staff to help identify potential patients, contact us when family members arrive, and alert us to changes in a patient's condition. Because

patients are enrolled from 6 critical care units located in 2 adjacent buildings, effective communication with many direct-care staff members is essential. We introduced the study during scheduled staff meetings and posted brief information flyers in the units. Study personnel also provided 1:1 communication with direct caregivers. Once a patient is enrolled, we post a flyer at the bedside, alerting the staff that the patient is enrolled in the study and that research personnel will provide the oral care and collect specimens. We provide contact information for reaching study personnel, including direct telephone lines. It is essential that direct care-givers be able to contact study personnel in the event of a condition change, scheduled or unscheduled procedure, or transfer. Halfway through the study, we reeducated staff via small group huddles.

Recommendations

Communication with direct-care staff must occur at the beginning of a study and regularly throughout. Flyers, other forms of print communication, and face-to-face discussions all are helpful.

Conclusion

Recruitment of patients and data collection are ongoing processes. We continually monitor processes associated with the oral-care intervention, data collection, and communication within the team and with patient-care professionals. Continuous monitoring allows us to rapidly identify any issues, work together to develop solutions, and implement any needed process changes. We have found flexibility, collaboration, and communication to be key elements in accomplishing a 24/7 research project (Table 2).

Designing, implementing, and executing a 24/7 research project has been challenging and rewarding. We had to innovate strategies and adapt procedures to meet study goals to overcome challenges that may have affected our ability to test nursing interventions 24/7. We are confident our communication and collaboration processes have contributed to our success and will continue to be part of our future research endeavors.

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FINANCIAL DISCLOSURES

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This article has been designated for CE contact hour(s). The evaluation demonstrates your knowledge of the following objectives:

1. Describe challenges in conducting a nursing intervention study around the clock (24/7).
2. Identify strategies to facilitate conducting a study 24/7.
3. Discuss the importance of planning, staffing, and continuous assessment of quality improvement opportunities when conducting a clinical trial.

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Table 1

Operation manual's table of contents

<u>Intervention Procedures</u>
<u>Specimen Collection</u>
<u>Specimen Storage and Processing</u>
<u>Oral Cleansing and Study Interventions per Group Assignment</u>
<u>Toothbrushing</u>
<u>Secretion Management/Comfort Care Between Interventions</u>
<u>Study End Points</u>
<u>Adverse and Serious Adverse Events</u>
<u>Documentation in Electronic Medical Record</u>
<u>Management of Isolation Patients</u>
Data Management and Integrity
Data Safety Monitoring Board
Screening Process Checklist
Study Completion Checklist
<u>Oral Care Procedure Checklists per Group Assignment</u>
Handouts/Forms
Bedside Flyer
<u>Competency Forms (Organization and Study-Specific)</u>

Table 2

Recommendations for a 24-hour research project

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- In-depth planning and training before protocol initiation
 - Employ enough full-time research coordinators
 - Secure, user-friendly data collection and entry (eg, REDCap)
 - Clear communication within the team and with clinical partners
 - Ongoing monitoring of data collection and protocol issues
 - Flexibility and collaboration
-