Online Exclusive Article

Validating the Clinical Research Nursing Domain of Practice

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Purpose/Objectives: To develop and validate a taxonomy for the domain of clinical research nursing.

Design: Survey.

Setting: Clinical research settings in the United States.

Sample: A purposefully selected expert panel of 22 nurses who were actively practicing or supervising in a clinical research environment.

Methods: A study team consisting of nurses with experience in clinical research synthesized peer-reviewed articles, academic curricula, professional guidelines, position descriptions, and expert opinion. Using the Delphi technique, three rounds of surveys were conducted to validate the taxonomy. The three sequential questionnaires were completed over five months.

Main Research Variables: Activities performed by nurses in a clinical research setting.

Findings: A taxonomy for clinical research nursing was validated with five dimensions and 52 activities: Clinical Practice (4 activities), Study Management (23 activities), Care Coordination and Continuity (10 activities), Human Subjects Protection (6 activities), and Contributing to the Science (9 activities).

Conclusions: This study validated activities for direct care providers and nurses with the primary focus of research coordination. The findings identify a variety of activities that are unique to nurses in a clinical research setting.

Implications for Nursing: Nurses play an integral role in the clinical research enterprise. Validating a taxonomy for the specialty of clinical research nursing allows for roles to be compared across settings, competency requirements to be defined, and nursing organizations to be guided in the development of specialty certification.

Descriptive and experimental research with human subjects has significantly advanced understanding of normal physiology and development, the etiology and course of diseases and disorders, treatment of disease and reduction of disability, and human responses to illness and health status changes. Since the 1940s, great strides have been made in clinical research to safeguard human subjects and ensure scientific integrity through discussion regarding ethical principles underlying clinical research, government regulations, and research staff training worldwide (Breslin, 2008). Consensus on standards for conducting research with human subjects is reflected in the International Conference on Harmonization (ICH) Guideline for Good Clinical Practice (ICH Expert Working Group, 1996), which has become the internationally acknowledged basis for the regulation of clinical research in the United States, European Union, and other countries (Fedor, Cola, & Pierre, 2006). International guidance provides the foundation for multisite, international clinical trials designed to evaluate new research compounds and treatment modalities and determine the potential benefits for individuals and human society as a whole.

Clinical trials are research studies conducted with human subjects and are designed to answer specific scientific questions using controlled experimental methods (Cassidy & Macfarlane, 1991). Trials require collaboration among a variety of agencies, such as academic medical centers, single institutions, cooperative groups, the healthcare industry, private and not-for-profit corporations, and government (Offenhartz, McClary, & Hastings, 2008). To ensure the protection of human subjects and scientific integrity amidst the complexities of the clinical research process, the expertise of various disciplines is required.

Nurses have a strong history of being involved in clinical research. However, nursing practice within the specialty of clinical research nursing only recently has begun to be formally defined (Castro et al., 2008). Significant diversity exists in the educational preparation

and training for nurses in the clinical research specialty. Some nurses are novices and learn the specialty while caring for research subjects or coordinate a clinical trial portfolio while being mentored by a more senior nurse, whereas others may receive didactic training in the clinical research specialty and have a defined orientation curriculum. Nurses in clinical research may practice in centers with numerous resources devoted to research and have a more defined scope of practice; at centers with fewer resources, however, nurses may function more as generalists, assuming activities ranging from direct patient care to administrative responsibilities (Oncology Nursing Society [ONS], 2010). The major responsibilities for any nurse involved in clinical research is ensuring research participant safety, study integrity, and ongoing maintenance of the informed consent process, all within the context of effective and appropriate clinical care. As the national and international clinical research enterprise expands, investigators, health policy makers, regulators, and sponsors of clinical research must understand the pivotal role of nurses.

Literature Review

Extensive literature exists describing the various nursing roles in clinical research. McCabe and Cahill Lawrence (2007) defined clinical research nurses as "specially trained nurses responsible for safeguarding research subjects and maintaining the integrity of the research study in settings ranging from ambulatory to inpatient with healthy to acutely ill subjects" (p. 13). Multiple titles (e.g., research coordinator, clinical research coordinator, clinical trials nurse, study coordinator) have been used internationally to identify nurses in clinical research (Bacon, 2008; Carlson, Reilly, & Hitchens, 2005; Gwede, 2008; Gwede, Johnsson, Roberts, & Cantor, 2005; Johnson & Scott, 2008). Three unique nursing roles emerge: (a) the clinical nurse as a direct care provider for research participants before, during, and after participation in clinical research, (b) the nurse as a study manager, coordinator, or clinical trials nurse who works closely with the principal investigator recruiting research participants and overseeing data management and regulatory compliance, and (c) the nurse researcher, who is the principal investigator on a research study (Grady & Edgerly, 2009; Mori, Mullen, & Hill, 2007; Offenhartz et al., 2008; Pitler et al., 2009). The nurse as a principal investigator follows good clinical practice guidelines and the Code of Federal Regulations when designing, planning, and conducting research (U.S. Department of Health and Human Services, 2010; U.S. Food and Drug Administration, 2010). However, the direct care provider and clinical trials nurse or research nurse coordinator do not have clear standards that define roles and responsibilities for the nurse in clinical research.

A broad range of specialized activities performed by nurses practicing in a clinical research setting have been identified, including protocol assessment, protocol planning, subject recruitment, informed consent process, education, implementation and evaluation, data management, and professional nursing role performance (Ehrenberger & Lillington, 2004). The activities are linked to the managerial, clinical, educational, professional, and research demands within a clinical research setting (Carlson et al., 2005; Carter, Jester, & Jones, 2007; Mori et al., 2007; Mueller, 2001; Spilsbury et al., 2008). Very little information exists about the actual time spent by clinical research nurses in various research-related tasks. Researchers have suggested that 32% of time spent running a clinical trial is associated with study management and care coordination activities (Emanuel, Schnipper, Kamin, Levinson, & Lichter, 2003). Another study found that 50% of nurse coordinators' time was spent attending study visits, managing ongoing study issues, and recruiting research participants (Duane, Granda, Munz, & Cannon, 2007). Those studies suggest that the scope of practice for nurses in the clinical research setting is unique and extends beyond direct clinical care.

Many sources of knowledge exist for nurses serving as clinical trials coordinators in the clinical research setting. First, academic programs recognize the importance of research coordination. Several U.S. universities offer certificate and degree programs in clinical research, with a focus on managing research activities and regulatory affairs, writing research grants, developing managerial skills to facilitate the implementation of clinical research, integrating and applying good clinical practice guidelines, maintaining ethics and conduct of responsible research, and research data management. Second, a significant number of standardized continuing education programs also are available to educate healthcare professionals from all disciplines in the conduct of clinical trials (Arant et al., 2007; Di Giulio et al., 1996).

Professional organizations dedicated to clinical research provide specialty certifications for those involved in clinical trial coordination and data management. The professional organizations and certifications are open to a variety of research professionals and are not limited to nursing. The Society of Clinical Research Associates ([SoCRA], 2009) sponsors certification for the clinical research professional. This certified professional focuses more on research activities such as protocol development, study design, grants and funding, data collection, and development of informed consents, and less on the direct care of the individual research participant. The Association of Clinical Research Professionals (ACRP) offers four distinct certifications, although none describes a healthcare professional providing direct care (ACRP, 2011a). The Academy of Pharmaceutical Physicians and Investigators and ACRP support chapters

throughout North America, Europe, Australia, Africa, and the Middle East that allow for networking, education, and support for research professionals (ACRP, 2011b).

The International Association of Clinical Research Nurses ([IACRN], 2010) is an emerging professional nursing organization dedicated to supporting educational and professional needs of clinical research nurses (Doorenbos et al., 2008). The goal of IACRN is to provide standards for nurses within the clinical research specialty, including the direct provider role. ONS is leading the way as an oncology organization in support of the clinical research specialty. ONS has a Clinical Trial Nurses Special Interest Group and has published *Manual for Clinical Trials Nursing* (Klimaszewski, Bacon, Deininger, Ford, & Westendorp, 2008) and *Oncology Clinical Trials Nurse Competencies* (ONS, 2010). The ONS research agenda identifies numerous topics related to clinical research, including clinical trials decision making, symptom and side-effect management, and quality of life (Berger, Cochrane, & Mitchell, 2009). To date, neither IACRN nor ONS offers certification in the clinical research nursing specialty.

Purpose

This article presents a validation study of a proposed taxonomy for the specialty of clinical research nursing. The development of any specialty requires identification of key roles and activities that are agreed upon by established experts. A taxonomy or formal system of classification is one approach to increase clarity and understanding (Bradley, Curry, & Devers, 2007). A taxonomy includes levels of concepts such as a domain (the specialty practice area), dimensions (distinct areas or categories of responsibility within the domain), and activities (specific actions, tasks, or job descriptors within a dimension) (see Figure 1). The purpose of the current study was to develop and test the validity of a taxonomy for nurses in the clinical research setting.

Methods

This study used two objectives to accomplish its aims: to develop a taxonomy for the domain of clinical research nursing and to validate the taxonomy using the Delphi technique. The taxonomy for the domain of clinical research nursing was intended to represent the full spectrum of nursing practice in the clinical research setting.

To develop the taxonomy, a study team composed of nurses with experience in clinical research was identified. The domain to capture the nursing specialty in a clinical research setting was titled "clinical research nursing." Five theoretical dimensions had been identified previously: Clinical Practice, Study Management, Care Coordination and Continuity, Human Subjects Protection, and Contributing to the Science (Hastings, 2007). To complete the taxonomy, a list of activities within each dimension was required.

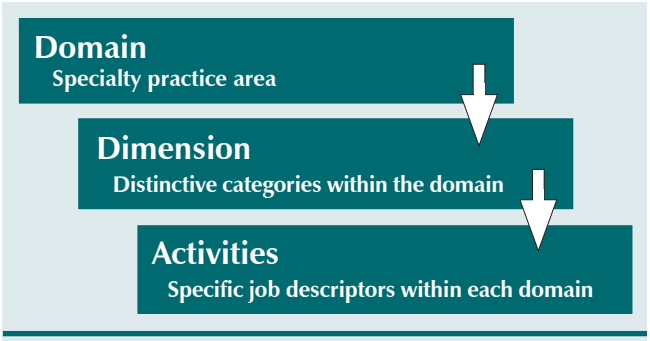

Figure 1. Taxonomy Structure

To identify activities performed by nurses in a clinical research setting, the study team synthesized peer-reviewed articles, academic curricula, professional guidelines, position descriptions, and expert opinion. The literature review used the PubMed and CINAHL® databases to identify 21 articles. Academic curricula that focused on preparing nurses for a role in clinical research included 16 centers from 11 states in the United States and one Canadian province. Only two professional research societies that offer certification and education in clinical research management were identified and resources from both were included. Finally, position descriptions for nurses working in a clinical research setting and expert opinion from the study team were incorporated. Those data sources were collated and reviewed by study team subgroups. Each subgroup presented their review to the full team for deliberation and consensus.

An extensive list of activities was identified by the study team. To address repetitiveness across data sources, a series of in-person consensus-building meetings were conducted. Redundant activities were removed, resulting in the identification of 49 unique activities. Based on the five dimensions for the clinical research nursing domain, a series of categorization activities were conducted by the study team to place each activity into a dimension. The final product served as the proposed taxonomy.

To validate the proposed taxonomy, the Delphi technique was used to achieve consensus regarding the dimensions and activities in the domain of clinical research nursing. This technique has been reviewed critically as a methodology in the field of nursing emphasizing the importance of sampling, anonymity, use of experts, rounds, and current application (Keeney, Hasson, & McKenna, 2001). The Delphi technique provides an avenue for a panel of experts to share their opinion without the burden of travel or group bias. This methodology uses a series of sequential surveys in an iterative process to gain consensus on an identified topic that serves as a starting place for future work in the area.

This survey research was approved through the Office of Human Subjects Research at the National Institutes of Health Clinical Center. Experts who agreed to participate were given a unique study code for tracking purposes that was known only to the principal investigator. Consent to participate was explicit once the participant completed the first survey.

Sample

A purposefully selected panel of expert nurses was approached for participation. No clear guidelines exist regarding how to define an expert for a Delphi panel (Baker, Lovell, & Harris, 2006), so the criteria in this study were slightly more broad, allowing for a heterogeneous sample of those working as nurses in clinical research settings. Potential participants were nurses actively practicing or supervising in a clinical research environment, with at least two years of experience, and providing or having provided direct care to research participants; serving or having served as a study research coordinator; or supervising in either position previously mentioned. Expert panel members included individuals from within the continental United States across areas of clinical focus such as pediatrics, gerontology, and oncology. Members of the study team were excluded from participation as experts on the Delphi panel.

Thirty experts were approached for potential participation and provided with an explanation of the study procedures. A telephone script was used by a member of the study team to provide a structured and consistent study overview. That included the understanding that a maximum of three rounds of questionnaires was possible. If the nurse agreed to serve as an expert panel member, the preferred method of contact to receive study materials was obtained (e.g., e-mail). The principal investigator provided a code for each expert to ensure the anonymity of survey responses.

Delphi Questionnaire

The taxonomy elements (dimensions and activities) were used to develop the survey questionnaire. Each questionnaire consisted of five sections representing the five proposed dimensions. The items were activity statements placed in a dimension by the study team. Each question contained two parts: (a) Using a five-point Likert scale (1 = strongly disagree to 5 = strongly agree), experts indicated their level of agreement with inclusion of an activity in the clinical research nursing domain and (b) to the question, "Does this activity belong in the designated dimension?" the experts could respond yes or no, with the option to indicate an alternative dimension as appropriate. A comment section accompanied each response, along with a final dimension-specific comment section at the end of each dimension.

Table 1. Demographic Characteristics of the Experts Who Completed the Survey and Those Who Did Not[a]

Characteristic	Completed the Survey (N = 22)	Did Not Complete the Survey (N = 5)
Nursing position		
Clinical research nurse	3	–
Research nurse coordinator	2	2
Clinical nurse specialist	3	–
Director	3	1
Nurse manager	6	2
Educator or staff development	2	–
Other	3	–
Direct patient care to research participants		
Yes	10	2
No	12	3
Percentage of time providing direct patient care[b]		
25%	6	1
50%	1	–
75%	–	1
100%	3	–
Current primary practice area		
Clinical and Translational Science Award site	6	2
General Clinical Research Center	4	–
Academic Research Center	2	–
NIH Clinical Center	5	1
NIH Institute (intramural)	5	1
Other	–	1
Primary patient population		
Pediatrics (0–18 years)	3	–
Adult (18–65 years)	19	5
Current patient care setting		
Inpatient	4	1
Ambulatory care	3	2
Ambulatory infusion center	1	–
Inpatient and ambulatory care	12	1
Other	2	1
Belong to SoCRA or ACRP		
Yes	7	2
No	15	3
Current professional certification through SoCRA or ACRP		
Yes	4	–
No	18	5
Highest nursing degree		
Associate	2	1
Bachelor	7	3
Master	12	1
Doctorate	1	–
Years as a practicing nurse		
1–5	1	–
11–15	4	2
16–20	1	2
More than 20	16	1

(Continued on next page)

[a] Three experts agreed but did not complete any rounds.
[b] Only respondents with direct patient care completed this item.
[c] Multiple responses permitted
ACRP—Association of Clinical Research Professionals; NIH—National Institutes of Health; SoCRA—Society of Clinical Research Associates

Table 1. Demographic Characteristics of the Experts Who Completed the Survey and Those Who Did Not[a] *(Continued)*

Characteristic	Completed the Survey (N = 22)	Did Not Complete the Survey (N = 5)
Years providing care to research participants		
1–5	1	–
6–10	4	1
11–15	7	2
16–20	5	1
More than 20	5	1
Years providing care to research participants		
1–5	1	–
6–10	4	1
11–15	7	2
16–20	5	1
More than 20	5	1
Training or education in clinical research[c]		
Organization-specific	21	5
Academic course	9	3
Certification program	3	–
Degree program	2	1
Cancer nurse training program	1	–
Principles and practice of clinical research	1	–
Age (years)		
20–29	1	–
30–39	4	2
40–49	9	2
50–59	6	1
60 or older	2	–
Gender		
Female	22	5
Race or ethnicity		
Asian	1	–
Black or African American	2	–
White or Caucasian	18	5
Other	1	–
Region of the United States		
West	1	1
Midwest	1	–
New England	5	–
Mid-Atlantic	13	4
South	2	–

[a] Three experts agreed but did not complete any rounds.
[b] Only respondents with direct patient care completed this item.
[c] Multiple responses permitted
ACRP—Association of Clinical Research Professionals; NIH—National Institutes of Health; SoCRA—Society of Clinical Research Associates

Participants were asked to complete a series of demographic questions at the end of the first survey.

The survey was developed using software by SurveyMonkey™. All experts had the ability to receive an electronic copy of the survey. The principal investigator distributed each survey electronically with a three-week deadline. Data were collated after each survey, with a summary of the group's results returned to the participants electronically at the time of the next survey. Data collation, analysis, and qualitative comment review by the study team, between each questionnaire, took approximately three weeks.

Data Analysis

The data were analyzed using SPSS®, version 15. Frequency distributions were used to summarize the sample demographic and practice variables. Internal consistency reliability (coefficient alpha) and inter-rater reliability for the agreement between experts were computed for each survey. Descriptive statistics including mean, standard deviation, and percentages were computed for each item response. The item responses from the final questionnaire were re-coded, collapsing strongly disagree and disagree into disagree and strongly agree and agree into agree to allow for definitive grouping of the activities.

Internal consistency was strong for surveys 1–3 ($\alpha = 0.96$, 0.95, and 0.9, respectively). Whereas internal consistency indicates the extent to which the activities represent a consistent set, inter-rater reliability or intraclass reliability indicates the degree to which raters agree on an activity. Inter-rater reliability estimates for surveys 1–3 ($\alpha = 0.95$, 0.91, and 0.88, respectively) also were high.

Results

Although 30 experts agreed to participate, 27 (90%) completed the first questionnaire, 24 (80%) completed the second, and 22 (73%) completed all three questionnaires (see Table 1). Expert panel members who did not complete all surveys most commonly cited lack of time for their inability to follow through. The experts who did not complete all three surveys had no particular demographic or setting variable that made them unique compared to the experts who completed the study.

Participants were female (100%), and most were Caucasian and practicing in the Mid-Atlantic region of the United States. Forty-one percent were aged 40–49 years, 23% were younger than 40, and 36% were 50 or older. Most had more than 20 years' experience as a practicing nurse, with only 5% indicating five years or less. Forty-five percent had been providing care to research participants for 16 years or more.

The three sequential questionnaires were completed over five months, from September 2008 to January 2009. In survey one, each dimension had the following number of activities: Clinical Practice (7 activities), Study Management (19 activities), Care Coordination and Continuity (9 activities), Human Subjects Protection (6 activities) and Contributing to the Science (8 activities). After completion of the first questionnaire, the research team reviewed the comments and revised the second

questionnaire to capture the experts' suggestions. Specifically, two activities were added to the Study Management dimension: (a) record data on approved study document (e.g., case report forms, research or study database) and (b) facilitate processing and handling (storage and shipping) of research specimens. Those activities previously were embedded in other activities and created significant confusion for experts. Based on feedback from the experts, one activity also was added to the Contributing to the Science dimension: "Serve as a resource for new investigators." Activities were not changed between the second and third questionnaires. Experts estimated 75–90 minutes to complete each survey.

Prior to reviewing the results of the third survey, the study team agreed that an activity with greater than 85% simple agreement would be deemed appropriate for the designated dimension or overall domain of clinical research nursing. Six activities had less than 85% agreement relative to inclusion in overall domain and all expert comments were discussed by the study team. After review, all six activities were retained in the domain because expert comments did not favor removing them; rather, they remarked on how the activities might be interpreted. That level of agreement suggests that the activities identified in the final survey accurately reflect the practice of nursing in a clinical research setting.

Although no new dimensions or activities were identified in the final survey, activities were relocated from their original dimension. Based on expert comments, the study team concluded that the following represented the best activity-dimension fit: (a) provide indirect nursing care (Care Coordination and Continuity), (b) record research data (Clinical Practice), (c) participate in the identification and reporting of study trends (Study Management), (d) identify clinical care implications during study development (Study Management), (e) comply with the ICH Guideline for Good Clinical Practice (Study Management), and (f) coordinate referrals to appropriate interdisciplinary services outside the immediate research team (Care Coordination and Continuity). The adjustments created a taxonomy that included the following five dimensions with associated activities: Clinical Practice (4 activities), Study Management (23 activities), Care Coordination and Continuity (10 activities), Human Subjects Protection (6 activities), and Contributing to the Science (9 activities) (see Figure 2).

Discussion

The study validated a clinical and a research focus for nurses in the clinical research specialty, differentiating between a more direct care provider role and one of research coordination and regulatory oversight. These findings support the assumption that clinical practice activities in this domain do not differ significantly from clinical practice in other nursing specialties, while identifying a variety of activities that are unique to nurses in a clinical research setting.

Expert panel participants engaged in a rigorous dialogue about the Study Management and Human Subjects Protection dimensions. Study Management is the largest dimension because it encompasses the greatest number of activities and, therefore, the most discussion. These activities describe the intricacies of supporting clinical research that are unique to this specialty practice. Participating in study development, preparing reports for regulatory boards and monitoring agencies, developing case report forms, and participating in audits are just a few examples of how the clinical research nursing specialty practice differs from other specialty practices. Overall, the experts concluded that Study Management and Human Subject Protection activities were a common thread providing the context for all activities in the clinical research nursing domain of practice. Occasionally, the expert discussion would identify that "some of these activities cross over all dimensions and they best belong in all dimensions." At times, the study group was challenged to clearly determine whether an activity was only in one dimension. One participant reported that, "It is the practice of the clinical research nurse and can be the practice of all team members. It does not belong in one domain [dimension] alone."

The dimension of Contributing to the Science created a forum for considerable dialogue surrounding the nurse's role in working with the principal investigator to publish research findings. Although all specialty practices are responsible for contribution to the literature and professional development, the dimension of Contributing to the Science represents the role nurses play in development of new ideas for study and exploration of the innovations arising from clinical research and their application to practice. Activities in this dimension include participating in the query and analysis of research data, identifying clinical research questions, and serving as resources to a new investigator. This dimension shows the difference this nursing specialty plays in furthering evidence-based practice based on research findings and using findings to develop study ideas.

Care Coordination and Continuity is common across nursing specialties, yet this dimension represents the extensive coordination of care that is required for research participants throughout the study trajectory. Activities include facilitating the education of the interdisciplinary team on study requirements, collaborating with interdisciplinary team members to ensure safe and effective collection of clinical research data, and providing indirect nursing care in the context of research participation. The activities validated that the coordination of research activities applies to both study requirements and clinical needs.

A limitation of the study may be the 27% dropout rate, the majority because of time constraints and inability to complete the surveys within the specified time frames. These lost participants may have had valuable input that the research team could not obtain. However, the remaining sample is well within the number needed to demonstrate a strong consensus using the Delphi technique (Powell, 2003).

The current study provides the validation of a taxonomy for the clinical research nursing specialty dimensions

Care Coordination and Continuity Dimension

Coordination of research and clinical activities to meet clinical needs, complete study requirements, and manage linkage with referring and primary care providers

1. Facilitate the education of the interdisciplinary team on study requirements.
2. Collaborate with the interdisciplinary team to create and communicate a plan of care that allows for safe and effective collection of clinical research data.
3. Coordinate research participant study visits.
4. Provide nursing leadership within the interdisciplinary team.
5. Coordinate interdisciplinary meetings and activities in the context of a study.
6. Coordinate referrals to appropriate interdisciplinary services outside the immediate research team.
7. Communicate the impact of study procedures on the research participant.
8. Provide nursing expertise to community-based healthcare personnel related to study participation.
9. Facilitate research participant inquiries and concerns.
10. Provide indirect nursing care (e.g., participation in clinical, unit, and/or protocol rounds; scheduling study related test) in the context of research participation.

Clinical Practice Dimension

Provision of direct nursing care and support, using the nursing process, to participants in clinical research, their families and significant others. Care requirements are determined by the scope of study participation, the clinical condition of the patient, and the requirements and clinical effects of research procedures.

1. Provide direct nursing care to research participants (e.g., interact with research participants to provide nursing care, administration of research interventions, specimen collection).
2. Provide teaching to research participants and family regarding study participation, participant's current clinical condition, and/or disease process.
3. Monitor the research participant and report potential adverse events to a member of the research team.
4. Record research data (e.g., document vital signs, administer research compound, participant responses) in approved source document (e.g., the medical record, data collection sheet).

Contributing to the Science Dimension

Contribution as a research team member to the development of new ideas for study and explorations of innovations arising for clinical research findings to practice

1. Disseminate clinical expertise and best practices related to clinical research through presentations, publications, and interactions with nursing colleagues.
2. Serve as an expert in a specialty area (e.g., grant reviewer, editorial board member, presenter).
3. Participate in the query and analysis of research data.
4. Generate practice questions as a result of a new study procedure or intervention.
5. Collaborate with the interdisciplinary team to develop innovations in care delivery that have the potential to improve patient outcomes and accuracy of data collection.
6. Identify questions appropriate for clinical nursing research as a result of study team participation.
7. Mentor junior staff and students participating as members of the research team.
8. Perform secondary data analysis to contribute to the development of new ideas.
9. Serve as a resource to new investigators.

Human Subjects Protection Dimension

Facilitation of informed participation by diverse participants in clinical research

1. Facilitate the initial and ongoing informed consent or assent process.
2. Support research participant in defining his or her reasons and goals for participating in a study.
3. Collaborate with the interdisciplinary team to address ethical conflicts.
4. Coordinate research activities to minimize subject risk.
5. Serve as institutional review board member.
6. Manage potential ethical and financial conflicts of interest for self.

Study Management Dimension

Management of clinical and research support activities to ensure patient safety, address clinical needs, and ensure protocol integrity and accurate data collection

1. Participate in study development.
2. Participate in research participant recruitment.
3. Participate in screening potential research participants for eligibility.
4. Coordinate and facilitate the collection of research specimens.
5. Develop study-specific materials for research participant education.
6. Perform quality assurance activities to ensure data integrity.
7. Participate in the preparation of reports for appropriate regulatory and monitoring bodies or boards.
8. Facilitate accurate communication among research sites.
9. Facilitate communication within the research team.
10. Contribute to the development of case report forms.
11. Participate in the setup of a study-specific database.
12. Comply with International Conference on Harmonisation Guideline for Good Clinical Practice.
13. Collect data on research participant based on study end points.
14. Facilitate scheduling and coordination of study procedures.
15. Provide nursing expertise to the research team during study development and implementation.
16. Protect research participant data in accordance with regulatory requirements.
17. Participate in site visits and/or audits.
18. Support study grant and budget development.
19. Oversee human resources (people) related to research process.
20. Record data on approved study documents (e.g., case report forms, research or study database).
21. Facilitate processing and handling (storage and shipping) of research specimens.
22. Identify clinical care implications during study development (e.g., staff competencies and resources, equipment).
23. Participate in the identification and reporting of research trends.

Figure 2. Activities and Dimensions Within the Domain of Clinical Research Nursing

and activities that will guide future work to establish a recognized specialty practice area. Mori et al. (2007) defined the role of the nurse in clinical research nursing as a basis for credentialing and developing a blueprint for specialty certification. They cited certification as key in delineating the unique role of the nurse in clinical research nursing as it represents specialized knowledge and skills. A role delineation study will help to further define the specialty and is a key step on the way to certification.

Conclusions

The specialty of clinical research nursing involves nursing practice with a focus on the care of clinical research participants and management of a clinical research protocol. The specialty encompasses care provided to research participants, as well as activities to support protocol implementation, data collection, and human subject protection.

What is the value that a nurse brings to the research team? What is the cost of adding nursing expertise to a research team? How do nurses demonstrate their unique contribution of nursing to the research specialty? Validation of the specialty domain of practice now allows for comparison and contrast of roles in different settings using agreed-upon categories, defined competency requirements, and guidance of nursing organizations in development of specialty certification. Clinical research is changing rapidly, penetrating all practice settings and extending into a global industry. Nurses must be able to demonstrate and articulate the clinical research nursing practice to communicate the important contribution of nurses to the integration of clinical care and research, assurance of subject safety, and implementation of good clinical practices across the research enterprise. The validation of the domain of practice hopefully will set the stage for an international dialogue that will further develop this important specialty worldwide.

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