ORIGINAL RESEARCH

The Clinical Research Nurse: Exploring Self-Perceptions About the Value of the Role

Findings indicate the CRN's unique and wide-ranging contributions.

In the contemporary health care environment, conducting sound clinical research requires a diverse team of experts.[1] Such teams often include clinical research nurses (CRNs), who are "focused on maintaining equilibrium between care of the research participant and fidelity to the research protocol."[2] Thus CRNs are positioned not only to provide high-quality patient care, but also to make important contributions to clinical research. In the United States, nursing involvement in clinical research has been noted in the literature as early as 1910, when Nancy Poultney Ellicott emerged as an early leader in this work.[3,4] Yet clinical research nursing has only recently come into its own as a specialty practice, with the American Nurses Association (ANA) officially recognizing it as such in 2016.[5] Its continued advancement requires empirical evidence that can reveal and substantiate the specific contributions of CRNs to patient care and the clinical research enterprise.

BACKGROUND

In recent years there has been a surge in clinical research activity in the United States and elsewhere,[6] as well as a heightened focus on safety as a result of past harms to research subjects. The last decade has brought increased awareness of clinical research nursing as a specialty practice, and progress has been made toward better describing the CRN's role.[7-10] Clinical research nursing has gained international attention for its contributions to the safe and ethical care of research subjects and to the efficient collection of high-quality research data.[11-14] The RN practicing as a CRN provides health care for patients who are research subjects and also performs research-related tasks, while balancing the requirements of both the patients and the study protocol.[8]

CRN specialty practice incorporates five domains: human subject protection, care coordination and continuity, clinical practice, contributing to the science, and study management.[15] Each of these domains involves dimensions and activities that are evident in a variety of professional roles, practice settings, and clinical specialties.[15] To better describe the CRN role, researchers have conducted role delineation studies.[9,16,17] These studies documented that CRNs work as direct care providers in roles such as staff nurse and advanced practice nurse. Additional roles can include nurse manager, clinical research coordinator, educator, regulatory specialist, and nurse scientist.[18] But the actual value of the contributions that CRNs make to research has not been well articulated.

Although the overall research enterprise is growing rapidly, funding for clinical research has not kept pace.[19] Researchers in this arena must be able to conduct low-cost trials that produce high-quality outcomes, including accurate data and safe patient care. Given that nursing care has been identified as a costly element of clinical trials,[20,21] it's incumbent upon CRNs to articulate their unique contributions and gather evidence demonstrating their value to the research enterprise.

The purpose of this study was to describe CRNs' perceptions of the value of their specialized practice as it relates to the care of clinical research subjects and the implementation of clinical research protocols. For the sake of clarity, in this article *participants*

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ABSTRACT

Background: Clinical research nursing is an emerging specialty practice. Clinical research nurses (CRNs) work to make protocol-related care safe for the research subjects while simultaneously maintaining protocol fidelity. They must continuously balance the needs of the research subjects and the study requirements.

Purpose: The purpose of this qualitative study was to describe CRNs' perceptions of the value of their role.

Methods: Two focus groups were conducted with a purposive sample of 18 CRNs. An interview guide consisting of eight open-ended items was used. Data analysis used critical elements from Krueger's systematic steps for analyzing focus group data.

Results: Five major themes emerged from 168 coded statements contained within the focus group transcripts: comprehensive nursing care of research subjects, training and education of research subjects and staff, contributions to clinical science, unique combination of clinical and critical thinking skills, and CRN practice attributes. Subcategories were also identified. In general, participants felt strongly about the value they added.

Clinical research nursing requires the use of a variety of abilities and skills, including critical thinking and problem solving, as well as clinical and research knowledge. The CRNs in this study described incorporating these and other elements into their practice, which they associated with their specialized role. The five themes that emerged help elucidate the importance and utility of including CRNs on research teams.

Conclusions: The unique combination of applied research knowledge and expert clinical skills sets the specialty of clinical research nursing apart. The study findings, in particular the five themes, provide an evidence-based framework that will be useful in the development of competencies for CRN specialty practice. In helping to bring research findings to bear on clinical care, the impact of CRNs' practice extends beyond the individual patient to larger patient populations.

Keywords: clinical research, clinical research nursing, nursing value

refers to the CRNs who participated in our study; *research subjects* refers to the healthy volunteers and patients in the studies these CRNs were involved in conducting.

METHODS

Study design. This qualitative descriptive study involved two focus groups made up of practicing CRNs. Focus group methodology employs a semistructured interview format to collect data on a specific topic from people who are experts or who understand the topic.[22] Using this method, we captured participants' perspectives related to their nursing role and the value of their work in clinical research. For the purposes of this study, we defined value as the importance, worth, or usefulness of something.[23]

Sample. A purposive sample of CRNs was recruited from among the 116 attendees of the Sixth Annual Conference of the International Association of Clinical Research Nurses (IACRN), held November 5–7, 2014, in Boston. Following approval from the institutional review boards of the investigators' organizations, an e-mail invitation was sent to conference registrants asking them to consider participating in the study. Flyers were also posted at the event. Interested participants contacted the support staff of the organization's management company to express interest and report which focus group they planned to attend. To be eligible for this study, prospective participants had to be currently practicing as a CRN in the United States or Canada, have the equivalent of two or more years of full-time practice experience as a CRN, and be fluent in English. Active members of the IACRN Scope and Standards of Practice Committee were excluded because of the nature of the committee's work.

Demographic data were collected from each group including age, sex, race and ethnicity, years of experience as an RN, years of experience as a CRN, highest level of education, highest nursing degree, practice setting, role, and patient population served.

Instrument. The focus group interview guide was developed by the study team and refined by clinical experts before its use in focus group sessions. Two of the experts were members of the IACRN Scope and Standards of Practice Committee. The final interview guide consisted of eight open-ended questions designed to elicit responses and stimulate conversation about the participants' experiences in clinical research practice and their perspectives on the value of the CRN role. For details, see *CRN Focus Group Discussion Guide*.

CRN Focus Group Discussion Guide

1. Please tell us what you enjoy about being a clinical research nurse (CRN).
2. Can you describe why you decided to focus your nursing practice in clinical research?
3. If we define value as "the importance, worth, or usefulness of something," how would you describe the value of a CRN in clinical research?
4. In clinical research, do you think CRNs compared to non-CRN staff[a] have an effect on the research? Please describe the effect. How would you describe the value?
5. In clinical research, do you think CRNs have an effect on research participants compared to non-CRN staff?[a] Please describe the effect. How would you describe the value?
6. Please think about your practice experience as a CRN. Can you talk about a specific situation when you believe your practice added value to clinical research?
7. If you think about your practice experience as a CRN, can you talk about specific activities you engage in that add value to clinical research?
8. Is there anything else you would like to say about the value of a CRN?

[a]Non-CRN staff are nonclinicians in clinical research roles, such as research assistant or research coordinator.

Data collection. Two focus groups were held at the annual meeting site. Informed consent was obtained before the start of each focus group. Each group was allotted two hours. Both groups were conducted by the same expert facilitator (one of us, JV). To promote free discussion and minimize bias, the facilitator was not a CRN and was not previously known to the participants. Each focus group began with a review of ground rules. This included reminders to participants to keep the content of the discussion confidential and to avoid using fellow participants' names. The facilitator kept the discussion focused and encouraged all CRNs to participate. Each session was recorded digitally. A research assistant, also unknown to the participants, observed each focus group and took field notes.

The digital recordings were transcribed verbatim by an outside transcriptionist; the transcripts were then checked by one of us (MM) for accuracy against the original recordings. All participants were deidentified in the digital recordings and transcripts, which were then securely stored in password-protected electronic folders.

Data analysis. The study team employed critical elements from Krueger's systematic steps for analyzing focus group data.[24] The content of the transcripts was analyzed according to the specific aims of the study. First, each transcript was coded independently by two coinvestigators (LB, SB, MJW). The context of the transcripts as a whole was considered during coding. Field notes describing the environment and participants' actions and behavior during the focus groups were also considered. No preconceived codes were used; rather, the codes emerged from the data. Second, each coder assigned their respective codes to categories. The categories were compared for congruence, and differences between coders were reconciled; this level of analysis was completed with review by and input from the entire study team. The goal was to reach consensus on emerging categories and subsequent themes. Lastly, the codes and categories were reviewed by a focus group participant to verify that they represented the essence of each focus group discussion. One participant from each group volunteered for this task.

RESULTS

Sample. A total of 18 CRNs participated in the study focus groups, seven in one group and 11 in the other. All participants were female, with a mean age of 49 years. They had practiced for a mean of 23 years as RNs and 13 years as CRNs; a majority had attained a master's degree or higher. For more demographic characteristics of the sample, see Table 1.

Findings. In general, the participants engaged actively in the focus group discussions and were passionate about the topics. Five major themes emerged from 168 coded statements contained within the focus group transcripts:

- comprehensive nursing care of research subjects
- training and education of research subjects and staff (study and clinical)
- contributions to clinical science
- unique combination of clinical and critical thinking skills
- CRN practice attributes

Each theme contained data from between two and five categories. See Table 2 for the complete list of themes and categories.

Theme 1. Comprehensive nursing care of research subjects. This theme included four categories: advocacy for patients and protocol, balancing patient care needs and protocol requirements, case management and care coordination, and patient safety. The CRNs' discussion revealed a holistic approach to advocacy that embraced advocacy for both the safety of research subjects and fidelity to the research protocol. They described using critical thinking skills to address the "higher level needs" of both, and discussed their accountability in this regard as going beyond "checklist activities." In a comment that highlighted this, one

participant said that as a staff nurse without CRN training, she "wouldn't have known what to advocate for."

When advocacy was discussed in the context of balancing patient care and protocol activities, the word "vigilance" was used. Several CRNs described themselves in a state of constant vigilance, maintaining heightened awareness in an effort to ensure equilibrium between patient care needs and protocol requirements. One participant said, "We know that you need to think about both things." Another said, "It's that [CRN] nursing framework that brings you there, and you are able to assess the protocol as you assess the patient."

Regarding case management and care coordination, focus group participants discussed the importance of applying their nursing perspective to coordinating the care needs of research subjects. They were aware that the nonmedical needs of patients with complex medical conditions are often challenging, and spoke to the value of their input as nurses:

> [We can] make referrals to a social worker or dietitian or something that really involves every aspect of [the research subject's] life.

> Being able to have their transportation needs met, that will enable them to maintain their participation in the trial.

The safety of research subjects was a strong element in the discussions overall. The CRNs described how having a combined knowledge of both clinical research and nursing expertise helped in this regard. They perceived themselves as a patient safety resource for the study team. They discussed the importance of their nursing knowledge, for example, when monitoring physiological trends and using critical thinking skills, especially in early phase studies. Although bedside and staff nurses also perform these tasks, CRNs must be especially diligent because of the unknown elements that characterize research; they must amplify and broaden their safety awareness. The focus group participants spoke to the CRN's need to process both clinical and research information, and agreed that doing so is critical to maintaining patient safety. One participant explained,

> I can't tell you how many times I have picked up on cues, words, just one word that comes out of the patient, and I know something's going south or north or whatever, whereas the [study] coordinator didn't.

They also noted the importance of the CRN's knowledge of research regulations and the ability to use critical thinking in applying such knowledge to patient care while carrying out protocol activities. They perceived this skill to be unique to CRN practice. As another participant said,

> [The nonnurses on the research team] missed all the early signs and symptoms and I think

Table 1. Demographic Characteristics of the Study Sample (N = 18)

Characteristic	Mean (SD)	Range
Age (in years)	48.8 (9.9)	29.8–64.5
Years practicing as an RN	22.6 (11.6)	6.3–42.3
Years practicing as a CRN	13.4 (7.9)	0.6–29
	n	**%**
Sex		
Female	18	100
Ethnicity and race[a]	8	
White	14	77.8
Asian	2	11.1
American Indian/Alaska Native	1	5.6
Highest level of education		
Bachelor's degree	5	27.8
Master's degree	12	66.7
PhD	1	5.6
Highest nursing degree		
Associate's degree	2	11.1
BSN	8	44.4
MSN	7	38.9
PhD	1	5.6
Type of practice site[b]		
Inpatient	9	
Outpatient or ambulatory	13	
Academic	5	
Role		
CRN	9	50
Manager	9	50
Patient population[b]		
Children	8	
Adult	16	
Older adult	11	

BSN = bachelor of science in nursing; CRN = clinical research nurse; MSN = master of science in nursing.
[a] One person declined to respond.
[b] Multiple choices may apply.

Table 2. Identified Themes and Categories

Themes	Categories
Comprehensive nursing care of research subjects	• Advocacy for both patients and protocol • Balancing patient care needs and protocol requirements • Case management and care coordination • Patient safety
Training and education of research subjects and staff	• Staff education • Patient education
Contributions to clinical science	• Data quality and accuracy • Protocol development, implementation, and feasibility
Unique combination of clinical and critical thinking skills	• Clinical thinking • Critical thinking
CRN practice attributes	• Expert autonomous practice • Unique and distinct role • Variety and diversity of work • Collaboration and teamwork • Relationship of trust

> that speaks to the value that only a nurse can bring to any trial. If we're deviating from the protocol, we're wasting time, money, we're adding risks to the patient. So by knowing that protocol, we're actually protecting the patient.

Theme 2. Training and education of research subjects and staff. This theme was discussed in the context of educating staff working in the study environment, research team members, and research subjects and their families; thus it included two categories: staff education and patient education. Focus group participants spoke of the importance of staff education in decreasing protocol variance to ensure the scientific integrity of the research. They were passionate about the need for education designed for team members who aren't clinicians (such as team coordinators or research assistants) and clinical staff outside the research team. Comments included:

> There is a huge need as we move research out to the floors . . . the most valuable thing . . . [is] to train the new nurses.

> Value is transcending that education down so that there's meaning for that person at the bedside who's struggling with "I don't understand why [a given procedure] has to be at 15-minute intervals."

Participants also emphasized the importance of education in better defining and supporting the role of nonclinician team members who interact with subjects.

Education of research subjects and their families was seen as an essential aspect of the CRN role. Participants noted that CRNs bring their broad clinical knowledge to bear on such education. They stated specifically that in doing so, CRNs include both disease-based and research-focused education. Research-focused education includes both general research and protocol-specific information, and is crucial in order for subjects to safely and willingly engage in research. One participant commented, "I think [research subjects and families] understand coming from a [CRN] what the drug is all about, more so than when they speak with the doctor . . . we can explain it at their level." Another saw the CRN's role as

> continuously making sure the patient or the research participant understands the next steps before we do anything, so that we're actually being that gatekeeper of safety . . . I go back to education and I do not think that someone who is not a [CRN] can provide the education.

The focus group participants viewed the CRN's contribution to the education of healthy volunteers and other "first-in-human" study subjects as particularly important.

Theme 3. Contributions to clinical science. The theme of contribution to clinical science included two categories: data quality and accuracy; and protocol development, implementation, and feasibility. CRNs discussed making vital contributions at every stage of protocol development, seeing themselves as "an integral part" of that work. They often focused on the practical aspects of ensuring accurate data collection and protocol implementation while maintaining fidelity to the research plan. One CRN said that if data collection practices vary,

> you don't get the same data quality and [staff nurses] miss time points because it's not what they're focused on, they have too much on their plate. [We're] saying, "Yes that can be done, but this is what you have to do [to] work within the standards of care for the patient['s] safety . . . and the quality of the data."

The topic of protocol feasibility also arose frequently. One CRN said,

> The physicians have the science but they do not understand the bedside patient care and

> what it takes, so they may have an idea and they write a grant but there's no feasibility.

Another stated,

> Before we have a protocol come out, it needs a nursing review, no matter what kind of a protocol it is, because we see things that [principal investigators] do not pick up on, that human piece.

A distinctive dimension of the CRN's practice is having scientific knowledge about data collection that uses multiple sources and methods: physiological, biological, observational, self-report, record, and narrative. As one participant expressed it, her role included "figuring out how to get research data in the midst of care of the [subject] . . . keeping the integrity of the data and figuring out how to make that happen."

Theme 4. Unique combination of clinical and critical thinking skills. This theme included two categories: clinical thinking and critical thinking. As described during focus group discussions, clinical thinking is based on the CRN's broad clinical knowledge. As one participant explained, CRNs "can pick up on nuances, the little things . . . [that] someone without a medical background isn't going to understand." Another said,

> I think it's our nursing background that lets us see the whole picture, to value the patient and how sick they're going to get [with] this intervention or what their potential risks are . . . I don't think anybody else sees that.

Moreover, participants noted that CRNs must often engage in critical thinking in the abstract, because of the nature of research. During discussions, they referred to being able to conduct independent problem solving in the presence of limited information. One participant said,

> [You can be a] really good nurse and you can be a critical care nurse, you can be a cancer specialist, but you are not necessarily the best [CRN] . . . [for myself,] having gotten to clinical research nursing and having that "Ah-ha" moment of what you do, you have realized you have the critical thinking skills of a research nurse.

The ability to combine both clinical and critical thinking was seen as unique to the CRN's role and adding to its value. One participant said, "What I have heard from the nurses I work with who are not CRNs is that [CRNs] . . . think a lot more . . . and more deeply about more things." Participants also saw CRNs' comfort with change as an important aspect of this ability to combine thinking skills. As another participant commented,

> If you change their routine, it really throws floor nurses off . . . the [CRN] is less thrown off, they want that change, they want to be able to impact change and [patient] care in a big way.

Theme 5. CRN practice attributes. This theme refers to the particular characteristics of the CRN role. It included five categories: expert autonomous practice, unique and distinct role, variety and diversity of work, collaboration and teamwork, and relationship of trust. Focus group participants discussed being sought out by research subjects, physicians, nurses, and other research and clinical staff for their expertise—their combined knowledge of nursing and clinical research. They spoke of how that expertise contributes to every phase of research, from protocol development to interpretation of findings and implementing change in clinical practice. Focus group participants voiced a clear belief that their role differed from other nursing roles. This came through in comments such as:

> Hospital [staff] nurses do what they do best, which is care for the patient, and then we will come and we will be complementary and we will take care of the research subject.

CRNs practice across the spectrum, working with healthy volunteers as well as critically ill patients in a role that encompasses diverse patient care and research-related activities. Participants found this variety in their work appealing; as one said, "I like the diversity of the patient population, and the work on the day-to-day basis is always different."

Collaboration and teamwork was a strong category in this theme. One CRN stated, "I love being on the cutting edge of science and the interdisciplinary comradeships that brings." Another spoke to the challenges of working within a hierarchical medical system:

> It is a challenging job but it is reward[ing] . . . there are moments when it is very interesting because everybody is part of a team that contributes to conducting the research.

In talking about the CRN's role on research teams, participants offered examples of ways they had applied their expertise and taken leadership throughout the research process. For example, they described identifying barriers and providing recommendations on how to operationalize a research plan within an inpatient facility that had competing priorities and regulations unrelated to research.

Focus group participants described themselves as bringing together two aspects of coordination vital to successful research: study coordination to ensure subjects' compliance with research activities, and care coordination to ensure subjects' ability to do so safely. For example, an initial protocol checklist might omit human considerations such as visual acuity, preferred learning methods, and transportation concerns. It might not assess an individual's needs in order to tailor resources for that person or use the teach-back method to ensure that subjects have an adequate understanding of health care information and research activity instructions. Several participants described bringing such elements to the attention of protocol developers. Several also described efforts to teach staff outside the research team, making themselves available to answer questions about specific research protocols, explain research regulations, and prompt staff regarding timely data and biological specimen collection. They expressed enthusiasm for and pride in these aspects of their role.

Our findings indicate that CRNs contribute to high-quality data, protocol integrity, and the safety of research subjects, and are skilled at navigating the health care system.

Participants' discussion about relationships of trust focused mostly on relationships between CRNs and research subjects, but relationships between CRNs and principal investigators (PIs) or the overall research team were also addressed. Participants felt that, in general, nurses build trusting relationships with their patients: "We are, I think, the number one trusted health care professional." They perceived this trust as carrying over to the CRN–research subject relationship, and noted that it might even be strengthened by the uncertainty that can characterize the research experience. One participant explained that such patients "look for that research nurse and that person is [whom] they will trust beyond anything that the PI will say." This relationship of trust was important to the CRNs, who acknowledged research subjects for taking risks and giving of themselves for a "greater good."

DISCUSSION

These findings contribute new insights and understanding of the value of the CRN role in clinical research. To our knowledge, ours is the third published focus group study involving CRNs. The first such study, conducted by Spilsbury and colleagues, focused on the experiences of CRNs in the United Kingdom and identified areas of challenge.[14] More recently, Tinkler and colleagues explored the experiences of CRNs in relation to factors that impact study delivery in the United Kingdom.[25] They found that CRNs struggled with a "perceived dichotomy" between caring for research subjects and meeting stakeholder requirements. Our study builds on this work by engaging CRNs in the United States and Canada in discussions about their perceptions of the value of CRN practice. The five themes that emerged help elucidate the importance and utility of including CRNs on research teams. These themes also provide an evidence-based framework that will be useful in the development of competencies for CRN specialty practice.

CRNs strive to make research-related care safe for study subjects while also meeting the requirements of the study protocol, maintaining equilibrium between the two. Toward this end, CRNs may contribute to the development of study protocols: our participants spoke of incorporating strategies to protect research subjects with special attention to safety, even before recruitment. Such efforts go beyond what has been set forth in the ANA's *Code of Ethics for Nurses with Interpretive Statements*[26] and the Canadian Nurses Association's *Code of Ethics for Registered Nurses*,[27] extending care beyond patient research subjects to healthy volunteers. Indeed, care of healthy volunteers is a vital part of CRN practice. Research subjects place themselves at risk, often for altruistic reasons, and CRNs may be the only health care providers interacting with them. Furthermore, CRNs' attention to protocol fidelity helps to ensure data integrity, justifying the study volunteers' involvement in the research.

CRNs often practice on the cutting edge of patient care, caring for patients who are receiving novel treatments and helping to generate evidence that may be used to set future practice standards, once such treatments become the new standard of care. In so doing, CRNs may play an active role in bringing research findings to bear on clinical care. Their impact thus extends beyond the individual patient to larger patient populations. Such far-reaching implications amplify the importance of introducing clinical research nursing to the curriculum at all levels of nursing education. The CRN role is relevant at every level, yet few nurses leave academic programs knowing about it. The ANA's recognition of clinical research nursing

as a specialty practice and its recently published *Clinical Research Nursing: Scope and Standards of Practice*[18] provide a foundation for change. CRNs are collaborating with nursing and clinical research colleagues to integrate pertinent content into nursing curricula, develop CRN certification, add to competencies being established for the clinical research workforce, and contribute to the development of standards for clinical research study sites.

A comprehensive examination of the value of the CRN role requires considering three dimensions—costs, specific contributions, and overall usefulness—all within the context of achieving high-quality outcomes with an emphasis on patient safety and data quality. The five themes that emerged from our analysis support the latter two dimensions. For example, the CRNs in our study described using both clinical and critical thinking skills to ensure the safety of research subjects while following elaborate study protocols. Indeed, CRNs are trained to obtain high-quality data in complex care situations, such as those often present in phase 1 trials. And CRNs' highly developed advocacy skills and constant consideration of ethical issues further ensure patient safety.

The third dimension, costs, was not evident in the emergent themes. But in any effort to reduce costs, it's essential to consider the potential impact on patient outcomes.[28] In clinical research, the quality of the research must also be considered. Two recent articles have pointed to the high costs of clinical research and of nursing care in that context—without mentioning the potential impact of lowering costs on patient outcomes and data quality.[20,21] Our findings indicate that CRNs contribute to high-quality data, protocol integrity, and the safety of research subjects, and are skilled at navigating the health care system. Thus it's more likely that CRNs help reduce overall costs without sacrificing these critical elements. Their presence on research teams may actually decrease findings' "time to market," allowing faster dissemination of new evidence into practice.

Lastly, it's appropriate to ask what the role of CRNs should be in team science. The National Cancer Institute describes team science as "a collaborative effort to address a scientific challenge that leverages the strengths and expertise of professionals trained in different fields," and notes that "coordinated teams of investigators with diverse skills and knowledge may be especially helpful for studies of complex social problems with multiple causes."[29] While a lead investigator's qualifications clearly matter, it's increasingly recognized that including team members with training and expertise in different fields fosters more successful research.[30] In this context, CRNs have much to contribute. The five themes that emerged from our data offer a summary of such contributions, which range from the practical (such as contributing to protocol development and ensuring accurate data collection) to the less tangible (such as building relationships of trust with subjects). And because CRNs possess both nursing and research knowledge, they can address aspects of research that others may not have considered.

Implications. As the specialty practice advances, CRNs should strive to obtain positions in the clinical research enterprise that value the breadth of their expertise: they can act as principal or coinvestigators, perform data analysis, contribute to the writing of protocols and articles, and lead or support dissemination activities. They must also strive to compile evidence that will lead to a better understanding of the CRN role in terms of costs, specific contributions, and overall usefulness. Organizations stand to benefit from leveraging CRNs' expertise to improve outcomes for research programs as well as subjects. Academic programs should build awareness of the CRN role into the curriculum at every level.

Limitations. The investigators are all nurses and four of us (MM, LB, SB, MJW) have worked as CRNs at some point. This may have introduced inadvertent bias. Focus group participants were recruited from attendees of an IACRN meeting. CRNs who don't attend professional meetings or engage with professional nursing organizations may have different perspectives from those who participated in this study. All of the focus group participants were female, and this too may have affected the content of discussions. Lastly, the only perceptions of the value of CRN specialty practice represented in this study are those of CRNs themselves. Other providers may have different perceptions. More focus group studies with larger sample sizes of CRNs and with other research team members, subjects, and families are needed to further elucidate the value of the CRN's role.

CONCLUSIONS

The unique combination of applied research knowledge and expert clinical skills sets the specialty of clinical research nursing apart. CRNs are often the only members of a research team with in-depth knowledge of both patient care and the research process, along with training in problem solving. Together these elements add up to a skill set that prepares CRNs to evaluate, interpret, and synthesize information while ensuring research subjects' safety, high-quality data, and protocol fidelity. Our investigation yielded rich descriptions and examples of how CRNs perceive their value as research team members. The findings, in particular the five themes, provide an evidence-based framework that will be useful in the development of competencies for CRN specialty practice. ▼

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