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Clinical coordination of research

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Abstract

A feeding study conducted at a tertiary care center's neonatal intensive care unit tested a predictive model of bottle-feeding readiness and feeding outcomes. The study examined how bottle-feeding experience influences both bottle-feeding readiness and outcomes. The clinical coordinator played an integral role in the success of the research by coordinating the education of nurses, data collectors, and families; communicating with various interest groups; managing recruitment, enrollment, and participant tracking; and overseeing data collection.

1. Introduction

Large complex clinical research projects in nursing are increasing in number. They often involve many patients or families over a long period and include numerous study variables. These complex studies often involve a large research team that may include a principal investigator (PI), collaborators, consultants, a grant manager, a data manager, data collectors, and students. Increasingly, researchers find that having a clinical coordinator (CC) is useful in ensuring the seamless day-to-day operation of research. This article describes the role of a CC, using the example of a federally funded feeding study conducted in a neonatal intensive care unit (NICU).

The CC for the study was hired immediately after receipt of funding. The position entailed a 20-hr work week and required a baccalaureate degree in nursing with at least 1 year of neonatal intensive care experience, strong communication and organization skills, computer competence, interest in research, self-direction, ability to work with a team, and willingness to commit to a 4-year study. The literature revealed no examples of the role expectations of a CC, but the PI and primary collaborator identified that the responsibilities of the role included participant recruitment and enrollment as well as day-to-day oversight of data collection.

With no firm blueprint to follow, the CC had the potential to be somewhat task oriented. However, the CC's role proved to be dynamic—requiring organization yet flexibility because of the need to continuously assess, implement evolving plans, and evaluate the processes important to the job. Developing systems was a critical part of the CC's role. For this project, systems needed to be developed in the areas of education, communication, recruitment, enrollment and participant tracking, and data collection.

2. Coordination of education of NICU nurses, data collectors, and families

The research setting was a 38-bed, Level III NICU in a university healthcare center. Education was necessary for the NICU staff nurses, data collectors, and families of participants. The NICU nurses actively participated in the research study by feeding the babies. Therefore, in collaboration with the nurse manager and PI, the CC developed a plan to address the learning needs of the staff and facilitate the smooth introduction of the study into the setting.

Training sessions designed by the PI covered the physiology of oral feeding, the purpose of the study, and the role of staff nurses in the study. The session aims were to increase awareness of the research, increase knowledge of oral feedings, and enhance the team's relationship with the NICU nurses. The CC arranged for the nurses to receive 2 hours of continuing education credit for attending training sessions. The challenge was scheduling 100 employees for the sessions; these had to be creatively planned around vacations and swing shifts to accommodate the nurses. The intermediate care nurses were the first group targeted because the babies in the study were likely to be located in the intermediate care room. The intensive care nurses were the second group targeted, especially newly hired employees with novice skills in preterm infant feeding. Although these novice nurses did not directly participate in the data collection, they benefited from the education because the primary goal was to increase understanding of preterm feeding behaviors for all nurses in the NICU. A second goal was to orient the nurses to the routines of data collection, the role of the data collector, and the role of the bedside nurse to minimize concerns.

The data collection process was designed to be minimally disruptive to nurses' and babies' schedules. Data collectors were trained to communicate with the nurse caring for the infant-participant before setting up for data collection and to negotiate the study feeding time with the staff nurse. This process of negotiation allowed staff nurses to participate in the research without feeling pressured to manage their own assignment in addition to a research project. The data collector also assisted with prefeeding care. The staff nurses fed the babies for study feedings while the data collectors monitored the computer data acquisition system. After completion of the study feeding, data collectors completed feeding the infants by gavage, if necessary, allowing bedside nurses to return to their normal routine in the NICU.

In an effort to further educate the nursing staff, the CC developed a communication book. The book provided information about the purpose and aims of the study, names and contact numbers of the research team, participant feeding schedules, data collector time sheets, descriptions of the staff nurses' role and the data collectors' role, a communication section for staff to write any concerns on, a section with study events, and a section with journal articles related to the study. The data collectors used the book to follow feeding schedules, to sign up for feedings, and to follow study progress. The staff nurses used the book to follow feeding schedules of the babies.

The research data collectors also needed education. Requirements for employment as a data collector included competence as an NICU nurse and current employment in the NICU. Over the course of the study, 20 data collectors received a 6-hr training class to become data collectors. This training was more extensive than the staff nurse training and included a thorough review of the theory behind the research, the physiology of oral feeding, the research plan, use of data tools, and use of the computer data acquisition system. Data collectors received a certificate and continuing education credits for the training. After the class, data collectors had two additional sessions with the CC to establish their reliability and competence in the data collection process. During the first session, the data collectors observed the CC completing the entire process of data collection including communication

with nurses, assessment of the participants, application of research equipment, completion of data tools, and the use of the data recording system. In the second session, the data collectors each completed the process independently as the CC observed and checked their reliability. If the process was successfully completed, a data collector could conduct feeding observations independently. Most data collectors were able to complete training in two sessions. If questions arose during the data collection, the PI and CC were available on page to assist with problem solving and questions.

Families primarily received education about the study through the consent process. The consent process was conducted in a confidential manner following all the guidelines for research. A verbal explanation of the study was given, including a hands-on demonstration of equipment application on a baby doll, similar to the babies in the study to help parents visualize their baby's participation. Each family was encouraged to touch the equipment and ask questions (Moon, Cheng, Patel, Baumshaft, & Scheidt, 1998). Once the demonstration and explanation of the study were completed, the CC offered the parents an opportunity to review the consent form. If any question of parental literacy was evident, the CC would offer to read the consent to the parents. Review of the consent was a critical part of the consent process, allowing the parents a moment to reflect on any question that they had for the CC. Often, the parents were eager to participate, expressing their belief that the baby would learn to feed from the bottle faster although the CC emphasized that the study was observational and not experimental. The CC also emphasized that the babies would receive the same level of care in the NICU whether they participated in the study or not (Langley, Halperin, Mills, & Eastwood, 1998; Rothmeir, Lasley, & Shapiro, 2003). Families were encouraged to contact a study representative with any question or concern during their baby's participation in the study.

During the data collection phase, the CC often talked informally with each family at their baby's bedside. Parents frequently asked questions about their baby's feeding progress and sought out the CC to express their feelings about their baby's hospitalization. Sometimes, parents contacted the study office or called the NICU directly to speak with the CC. Most calls focused on the parents' need for reassurance about their baby's stability and overall progress and were not necessarily related to feeding progress. Once babies were discharged from the hospital, some parents contacted the CC to notify her of their baby's progress, their baby's rehospitalization, or to seek guidance regarding their baby's needs (Miles & Holditch-Davis, 1997). Often, education of the parents extended beyond the hospitalization into the period of transition to home.

3. Coordination of communication

Communication is a key element of the clinical coordination role. To handle the daily business associated with the study, the CC consistently communicated with core research team members including the PI, data collectors, collaborators, the grant manager, and the data manager. In addition to monthly study meetings, the CC met monthly with the PI to discuss the progress of the study as it related to clinical coordination. At times other than the monthly meeting, the PI and CC communicated by email or telephone. The PI was available by page 24 hr a day. Core team members assisted the CC with data organization and preparation for entry into the database. Communications took place via email, in person, intraoffice meetings, and notes placed in a mailbox system.

Communication with data collectors was complicated, involving the use of emails, schedules, time sheets, pagers, and meetings. Data collectors reported directly to the CC and they were encouraged to contact the CC at any time with questions or concerns. Concerns

requiring immediate attention were communicated through direct telephone contact or by use of the pager system.

Data collectors received feedback about data collection through one-on-one communication with the CC and through biannual data collector meetings. The purpose of the meetings was to maintain reliability of data collection. The agenda included an overview of progress of the study, data collection concerns, and an open forum for suggestions for improved data collection. Certificates of recognition were presented to the data collectors for their support to the research study.

Communication with NICU nurses occurred daily on an informal basis. The CC gathered information about the study by listening to the nurses. By communicating with staff nurses daily, the CC maintained open lines of communication and enhanced a trusting relationship in the research setting.

Communication with families occurred primarily during the time of consent. Although parents had contact numbers of research team members, they generally did not use them. When necessary, the CC contacted a mother by email, by telephone, or in person.

4. Coordination of recruitment, enrollment, and participant tracking

Recruitment of participants was a key component of the CC's role. All NICU admissions were monitored biweekly for potential inclusion in the study. The challenge for the CC was to meet the enrollment plan knowing that a multitude of variables can affect preterm infants' ability to bottle feed.

All babies identified as meeting the inclusion criteria were followed until they were 32 weeks old and ready to bottle feed or were medically excluded from the study. For the recruitment process to succeed, the CC developed a recruitment record to follow the status of potential enrollees. The record included the projected date when a baby would be 32 weeks postconceptual age (PCA) as well as any pertinent medical status and contact information. Recruiting participants required close monitoring of potential enrollees for a period ranging from 7 weeks for a 24-week PCA baby to as short as 1 day for a newly born 32-week PCA baby. Time investment for monitoring potential participants thus varied considerably.

As potential enrollees neared the 32nd-week PCA, the CC began to gather demographic data along with contact numbers of the families. Once a baby was medically ready and 32 weeks PCA, the CC approached the family for consent. In approaching the consent process with the family, the CC took into consideration the psychosocial dynamics of the family. Although the babies considered for participation were the most stable babies in the NICU, a family's perception of their child's health was not necessarily one of health (Allen et al., 2004; Bass, 1991). The CC thus had to assess the family's current frame of mind.

The CC first contacted the family by phone or introduced herself at the bedside and became acquainted with the family. Once the initial contact occurred, the CC offered to meet parents at a later time to allow for a more thorough discussion about the study at a time more convenient to them. Before the appointment date, the CC telephoned the parents to remind them of the appointment.

On the day of the appointment, the CC met the parents at their baby's bedside. Parents were given an opportunity to express any concern or exciting news that they had received about their baby's progress. This brief period of sharing gave the CC insight into the parents' mood.

A key consideration for the study was having a CC who understood the care of neonates because families often expressed a need for information about all of their baby's needs, not just feeding (Bass, 1991; Miles & Holditch-Davis, 1997). Often, the conversation naturally flowed into talk about the baby's current and anticipated needs. Because the CC had experience in the NICU, she was able to provide parents with information about their baby, reinforcing the relationship between the CC and the parents (Langley et al., 1998). Also, the CC provided the family with educational pamphlets regarding the care of their baby.

Once enrolled, the participants were followed for medical status and progress in the study. The CC checked each participant's status using participant schedules, medical record review, and data collector input. Each participant was monitored for stability and progress throughout the feeding study. If a baby became medically unstable during the schedule and could not bottle feed, the baby was excluded for the remainder of the study.

Once a baby completed the 2 to 3 weeks of initial observation, the next step was an evaluation of feeding at discharge. The CC and data collectors were on call to complete a discharge feeding observation. Once the baby completed the study schedule, the CC sent a thank you letter and gift card to the parents.

5. Coordination of data collection

The CC was critical to the data collection process. First, she notified the NICU staff, research team, and data collectors of the participant's enrollment. The CC then entered a dietary order on the medical plan of care outlining study-specific information necessary for nurses to know, including dates of participation on study, frequency of observations, and how to contact the PI or CC if needed. Each participant's schedule was placed in the study communication book. Emails using a code number for the participant were sent to the research team and the data collectors outlining the study schedule for the baby. Only a participant's study identification number was used in communication. No other identifying data were used to label a participant during correspondence by email.

Once notified of a study participant's enrollment, the data collectors signed up for feeding observations. Thus, if three babies were enrolled within a few days from one another, there could be as many as 42 feeding observations over a 2-week period. Much like the dynamics of staffing a NICU with a flexible daily census, the challenge of clinical coordination of the research study came with multiple enrollments. Any feeding observation not covered by the data collectors was the responsibility of the CC. Most of the time, the CC was able to negotiate coverage of all feeding observations through use of email and telephone calls to the data collectors.

When a participant was enrolled, a participant file was prepared including all tools necessary for data collection and all research equipment. Each file contained single folders representing each feeding observation day, and each folder containing the necessary data tools and equipment was labeled with the feeding observation date, participant identification number, and feeding observation number. The information written on the folder helped the data collector to verify the identification of a study participant and ensured correct labeling of data sets in the electronic file. Once the participant folder was prepared with all feeding observation folders, the CC placed the participant folder on the cart with the computer acquisition system.

Once feeding observations for a participant began, the CC collected completed data folders biweekly and returned data to the study office. Data tools were checked for accuracy, legibility, and participant progress. Reviewing the completed data forms allowed the CC to

review the data collectors' performance and give feedback on their job performance. In turn, the CC received valuable information about ways to improve data collection processes.

6. Summary

This study illustrated the importance of a CC in successfully conducting clinical research. When embarking upon clinical research, the PI should give careful consideration to the clinical coordination role. The CC should be someone qualified to run day-to-day operations of the research study in a seamless manner. He or she needs to be qualified as an educator, clinician, mentor, communicator, manager, and leader. The CC should be someone who understands research as a necessary part of everyday nursing practice.

To be recognized as a substantial contributor to health-care community, the professional nurse must raise the bar of professional measurement through research. Nursing research is an important component of professional nursing, validating and measuring our professional contribution. The CC can make nursing research a success now and in the future. In this study, the CC was a nurse. Nurses are uniquely qualified to meet the role expectations of a CC because many activities of a CC are an extension of the role of the professional nurse of today. The CC's role is one of diversity in skill and knowledge, flexibility in time management and coordination, and autonomy in professional development and leadership.

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