

Capturing the value and core concepts of the Clinical Research Nurse

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Abstract

Background: As nurses, we identify our profession as a caring one, but how does this identity translate from a conceptual definition, to real-world practice for the Clinical Research Nurse?

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Aim: To offer a novel, four-point conceptual model that encapsulates the Clinical Research Nurse's intrinsic value, active leadership, and direct contribution to high quality, person-centered, safe care, addressing current misperceptions of research nursing.

Methods: This paper describes the provision of 'care', safely delivered by the Clinical Research Nurse through a four-point conceptual model and case-driven example.

Discussion: Clinical research nursing is conceptualized within the domains of Care and Trust, Role, Impact, and Integration. The case example demonstrates real-world application of these domains and the expertise required to balance the complexities of clinical needs and research demands in a healthcare environment.

Conclusions: This paper offers a mechanism for understanding the importance of the Clinical Research Nurse and their role in maintaining safety and a high-level view of the care arena. These reflections are considered with an international application for the role.

Keywords

clinical, concepts, research impact, research nurse, value

Introduction

Nursing is widely considered an art and a science (Jairath et al., 2018), incorporating a systematically organized scientific body of knowledge and evidence-based care (Sten et al., 2021), alongside innovative and thoughtful approaches that ensure safe processes of care delivery.

The art and science of the Clinical Research Nurse (CRN) role is found within the weaving of care throughout the research process, and the value added to patient care that this produces. CRNs play a vital role in improving patient care and contributing to enhanced treatment pathways through delivering and leading clinical research activities (Gibbs & Lowton, 2012), but research nursing is not simply about task-based actions. Rather, it amplifies the nursing values consistent within patient care provided by nurses across all settings. Recognition of this connection to the nursing process and the inherent skill of the CRN role can be difficult to capture (Tinkler et al., 2018). In addition, the role is often misunderstood within wider clinical practice, and the scope, value, and skills of the CRN are often under-utilized, possibly further exacerbated by a lack of formal research into the topic (Cleaver, 2020).

This paper describes the provision of "care" safely delivered by the CRN, drawing from the limited evidence base (Cleaver, 2020), and the experience and expertise of our authorship team who are clinical, research and academic nurses from the UK, Australia, and the US (see Supplemental 1). In particular, we offer this work in *response* to the limited evidence base that does not do justice to the complex mechanisms that the CRN operates within, and does not adequately capture daily clinical, research and academic work with its challenges and opportunities. The conceptual framing maps our work within a formal model that others may also find useful.

Within this paper, those who do not have research as a dedicated aspect of their role are referred to as Clinical Nurses (CNs), and those who have research design and/or delivery as a partial or complete role are referred to as CRNs. We make this distinction to emphasize the importance of

direct nursing care within both roles. We propose the ideas of trust and care, role, impact, and integration to be of equal importance when considering the delivery of high quality, safe, person-centered care by CRNs. CRNs have fundamental expertise in speaking to these concepts, and aligning nursing art, science, and clinical care delivery (Shoghi et al., 2019).

Conceptual model and case example

The function of the CRN role is complex, but complementary to that of the CN. To capture this complexity, the concepts of care and trust, role, impact, and integration of the CRN into practice are presented as a four-point conceptual model (Figure 1).

The proposed model components were derived over a nine-month period with a process including four sources, which was intended to fill the gap in knowledge stemming from the aforementioned lack of specific evidence. First, our authorship team met weekly for nine months, discussing and building the proposed model and its components, drawing from our combined clinical and research experience (Supplemental Table S1). Second, to determine if our model components were supported by the literature, we carried out a broad literature review. Led by CW who is undertaking a PhD focused on the impact of research by CRNs, we reviewed 453 articles with specific and adjacent relationship to the CRN role—the majority of these were adjacent but supported the four components we had identified. Third, we conducted a series of TweetChats (hour long live chats on the Twitter platform) in November 2020, over seven sessions in four time zones A) to confirm if our components were reflected within the experiences of the wider community of CRNs, patients, and other stakeholders and B) identify any gaps in our model. During these TweetChats we asked clinical research communities internationally for their perspectives, opinions and experiences about the CRN role in relation to

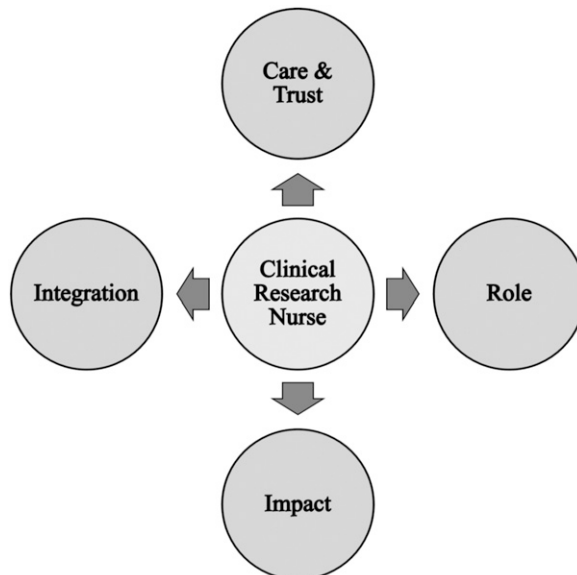


Figure 1. The 4-point conceptual model.

care. Three hundred and thirty individual twitter accounts participated across the seven TweetChats, with a reach of over one million impressions. Wordclouds were generated from the conversation text against each question asked, with the larger words being those which were said the most (Figure 2–5).



Figure 2. “What does care mean to you?” TweetChat wordcloud.



Figure 3. “What care do research nurses provide?” TweetChat wordcloud.



Figure 4. “What are the challenges in delivering care faced by research nurses?” TweetChat wordcloud.



Figure 5. “Benefits to care provided by research nurses” TweetChat wordcloud.

We then undertook a rapid thematic analysis (Taylor et al., 2018) of the responses to help inform and refine the components. Finally, as our purpose for this paper is to offer an argument for greater value of, consideration for, and investment in this vital nursing role, we identified a case of a real-world scenario that demonstrates the practical application of the conceptual model (Box 1). Following the first three steps, it was the addition of this case which made explicit the implicit

components of the model, and providing the direct link demonstrating the value of the CRN from theory to practice. From this process, we identified the CRN's underpinning ethos stem from a natural desire to care, developed by his/her/their nursing and research training. We explore each of the four components of the conceptual model, using the lived experience of the CRN to offer more in-depth reflections (Figures 6–9).

Concepts of care and trust

Our model begins with care and trust (Figure 6) as these are fundamental underlying concepts that govern what we, as nurses, do (Gilbert, 2020; Adams, 2016).

Nursing theorists have held the concepts of care and trust as core tenets of the profession for decades (Chapman, 2018; Leininger, 1991). As found within the case (Box 1 and Figure 6), care and trust are woven throughout the nursing codes of conduct in each of the authors countries (American Nurses Association, 2015; Nursing and Midwifery Board of Australia, 2016; Nursing and Midwifery Council, 2018), directing our practice, without regard to the systems we work in, or the titles we hold. Nurses identify the profession as a caring one (Andersson et al., 2015), but how does this identity translate from a conceptual definition to practice across contexts, given the different interpretations and perceptions attached to it? Care has traditionally been a core argument supporting the value of nursing within the direct clinical delivery role (Dick et al., 2017) but within a research capacity, the “caring” link is not always explicit. In the case, within the context of care and trust, we highlight Jody's driving concern of care, her ability to establish trust, and the impact of her actions, as demonstrated through her interactions with both the patient and CNs (Figure 6). Supporting Jody's work is the ethos of a “duty of care,” which incorporates legal, ethical, and professional responsibility and accountability. Within clinical research, “Good Clinical Practice” (European Medicines Agency, 2016) (U.S. Food and Drug Administration, 2018) also provides

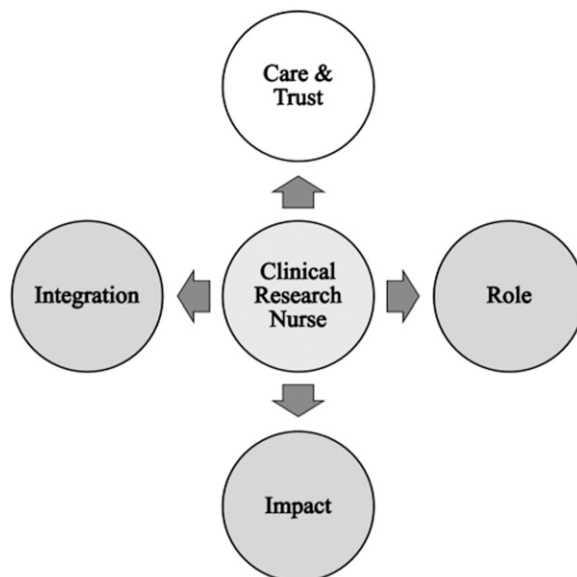


Figure 6. Application of case example to conceptual model highlighting care and trust in the CRN role.

international standards for ethical and scientific quality of design, conduct, and reporting of trials that include human participants. Therefore, the foci of both clinical care and research with human participants are safety, quality, and provision of ethical care (Waring et al., 2016).

The CRN is employed principally to undertake research within the clinical environment; working and communicating within a multi-disciplinary team (Frances Ndyetukira et al., 2019; Kunhunny and Salmon, 2017). CRNs are focused on maintaining equilibrium between care of the research participant and fidelity to the research protocol (American Nurses Association, 2016; U.S. Food and Drug Administration, 2018). There are many synergies across the CN and CRN roles, and as our conceptual model highlights, it is the core tenets of care (conceptualized as an essential component of nursing) (Morse et al., 1990), and trust that underpin nursing (Box 2, Figure 6), and often serve as the unique identifiers for the nursing profession (Milligan, 2001). In particular, the nurses' skilled understanding of the mechanisms of care enable rapid and repeated establishment of trust with patients (Berg and Danielson, 2007; Milton, 2018), leading to the reputation of nursing as the most trusted profession (Milton, 2018).

While there is growing recognition of nurses as instrumental to improving care across domains, such as policy, education, research, and activism (Drevdahl and Canales, 2020; Tinkler et al., 2018), stigma can be attached when transitioning away from clinical to "other types" of care delivery, including the CRN role (Kunhunny and Salmon, 2017). Yet, what is most notable about the presence of nurses in varied delivery settings is the consistent integration of care and trust that guides their practice.

Role of the clinical research nurse

The second component of the CRN model highlights the core elements of the CRN role, with a special focus on its overlapping and complementary nature to the CN role (Figure 7).

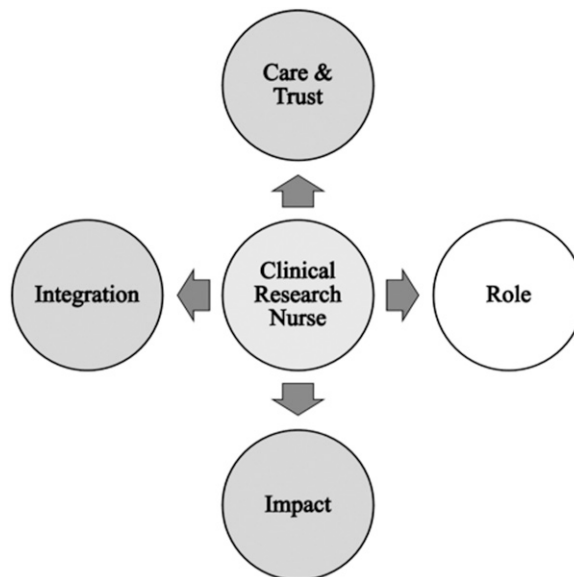


Figure 7. Application of case example to conceptual model highlighting the role of the CRN.

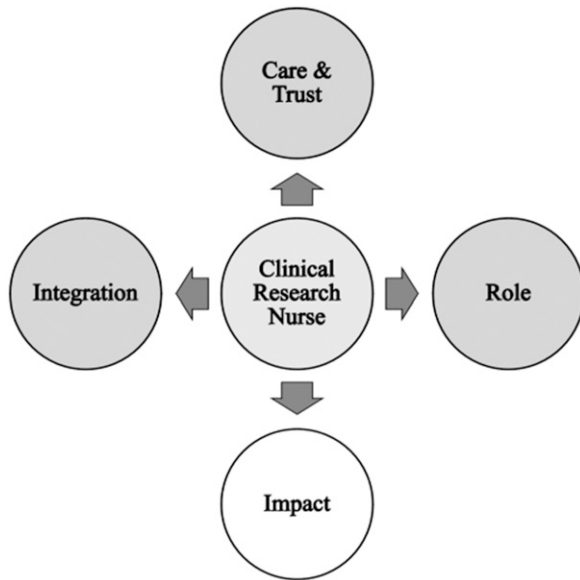


Figure 8. Application of case example to conceptual model highlighting the impact of the CRN.

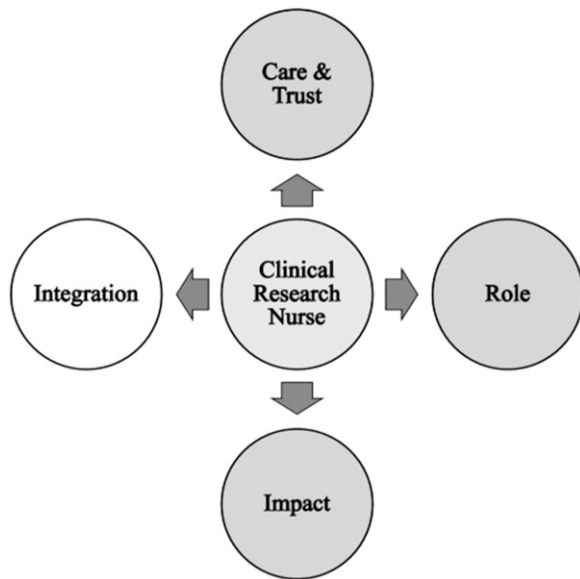


Figure 9. Application of case example of conceptual model highlighting the integration of the CRN.

In pushing for greater recognition and integration of the CRN, it is important to address critical concerns, such as questions of the veracity of a unique nursing research role when research activities are an expected part of the CN role. As shown in the case, the daily reality of demands on CNs often makes this impossible, particularly when short staffing, increasing acuity of patients, and scarcity of

resources are taken into consideration, all of which are now further exacerbated by the global challenge of the COVID-19 pandemic (Shen et al., 2020; Wang et al., 2020). We also argue that while research should be included in the knowledge base and feed into the CN role, there is a distinct need for specialty research nursing staff given the complexity and safety needs of research activities (Figure 7) (Lavender and Croudass, 2019). Dedicated research positions enable ongoing generation of vital new knowledge without compromising patient safety and care (Gibbs and Lowton, 2012).

CRNs fulfill a vital function in their own right, bringing highly developed research skills, application of lateral analysis, critical thinking and problem solving, and a unique combination of applied research knowledge and expert clinical skills. (Gibbs and Lowton, 2012; Hill and MacArthur, 2006; Whitehouse and Smith, 2018). The CRN may engage in protocol development, ethics review, and expert recommendation, ensuring compliance with specific legislative and regulatory requirements related to research (Raja-Jones, 2002).

The CRN role adheres to professional governing body standards, such as the Nursing and Midwifery Council in the UK (Nursing and Midwifery Council, 2018), or the American Nurses Association in the US (American Nurses Association, 2015), but it also demands detailed knowledge and understanding of national and international legislation and guidelines, which include, for example, Clinical Trials Regulation EU 2014, and ICH GCP (European Union, 2014; U.S. Food and Drug Administration, 2018). The high-level conceptual thinking of the CRN must also be supported by clinical nursing knowledge (Larkin et al., 2017). This includes comprehensive knowledge of the specialty under investigation, patient advocacy, implementation of safety precautions, practical and therapeutic support for patient and family participants, in addition to managerial, organizational, teaching, mentoring, communication, and technology skills (Tinkler et al., 2018).

While this paper primarily focuses on the application of the role of the CRN in an inpatient setting, the CRN role transcends this to include community-based or primary care settings, and clinical trials sponsored by industry or government that are set in research facilities. The CRN still maintains the focus on care and trust within their role, and it could be argued to demonstrate even greater value in these settings as they may not have the inherent layers of safety and support provided by inpatient nursing care. For example, one of our authors recounts an experience of gathering data in participant homes in the community setting (Blackwell, 2015). The participant shared personal experiences that indicated a significant potential safety risk to their well-being. The participant was not under the support of any healthcare team, and there were no clear referral connections. The author balanced CN and CRN skills in communication and assessment, offering insight and support while remaining within the research protocol. That situation resolved safely and the participant shared that their experience had been cathartic, but we highlight the lack of clinical protocol or support network due to the setting. This contrasts with the various lines of support that Jody was able to pull on and connect with in the case (Box 3 and Figure 7). Recognizing the need for greater reflection and consideration of this aspect of the CRN role, the authors are developing another manuscript to explore this more thoroughly.

At its essence, CRNs traverse two equally balanced and important factors, clinical and research care (Figure 10). The scales can tilt in favor of one priority over the other depending on the patient need, and the equilibrium is only safely maintained when both functions are fully understood. Figure 7 demonstrates how Jody maintains this balance, using her training and abilities to improve the safety and rigor of the study, as well as wider relationships and patient care. The balance exists in the care of both healthy people and those with health conditions who have volunteered their time as research participants, to help advance health sciences. Often, these volunteer participants step outside the mainstream of clinical care, known as the “standard of care,” willingly giving for the

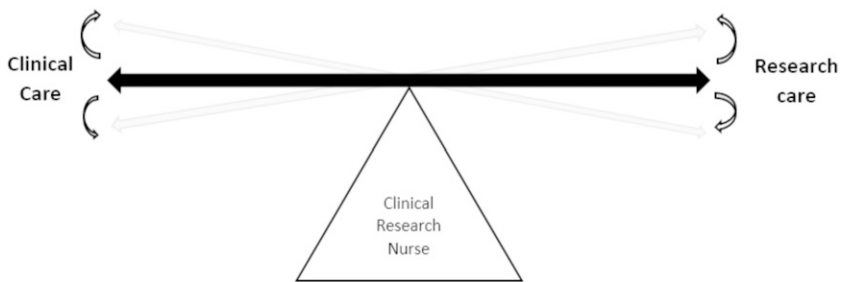


Figure 10. The balancing of clinical and research care.

greater good by participating in clinical research. Clinical research participants deserve the same level of specialized nursing care that ensures exceptional, ethical, safe care that can also yield high-quality data.

Impact of the Clinical Research Nurse

The third component of our model speaks to the impact of the CRN role on patient outcomes, research conduct, and clinical practice. Part of our reason for this focus is that while CNs may recognize the importance of research, there can be difficulty in identifying how to be involved or how it relates to routine clinical practice (Gibbs and Lowton, 2012). Box 4, Figure 8 demonstrates the potential breadth for the application of the concept of CRN “impact” within practice.

In particular, the second scenario described in Box 1 shows how patient harm is rarely caused by one factor, but is often the result of a cascading chain of events more commonly referred to as the “Swiss Cheese Model” (Noh et al., 2020). In this model, harm or near harm events are reviewed from a multi-level perspective, with consideration of macro, meso, and micro factors at systems, organization, unit, and individual levels (Noh et al., 2020). Jody encountered the culmination of one such event, a busy unit, short staffed with newly qualified CNs with limited scope of practice who were confronted with an additional research-related activity without the clarity or patient-centered focus required. In this situation, the impact of a CRN who was able to identify the multi-level risk factors, avoid directing blame, and implement mechanisms to improve relationships, knowledge, and patient safety is demonstrated by remarkable outcomes. Even when research participants are comprised of healthy volunteers, clinical emergencies can occur, and the CRN fills a similarly essential role in those cases.

Integration of the Clinical Research Nurse

Jody’s case study demonstrates the ability of the CRN to integrate into varied clinical settings (Box 1, and Figures 6, 7, and 9). Jody’s skill was in identifying and responding to verbal and non-verbal cues to support CNs, build trust and rapport, and effectively conduct vital research.

Other mechanisms to highlight the parallels and potential for integration of activities between the CRN and CN exist which may be more accessible to a nursing audience. The nursing process is often taught using the “Assessment, Analysis, Planning, Implementation, Evaluation” model (Glasper, 2020). This model is

Box 1: Case ExampleThe Person in the Practice

Jody is a CRN and the following case example is adapted from her clinical practice, edited for confidentiality. When she presented this example, Jody first shared insight into who she is in a way that resonates with the heart and soul of the nursing profession. She reflected on herself as a person who cares first and foremost, and found nursing to be an extension of her natural concern. She sees herself as a nurse first, and a research nurse second and sees that her role adds value. This means that Jody's research priorities never supersede the needs of a patient or participant in her care. She works to ensure that every interaction adds value, and that she supports multidisciplinary colleagues, beyond a direction to 'just read the protocol'. Each interaction returns focus back to the patient, and in practical application this means that she always prioritises patient care.

Patient Scenario Part 1:

Jody works on a large study with several thousand patients recruited and randomized. Jody goes to a participating clinical unit that has a patient randomized to the treatment arm of the study, and informs the CN in charge of the patient's involvement. Jody personally takes the study prescription to the pharmacy, and returns the medication to the unit. Jody hands treatment information over to the CN taking care of the patient, making sure that she also leaves her contact details. Using various communication strategies drawn from her nursing training to ensure understanding of the protocol and processes, Jody first ensures that the CN understands she is available to provide support, then documents her activities and conversations, and takes time with the patient to receive continuing consent before leaving the unit.

Patient Scenario Part 2:

Jody's research colleague is working on the same study and also recruits and randomizes a patient on a different unit. They inform the CN that the patient gave consent, hands the study prescription to the CN to fill and administer according to the study protocol, then leaves the unit. Due to the clinical priorities of the CN team within this unit, the prescription was not prepared until much later in the day. Later review of nursing documentation lacked mention of any study protocol activities for this patient. Due to Jody's established relationships with the CNs on the unit, she received a message from the CN the following day stating the treatment had not been given and asking for advice. Jody responded by first reassuring the reporting CN and building rapport. Upon further discussion, Jody discovered the delay in filling the prescription was compounded by a shift change, and the incoming shift did not include personnel with sufficient training to administer the treatment. For safety reasons, the treatment was withheld until contact could be made with the research staff. Jody followed up immediately, and working with her established nursing leadership connections, she reviewed the patient's laboratory levels, and went to the unit to support the CN who was extremely anxious about the ramifications for the patient. Jody again reassured the CN and reviewed the protocol with them. In this instance, due to various possible timeframes for treatment administration, no harm had occurred and the patient continued in the study without protocol deviation. When reflecting on the encounter Jody recognized: a) nursing needs, b) potential for future risk and harm due to inadequate communication, both in research staff to CN interactions, and in electronic patient record documentation. In response, Jody developed and implemented a simple communication tool to facilitate research and clinical staff communication, allowing them to consistently highlight concerns that the electronic patient record wasn't designed to accommodate.

Box 2: Application of Case Example to Conceptual Model: Care & Trust

In the first part of the scenario, Jody establishes care and trust between herself and the patient, but also between herself and her colleagues across the care team. The incorporation of the CRN means that the patient now has another nurse added to their team, who is aware of their needs and working to ensure that the best care is provided. For the CN, though there may be some trepidation that the research will add ‘another thing’ for them to do, in Jody’s case they are provided with a supportive colleague who is making every effort to ensure that the research activities extraneous to direct patient care are covered.

In the second part of the scenario, Jody recognized that research activities had taken place in a manner that was not perceived as caring for the patient in terms of added value from involvement in the study, but also without care or concern for the capacity of the unit staff. Perceptions of care or absence of care were recognized to be fundamental to good relationships, trust forming, and subsequently, conduct of safe practice. Jody highlighted in her retelling that she avoided blaming and saw this as an opportunity to build relationships with the unit staff. She provided care and education to CNs working under high levels of stress, all with a goal of establishing safe care for the patient and the progression of their involvement in a study designed to aid their recovery.

Box 3: Application of Case Example to Conceptual Model: Role

Jody states the paradox of the CRN role is that it is ‘not an exact science’. By this, she explained that she is guided by protocols to ensure safe research conduct, however, if she sees a patient need that is outside of the study but within her scope of practice as a nurse, she will not overlook it. Working on research studies during the 2020 COVID-19 pandemic, Jody was often one of the few people seen in person by patients. In addition to recruitment, treatment, and documentation, Jody also responded to personal needs. For example, she was able to draw on her nursing skills to support the CNs, such as confirming if slipped facemasks need repositioning, how oxygen levels were set, and to assess if it was clinically appropriate for her to carry out the research-oriented task. None of these behaviors were outside of her wider nursing role, and all offered a means of supporting CNs, and building a team that bridged roles because of a shared focus on patient wellbeing. Jody stressed that providing support to unit staff via activities such as these, or providing a drink, aiding with repositioning, or lunchtime feeding became a means for building rapport with clinical teams that would facilitate research involvement and awareness long-term.

reflected in the research process and although there may be differences in roles, there is a synergy between the processes and practical application of nursing knowledge across both clinical and research care.

CRNs possess a repertoire of knowledge and skills that transcends their established expertise in clinical practice (Iles-Smith et al., 2020). They must know the complex tiers of regulations governing health research in general, as well as the intricate protocols and diverse clinical skills required by each specific research study. Yet they are also skilled at providing care in the research setting to both participants and colleagues. This again demonstrates that trust and care are inseparable from the CRN, which speaks to the design of our conceptual model and its integrated components. Patients and healthy participants volunteer themselves and their time, trusting that their welfare is the paramount concern in the conduct of all research with human participants (Persaud and Bonham, 2018). As Jody

Box 4: Application of Case Example to Conceptual Model: Impact

In the first scenario Jody spoke to the consideration she gave to the workload of the CNs by looking for ways to ensure that research activities were as easy to implement as possible, with the least amount of stress and concern for CNs and the greatest amount of support. She measures her impact by the growth in positive relationships and responses to her presence, willingness to engage in research activities, and means by which she can see ‘value added’ from her presence on the units.

In the second scenario, Jody highlighted the ease with which safety can be compromised and how effective communication and documentation measures can prevent harm, which are fundamental nursing principles. Her thoughtful, reassuring, and measured response to what could have been an entirely negative encounter resulted in improved relationships between the CN team and study team, as well as identification of risk and resulting intervention to mitigate this risk.

thoughtfully expressed, the CRN is still a nurse first and foremost, and this means ensuring the health and safety of all to whom the CRN provides care, whether patient, participant, or colleague.

Discussion

The intrinsic value brought by nurses to patient care can often be hard to define based on its holistic and inclusive nature, meaning value can be found in “everything,” as well as specific and individual outcomes. Demonstrating value and capturing the scope of the CRN sets greater challenges as the reach and impact is even farther reaching based on the duality of the role and the delivery of practice grounded in years of clinical experience. By describing the provision of care, safely delivered by the CRN within the context of a conceptual model, this paper has sought to make the value and scope more explicit. The 4-point conceptual model captures the value and core concepts of the CRN within the four domains of Care and Trust, Role, Impact, and Integration. This simple model contains complex concepts which in and of itself reflects the practice of the CRN. Our use of the threaded case study further demonstrates the importance of the CRN role in the context of “care,” within healthcare and research practice settings, providing a reflection on each aspect of the model in turn.

Nurses involved in research, regardless of role, have a responsibility to promote ethical conduct of clinical research (Bierer et al., 2020). Fulfilling this responsibility requires an in-depth understanding of clinical research ethics and governance, allowing the CRN to determine when to take action, and to do what is right in the particular situation for the participant and for the integrity of the research study, as demonstrated in the case study (Box 1). This advocacy for patients, participants and research is fundamental to the CRN role (American Nurses Association, 2016). Indeed, the impact of the CRN must be considered in multiple ways, through measurable outcomes, achievement of research goals, dissemination of study findings, adherence to ethical guidelines, and increased public trust in research with human participants (Hill and MacArthur, 2006). A harder to capture, but no less meaningful, analysis is warranted to understand the impact of the “small but significant” (and often not-so-small) actions that build relationships, identify and respond to potential harm, support colleagues, and ensure that research participation is a positive experience for patients. For, while the profession of nursing has been steadily advancing for decades, we still lack a strong evidence base that speaks to the multiplicity of the potential of the nursing role. Regardless, for CRNs, we advocate for greater research into the role, relationships, international application, and cross-pollination of learning, potentially using the conceptual model as a supporting framework for demonstrating their value in ensuring person-centered care.

We recommend the model is now tested in practice and across care settings including primary, secondary tertiary and social care. We acknowledge that although we are an international team, our model is derived from a Western perspective and therefore applicability of the concepts within other regions would also need to be explored.

Conclusion

We advocate that the CRN role is fundamental both from “research” and “clinical” perspectives of care, with both in fact being the other, enhancing patient and participant safety, advocacy and ensuring that the patient is at the heart of healthcare advances. In raising awareness of the core concepts of the CRN, we have made explicit those core concepts, which we believe have long been implicit, and which demonstrate the value of the CRN and the need for greater consideration and investment in this vital nursing role in person-centered care.

Key points for policy, practice, and/or research

- The 4-point conceptual model captures and demonstrates the value of the CRN across clinical and research practice settings.
- Inclusion of CRNs in clinical and research settings enhances participant safety and advocacy.
- Awareness of the core concepts of the CRN role will help CRNs to balance and make explicit what has long been implicit in the CRN role.
- There is a significant need and opportunity for CRNs to lead future research to focus on exploration and demonstration of the measurable impacts and added value of the integrated CRN role.
- The 4-point conceptual model should next be tested in practice across care settings. We also recommend exploration of the applicability of the concepts within regions outside of the authors’ countries.

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Ethics

No ethical permissions were required for this paper.

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Supplemental Material

Supplemental material for this article is available online.

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