

Defining Clinical Research Nursing Practice: Results of a Role Delineation Study

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Abstract

Clinical research nursing is a specialty nursing practice focused on the care of research subjects and implementation of clinical research. A five-dimensional model (Clinical Practice [CP], Study Management, Care Coordination and Continuity, Contributing to the Science [CS], Human Subjects Protection) has been validated nationally to represent the domain of clinical research nursing practice. The purpose of this study was to describe the frequency and importance of activities within each dimension as performed by nurses in clinical research and to describe differences between roles. One thousand and four nurses from the NIH Intramural Campus in Bethesda, Maryland, were invited to participate in an anonymous web-based survey. Participants ($N = 412$) were predominantly female (90%) with ≥ 11 years research experience (70%). Two hundred eighty-eight respondents (70%) identified themselves as clinical research nurses (CRNs) and 74 (18%) as research nurse coordinators (RNCs). CP activities were reported most frequent and important whereas CS activities were least frequent and important. CRN and RNC activity frequency differed across all dimensions ($p < 0.001$) with CRNs reporting significantly higher levels of CP activities and significantly lower levels in other dimensions. Delineating specialty activities and practice across roles enhances the understanding of nurses' role in clinical research and provides groundwork for role-based training. Clin Trans Sci 2011; Volume 4: 421–427

Keywords: clinical trial, clinical research, nursing staff organization, research personnel, role delineation study, research professional, clinical research nurse/ing

Introduction

Clinical research is a broad endeavor that involves investigators from a wide range of disciplines working with human subjects to characterize health and illness, and invent, test, and evaluate treatments. Nurses have always been integral to the conduct of clinical research at every level, including providing care to participants, coordinating and implementing studies, and designing and implementing programs of research as principal investigators.¹ The clinical role of nurses in research has been most thoroughly documented and described in oncology clinical trials,^{2,3} perhaps because such trials involve subjects who often receive treatments that are complex, requiring long-term follow up. There has been less clarity of the role of nurses in research studies outside of the oncology specialty such as those involving healthy volunteers, phenotyping of patient cohorts with chronic but stable disease, and implementation of pharmaceutically sponsored early phase studies in primarily healthy populations.

As finances tighten in all sectors of clinical research, it has become important to describe and document the roles and contributions of nurses providing care to research subjects in various clinical settings. In contrast to traditional nursing roles, the specific clinical activities, competencies and educational requirements for nurses implementing and managing patient-care in a research setting are not well-delineated.^{4,5} Furthermore, there is a lack of formalized role descriptions that link nursing job titles to specific knowledge and skills essential when performing in clinical research environments.⁵

The work of defining clinical research nursing practice began in areas where there has historically been a "critical mass" of nurses supporting clinical research: the NIH Clinical Center and the NIH funded General Clinical Research Centers (GCRCs) at academic medical centers around the country. Building on collaborative work with the nurses from the former GCRCs and

current Clinical and Translational Science Award sites,^{6–8} nursing at the NIH Clinical Center launched a 4-year project in 2007 to create and validate conceptual tools in support of specialty clinical research nursing practice.^{9,10} One of the first outputs from this project was a conceptual model of the domain of practice that informs the clinical practice of nurses directly involved with research subjects. This domain includes study implementation, study coordination, and all the resulting clinical activities required to maintain and manage research requirements while balancing accompanying "standard of care" treatments. The domain description was developed at the NIH Clinical Center based on the observation that nurses supporting clinical research tend to focus primarily in either (1) delivering care needed to implement a clinical study or (2) coordinating and managing a study on behalf of a principal investigator. These two areas of focus carry multiple titles nationally and internationally, which has been a source of confusion in the field.^{7–9,11} Therefore, one of the first activities of the project was to define and name two distinct roles: clinical research nurse (CRN), known in many research settings as "clinical nurse" or "staff nurse" and research nurse coordinator (RNC), commonly known as "study coordinator" or "clinical trials nurse" or simply "research nurse." Both of these roles were conceptualized within the domain of clinical research nursing, with a common expertise and competency base, but with different areas of emphasis. Further complicating clear role delineations is the fact that many nurses practice in roles that are a blend of CRN and RNC, and that roles in a given program of research may shift over time as nursing programs change.

The next step in defining clinical research nursing practice was to apply the Delphi technique to reach consensus on the domain of practice among a group of national experts in clinical research. This domain description included a framework for

specialty practice identifying activities categorized into broad dimensions associated with clinical research nursing. After three Delphi rounds, participants reached consensus and validated a five-dimensional model including clinical practice (CP), Human Subjects Protection (HSP), Care Coordination and Continuity (CCC), Study Management (SM) and Contributing to the Science (CS) with 52 specific activities.¹² The resulting taxonomy provided the conceptual framework for this role delineation study.

Study Purpose

The primary purpose of this study was to describe the frequency and perceived importance of the activities performed by nurses in a large clinical research setting and to delineate the differences in practice across the various roles of nurses in the setting. A secondary aim was to provide additional validation of the proposed conceptual framework of the NIH Clinical Center clinical research nursing domain of practice by using the taxonomy to characterize the activities of CRNs and RNCs.

The Setting

The NIH Clinical Center, located on the NIH campus in Bethesda, Maryland, is the world's largest institution devoted exclusively to biomedical research. The center has a 240-bed inpatient hospital, outpatient clinics and day hospitals that provide research and clinical support to intramural researchers from any of the 27 institutes and centers of the NIH. In support of the NIH mission, there are approximately 582 clinical research nurses (CRN) that provide direct care to clinical research study subjects and approximately 422 registered nurses and nurse practitioners (NPs) who work with Principal Investigators to coordinate, implement or facilitate research studies at the NIH Clinical Center. Services are provided to research participants free-of-charge, and to investigators as a component of the intramural program.

Methods

Design

A nonexperimental, cross-sectional design using a web-based survey was used to address the objectives of this study. The sample of nurses working in a clinical research setting was drawn from the NIH Clinical Center intramural research program in Bethesda, Maryland. All survey responses were anonymous. The study proposal was reviewed and approved by the NIH Office of Human Subjects Research Protection.

Participants

The sample included registered nurses from a database of credentialed nurses who work at the NIH Clinical Center and a list of NPs credentialed to practice at the center. The lists were reviewed for accuracy and to ensure current employment at the NIH. Nurses not directly involved with research subjects (i.e., nurse administrators) were excluded.

Before launching the study, a focus group of NIH nurses (N = 10) holding a variety of positions in clinical research, agreed to test the web-based measure for feasibility and potential implementation issues. Focus group participants provided information to the study team related to (1) length of time for survey completion, (2) system accessibility, and (3) item comprehension. This feedback was incorporated into the final survey instrument.

Potential nurse participants were recruited to participate using a variety of methods including an email invitation, announcements

made at nursing leadership and staff meetings, and through key stakeholders within the NIH Clinical Center. The rationale and explanation of the purpose for the study was described in an email invitation letter. If interested in participating in the study, participants were instructed to determine their eligibility. Criteria for eligibility included being a registered nurse credentialed through the nursing department, working either full-time or part-time, and a positive answer to any of the three following statements: (1) provide care to research participants seen at the NIH Clinical Center, (2) direct contact with research participants, or (3) are involved in clinical research study activities. Nurses that chose not to participate or determined themselves ineligible were provided an electronic link to report their reasons for not participating. If nurses deemed themselves to be eligible, they were provided an anonymous web-based link to complete the survey. Subjects were informed that consent was presumed by survey completion.

Measure

The activities determined essential to clinical research nursing practice were previously validated¹² and formed the basis for the survey. Of the 52 items in the clinical research nursing domain of practice, six items were noted to include two distinct activities within the same statement. These six activity statements were split into two separate statements to allow for individual responses. The final measure, coined the "CRN Role Delineation Measure," consisted of 59 activity statements. The list of activity statement items by practice dimension is presented in *Table 1*. In this study, the coefficient alpha reliability estimates were robust for the frequency ($\alpha = 0.95$) and importance ($\alpha = 0.96$) scales. The estimates for the individual dimension scales were also robust, 0.76 (CP), 0.90 (SM), 0.81 (CS), 0.82 (CCC), except for the HSP scale which was fair ($\alpha = 0.68$).

Participants were asked to rate both the "frequency" with which they perform each activity and the level of "importance" that each activity has in their current role on two 6-point Likert scales ("frequency" scale responses included: 0 = "not part of my practice," 1 = "infrequently/1–2 times/year," 2 = "multiple times/year; monthly," 3 = "more than once/month, weekly," 4 = once/day, and 5 = "multiple times/day;" importance scale responses included: 0 = "not part of my role," 1 = "not important to my role," 2 = "somewhat important to my role," 3 = "important to my role," 4 = "very important to my role" and 5 = "essential to my role"). The reference time was "over the last year." Seventeen demographic questions were included to characterize the participants without including personally identifiable information.

Data Analysis

Frequency distributions and measures of central tendency were used to summarize the sample demographic and practice variables for study participants and the activity frequency and importance scores within each dimension, both for the sample as a whole and by role (CRN, RNC, NP and "other"). Frequency was then dichotomized to summarize infrequently performed activities (frequency responses 0 and 1) and frequently performed activities (frequency responses 2 through 5). Pearson's correlation coefficient (r) or a Student's t -test was computed to explore the relationship between participant characteristics and dimension frequency scores depending on the characteristic of each variable (interval vs. categorical). The data were analyzed using SPSS (version 17.0; SPSS Inc., Chicago, IL, USA).

Descriptor	Total	CRN	RNC
	N = 412 Mean (SD)	n = 287 Frequent* n (%)	n = 74 Frequent* n (%)
Clinical practice			
Provide direct care to research participant (RP)	4.30 (1.33)	284 (99)	56 (75.7)
Monitor RP for potential adverse events	4.20 (1.42)	269 (93.7)	69 (93.2)
Report potential adverse events to research team (RT)	3.15 (1.46)†	247 (86.1)	60 (82.2)§
Record research data in approved source document	4.15 (1.52)	272 (94.8)	60 (81.1)
Provide teaching to RPs and family regarding study participation	3.97 (1.46)	265 (92.3)	70 (94.6)
Subscale	3.96 (1.03)		
Study management			
Participate in RP recruitment	1.30 (1.81)	34 (11.8)	70 (94.6)
Support study budget development	0.30 (0.86)†	13 (4.5)	13 (17.8)§
Collect data on RP based on study end points	3.07 (1.99)†	196 (68.3)‡	71 (95.9)
Contribute to the development of case report forms	0.92 (1.46)	41 (14.3)	50 (67.6)
Coordinate the collection of research specimens	3.72 (1.49)†	267 (93.4)‡	68 (91.9)
Facilitate the processing of research specimens	2.52 (2.03)†	179 (62.4)	54 (73)
Provide nursing expertise to the RT during study development	1.93 (1.70)†	130 (45.3)	61 (83.6)§
Record data on official study documents	2.28 (2.09)†	139 (48.4)	66 (90.4)§
Participate in reporting of research trends	1.04 (1.47)†	53 (18.5)	50 (68.5)§
Comply with ICH good practice guidelines	2.14 (2.28)	116 (40.4)	57 (77)
Perform quality assurance to ensure data integrity	2.47 (1.87)	176 (61.3)	63 (85.1)
Facilitate accurate communication among research sites (i.e., multisite studies)	0.74 (1.39)	40 (13.9)	29 (39.2)
Participate in the screening of potential RPs for eligibility	1.59 (1.98)†	73 (25.5)‡	69 (93.2)
Support study grant development	0.10 (0.46)†	6 (2.1)‡	0 (0)
Identify clinical care implications during study development (i.e., staff competencies and resources, equipment, etc.)	1.57 (1.59)†	118 (41.4)‡	46 (62.2)
Participate in the preparation of reports for appropriate regulatory monitoring bodies/boards	0.76 (1.39)	27 (9.4)	48 (64.9)
Participate in the identification of research trends	0.84 (1.27)	37 (12.9)	45 (60.8)
Participate in study development	0.81 (1.32)	26 (9.1)	43 (58.1)
Develop study specific materials for RP education	1.67 (1.55)	112 (39)	53 (71.6)
Participate in site visits and/or audits	0.63 (1.10)†	32 (11.2)‡	34 (45.9)
Oversee human resources related to research process	1.43 (1.92)†	91 (31.7)	44 (60.3)§
Protect RP data in accordance with regulatory requirements	4.24 (1.48)	262 (91.3)	73 (98.6)
Participate in the set up of a study specific database	0.78 (1.34)†	30 (10.5)‡	38 (51.4)
Facilitate communication within the RT	3.85 (1.49)†	258 (89.9)	71 (95.9)
Facilitate the handling (storage & shipment) of research specimens	2.33 (1.97)†	163 (57.4)‡	59 (79.9)
Provide nursing expertise to the RT during study implementation	2.69 (1.71)†	186 (65.7)‡	66 (89.2)
Subscale	1.76 (0.88)		
Care coordination and continuity			
Facilitate scheduling study procedures	2.69 (2.01)	172 (59.9)	68 (91.9)
Collaborate with interdisciplinary (ID) team to create and communicate a plan of care that allows for safe and effective collection of research data	3.93 (1.42)	261 (90.9)	70 (94.6)
Provide leadership within the ID team	3.27 (1.75)†	225 (78.7)‡	65 (89)§
Communicate impact of study procedures on RP	3.55 (1.67)	243 (84.7)	68 (91.9)
Provide nursing expertise to community based health care personnel (i.e. referring physician or center) related to study participation	1.10 (1.53)	46 (16)	52 (70.3)
Coordinate ID meetings and activities in the context of a study	1.41 (1.41)	91 (31.7)	53 (71.6)

Descriptor	Total N = 412	CRN n = 287	RNC n = 74
	Mean (SD)	Frequent* n (%)	Frequent* n (%)
Coordinate referrals to appropriate ID services outside immediate RT	1.88 (1.72)†	130 (45.3)	59 (80.8)§
Coordinate RP study visits	1.91 (2.16)†	82 (28.6)‡	67 (90.5)
Provide indirect nursing care (i.e., participation in clinical, unit, and/or protocol rounds; scheduling study related tests, etc.) in the context of research participation	2.71 (1.92)†	174 (60.8)‡	69 (93.2)
Facilitate research participant inquiries and concerns	3.23 (1.76)†	225 (78.7)‡	72 (97.3)
Facilitate the education of the ID team on study requirements	1.91 (1.78)†	127 (44.4)‡	62 (83.8)
Subscale	2.50 (1.05)		
Human subject protection			
Serve as institutional review board (IRB) member	0.08 (0.44)	4 (1.4)	0 (0)
Collaborate with ID team to address ethical conflicts	2.36 (1.33)†	200 (69.7)	58 (79.5)§
Facilitate initial informed consent/assent process	2.08 (1.81)	143 (49.8)	66 (89.2)
Manage potential ethical and financial conflicts of interest for self	1.17 (1.41)†	64 (22.4)‡	33 (45.2)§
Support RP in defining his/her reasons and goals for participating in a study	2.38 (1.79)	174 (60.6)	64 (86.5)
Coordinate research activities to minimize subject risk	3.17 (1.96)	201 (70)	69 (93.2)
Facilitate the ongoing informed consent/assent process	2.90 (1.80)†	204 (71.1)‡	68 (93.2)§
Subscale	2.02 (0.92)		
Contributing to the science			
Perform secondary data analysis to contribute to the development of new ideas	1.43 (1.61)†	80 (27.9)	56 (76.7)§
Identify questions appropriate for clinical nursing research as a result of study team participation	1.80 (1.72)†	144 (50.2)	31 (42.5)§
Collaborate with the ID to develop innovations in care delivery that have the potential to improve patient outcomes and accuracy of data collection	2.70 (1.58)	206 (71.8)	61 (82.4)
Serve as a resource to new investigators	1.77 (1.73)	115 (40.1)	54 (73)
Serve as an expert in a specialty area (i.e., grant reviewer, editorial board, presenter)	0.49 (1.15)	19 (6.6)‡	14 (18.9)
Participate in the query of research data to prepare for analysis	0.97 (1.54)	40 (13.9)	58 (78.4)
Participate in the analysis of research data	0.70 (1.24)†	27 (9.4)‡	40 (54.1)
Generate practice questions as a result of a new study procedure or intervention	0.87 (1.23)†	66 (23.1)‡	26 (35.1)
Disseminate clinical expertise and best practices related to clinical research through presentations, publications, and/or interactions with nursing colleagues	1.70 (1.52)	119 (41.5)	32 (43.2)
Mentor junior staff and students participating as members of the RT	2.18 (1.75)†	174 (60.8)‡	49 (66.2)
Subscale	1.46 (0.92)		

*Frequent = responses range from "Monthly" to "Multiple times per day."
†Missing data (range n = 1–n = 6).
‡Missing data (range n = 1–n = 14).
§Missing data (n = 1).

Table 1. Activity frequency for total sample and CRN and RNC roles.

Results

Participant demographics

Of the 1004 eligible nurses contacted, 412 (41%) participated in the web-based survey (Table 2). Eleven (1%) provided reasons for not participating. Seven determined themselves ineligible whereas four declined to participate. Most study participants were Bachelor's prepared (n = 282; 68.4%) working full-time

(n = 348; 84.5%) and had been practicing in clinical research for more than 1 year (n = 372; 90.3%). Also, the majority (n = 287; 70%) of participants had been practicing as a registered nurse for more than 11 years.

Professional characteristics for participants are presented in Table 3. Participants identified their current nursing positions according to the following titles: CRN, RNC, NP or Other (write-in). The majority of the respondents indicated they were CRN

	<i>n</i>	%
Gender (Female)	371	90.3
Age (in years)		
20–29	38	9.2
30–39	89	21.6
40–49	119	28.9
50–59	140	34.0
≥60	26	6.3
Entry level degree*		
Diploma/associate	120	29.2
Bachelor's	282	68.6
Graduate	9	2.2
Highest degree		
Diploma/associate	92	22.3
Bachelor's	279	67.7
Graduate	41	10.0
Part-time/full-time status		
Full-time	348	84.5
Part-time	64	15.5
Years practicing as a registered nurse		
<1 year	5	1.2
1–5 years	66	16.0
6–10 years	54	13.1
11–20 years	101	24.5
>20 years	186	45.2
Years practicing in current position*		
<1 year	56	13.7
>1 year	353	86.3
Years experience in clinical research*		
<1 year	37	9.0
>1 year	373	91.0

*Missing data.

Table 2. Sample demographics (N = 412).

(*n* = 287; 69.7%). Of the participants who selected “Other” (*n* = 21; 5.1%) for their current nursing position, nine individuals identified themselves to be in roles with both clinical and administrative or program support responsibilities—a dual role that might dilute their clinical research activity profile. The roles of 12 participants, despite their determination of eligibility, could not be determined based on their write-in titles.

The majority of the respondents provide direct care to research subjects (*n* = 371; 90.0%) who are adults (*n* = 360; 87.4%). The majority identified oncology (*n* = 168; 40.8%) or medical/surgical nursing (*n* = 170; 41.3%) as their clinical specialties. Over one-half of the participants indicated that they received organization/center-specific training only (*n* = 226; 54.9%) to prepare them for their current position. Although no national certification currently exists for the specialty of clinical research nursing, respondents were queried to determine if they belonged to or

	<i>n</i>	%
Current nursing position		
Clinical research nurse	287	69.7
Research nurse coordinator	74	18
Nurse practitioner	18	4.4
Other	33	8.0
Provide direct patient care		
Yes	371	90.0
Primary subject population		
Adults	360	87.4
Primary specialty population		
Oncology	168	40.8
Behavioral/mental health	39	9.5
Medical/surgical	170	41.3
Critical care	9	2.2
OR/PACU	5	1.2
Other	21	5.1
Clinical research training		
Organization/center-specific	226	54.9
Academic course/no degree	54	13.1
Academic courses/degree	51	12.4
Certification program	68	16.5
Continuing education classes	27	6.6
Clinical research professional organizations		
SoCRA	19	4.6
ACRP	12	2.9
Clinical research professional certifications		
SoCRA	9	4.6
ACRP	13	2.9

OR = operating room; PACU = postanesthesia care unit; SoCRA = Society of Clinical Research Associates; ACRP = Association of Clinical Research Professionals.

Table 3. Professional characteristics.

held certifications with interdisciplinary research organizations such as Society of Clinical Research Associates (SoCRA) or the Association of Clinical Research Professionals (ACRP). Very few respondents belonged to SoCRA (*n* = 19; 4.6%) or ACRP (*n* = 12; 2.9%). Even fewer respondents reported holding a professional certification in research (*n* = 22; 5.4%) from either of these organizations.

Activity frequency and importance

The means and standard deviations for the frequency and importance of each activity are presented in *Table 1*. Nurses working in a clinical research setting report a pattern in scores that is similar between frequency and importance; activities reported as more frequent were also reported as more important. The highest frequency and importance scores were reported for activities in the CP dimension. For example, the provision of direct care and monitoring of research subjects for adverse events were most frequently performed and also rated as most

important. The next most frequent and important scores were 1 and 1.5 points lower (respectively) and included activities in the CCC dimension. Activities specific to this dimension include collaborating with the interdisciplinary team to complete study requirements and facilitating subject inquiries or concerns. The activities that demonstrated the lowest frequency/importance were in the CS dimension. Specific activities in this dimension were related to data management and analysis. Relative to the individual activities, three were noted to have a mean frequency <0.5 (range 0–5) and were “not part of role” for $\geq 85\%$ of participants. These included (1) supporting study grant development; (2) study budget development, both activities within the SM dimension; and (3) serving as an IRB member from the HSP dimension.

Role delineation

The frequency of activities supported the existence of two distinct nursing roles in a clinical research setting that cut across all dimensions of the previously validated Domain of Practice. The first, the CRN, has a significantly ($p < 0.05$) higher level of activity frequency within the CP dimension (CRN $M = 4.20 \pm 0.84$; RNC $M = 3.43 \pm 1.14$) and significantly lower level of frequency in SM (CRN $M = 1.59 \pm 0.75$; RNC $M = 2.65 \pm 0.77$), CCC (CRN $M = 2.22 \pm 0.91$; RNC $M = 3.46 \pm 0.93$), HSP (CRN $M = 1.89 \pm 0.89$; RNC $M = 2.53 \pm 0.81$), and CS (CRN $M = 1.30 \pm 0.86$; RNC $M = 1.98 \pm 0.83$) compared to the second role, the RNC. This pattern of activity performance suggests the focus of the CRN role is the provision of direct clinical and research care to individual participants. In addition to the high frequency of all CP activities, the CRNs frequently performed activities such as facilitating communication with the research team (SM), communicating the impact of study procedures on participants (CCC), coordinating activities to minimize risk to participants (HSP), and developing innovations in care delivery to improve participant and study outcomes (CS). In contrast, the primary activities of the RNC role were oriented to a specific study or principal investigator(s). The RNCs frequently performed activities included participant recruitment (SM), coordination of study visits (CCC), activities involving informed consent process (HSP), and the query of research data (CS). Activities performed frequently by nurses in either roles included monitoring the participant for potential adverse events and providing teaching to participants and their family (CP), coordinating the collection of research specimens and protecting participant data in accordance with regulatory requirements (SM), and collaborating with interdisciplinary team members to plan safe and effective collection of data (CCC).

A discrepancy between the frequency that an activity was performed and the perceived importance of the activity might suggest a role conflict for the nurse. Therefore, the fact that, across the two roles, nurses participants reported little-to-no discrepancies, suggests that the majority of activities frequently performed by CRNs and RNCs were considered important to the role. The highest level of discrepancy for both roles was in the CS dimension where CRNs (11.5%) who performed secondary data analyses considered this activity “not part of their role or not an important part of their role” and a subset of the RNC group (11%) reported that identifying questions to guide nursing research was “not part of their role or not important to their role.”

Another role for nursing in the clinical research setting, an NP, was identified in this study. This role had a general pattern of activity that was similar to the RNC in the dimensions of CP

($M = 3.22 \pm 1.29$), SM ($M = 1.52 \pm 0.76$), CCC ($M = 2.58 \pm 1.09$), and HSP ($M = 1.86 \pm 0.86$), and a significantly ($p < 0.05$) higher level of frequency in CS ($M = 1.20 \pm 0.80$). The activities that are common for the NP focus on the provision of direct care and monitoring of research subjects for adverse events, which are critical components of an NP practice, patient assessment. Of note, NP participants had the highest activity frequency and importance for CS activities compared to all other roles. The activity that contributed to the increased score was related to their professional activities as an advanced practice nurse serving as an expert beyond the primary responsibilities of their job; such as presenting, serving as editorial reviewer and participating in authorship activities.

Discussion

The findings from this study suggest that nurses who work with study participants in a clinical research setting, regardless of the specific role, perform activities that do indeed represent the practices proposed in the CRN domain of practice. Moreover, these activities are multidimensional and span clinical specialties such as medical surgical, oncology, neurology, and mental health. Despite the variation in clinical specialty, nursing activities were primarily study driven; nurses report spending the majority of their time providing a service to and for research subjects as opposed to supporting study coordination or facilitating the work of a specific investigator. This may challenge the reported practice of staffing clinical studies using the nurse to protocol ratio as opposed to the nurse to subject ratio.¹³

The title of “research nurse” has been generically applied to nurses working in a clinical research setting. However, a variety of terms have been created by individual agencies to identify specific roles. Delineating specialty activities and identifying practice differences across roles as well as providing titles that are generically meaningful will enhance an understanding of varying nursing roles in clinical research. The frequency pattern of activities reported in this study suggests that there are two distinct roles for nurses supporting clinical research; CRN and RNC. The role of the CRN as distinguished from the RNC is to integrate specialized knowledge and skills and collaborate with a variety of patients care services to ensure comprehensive care to research subjects.¹⁴ The role of the RNC focuses most heavily on study management and care coordination and continuity, but includes aspects of all the dimensions. Previous work describes the components of a clinical trials nurse in the extramural community, specifically in oncology, with activities that are similar to those reported by the research nurse coordinators in this study.² It is conceivable that limited program resources might only support one specialized nurse and/or research participants may be dispersed on more than one patient care unit. Thus, an RNC might oversee the implementation of the studies by staff nurses who provide clinical care to the research participants but who are not trained as CRNs. However, identifying the core components of the domain of practice for clinical research nursing, despite the roles, allows a program to be flexible while ensuring quality care in a clinical research setting.

We also found evidence that advanced practice nurses working as NPs in a clinical research team have role components that overlap with the CRN domain of practice. The activities performed by the NPs in this sample included advanced CP responsibilities as well as activities in the dimensions of study management and coordination of care that were similar to the RNC. These findings are similar to previous work that has

described the research role of the NPs to include responsibilities specific to the medical management of research subjects including research, educational, and administrative responsibilities.^{15,16} The activities identified by the NPs reflecting more professional accountability are likely related to their advanced education and side-by-side work with the clinical fellows and other members of the research team. The specific role of an NP in clinical research is just beginning to be refined and as one participant stated “*It has been a huge struggle to define my role. I have a DNP (Doctor of Nursing Practice) and find that there is always confusion as to my degree and scope of practice.*”

As a single-site study, there are limitations that should be recognized. Although the NIH CC is the largest research-intensive center in the country, the representation of the different roles in this study was not balanced. Only 18% of the participants in this study were serving as a RNC and even fewer, 4.4%, as an NP. The uniqueness of the intramural research program likely contributed to the low frequency of certain activities involving grants and funding.

Conclusion

The role of nurses as a member of a clinical trials team positions them well to help address translational challenges from basic research to practice.¹⁷ Currently, nurses often come into research settings, such as Clinical and Translational Science Award sites (CTSAs), without prior research training. The findings from this study serve as the foundations for delineating nursing roles in clinical research and for developing role-based competencies and certification of nurses in clinical research environments that can comprehensively address this lack of formal clinical research training. As the number and complexity of clinical trials expand, understanding the delineation of roles and the contributions that nurses specializing in clinical research becomes increasingly important. Nurses specializing in clinical research make important contributions to research integrity, patient care, care coordination, and human subjects protection; their specialized knowledge and practice is vital to the clinical research enterprise.

Acknowledgments

The authors would like to thank the nurses at the National Institutes of Health Clinical Center (NIH CC) who participated

in this study. We are grateful for their shared commitment to the recognition and advancement of Clinical Research Nursing as a formally recognized specialty. The authors would also like to thank The NIH Clinical Center's Nursing and Patient Care Services leadership staff for their work in supporting and advancing the CRN²⁰¹⁰ initiative over the last 3 years. We also acknowledge funding by the Intramural Research Program of the NIH Clinical Center.

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