Received: 7 January 2022 | Revised: 23 June 2022 | Accepted: 17 July 2022

DOI: 10.1111/jan.15397

ORIGINAL RESEARCH: EMPIRICAL RESEARCH - QUALITATIVE

JAN Leading Global Nursing Research WILEY

Transitioning to the clinical research nurse role – A qualitative descriptive study

Beatrice Backman Lönn[1,2] | Åsa Hörnsten[1] | Johan Styrke[3] | Senada Hajdarevic[1]

[1]Department of Nursing, Umeå University, Umeå, Sweden

[2]Department of Research & Development, Region Västernorrland, Sundsvall Hospital, Sundsvall, Sweden

[3]Department of Surgical and Perioperative Sciences, Urology and Andrology, Umeå University, Umeå, Sweden

Correspondence
Beatrice Backman Lönn, Department of Nursing, Umeå University, Department of Research & Development, Region Västernorrland, Sundsvall, Sweden.
Email: beatrice.backman@umu.se

Funding information
Region Vasternorrland, Sweden

Abstract

Background: Studies have reported on the important role of the clinical research nurse in clinical studies. Yet, there is no international consensus about the role's competencies and tasks. Furthermore, the literature offers a little description of the career pathway from a ward-based registered nurse to a clinical research nurse. More knowledge about this specific role could benefit the nursing profession as well as increase the quality of clinical research.

Aim: The aim of the study was to explore Swedish registered nurses' experiences transitioning into the clinical research nurse role.

Design: The study had a qualitative design. Data were collected via semi-structured interviews. Inductive qualitative content analysis was employed.

Methods: Ten participants (i.e., clinical research nurses) were interviewed in the spring of 2017. A semi-structured interview guide was used to address the transition into the clinical research nurse role, experience working in a new role, experience of ethical dilemmas and experience of organizational and professional issues related to the role. The interviews were analysed inductively using qualitative content analysis.

Results: The registered nurses described experiencing reality shock when they became clinical research nurses; that is, it was a challenging and transforming experience. The main theme, a challenging transition, was developed from the four subthemes highlighting that it defied their previous nursing role. They experienced an unclear professional identity, extended professional mandate, increased professional status and growing ethical consciousness in their new role.

Conclusion: The results highlight that registered nurses who became clinical research nurses had needs that were both distinct from and overlapped with those of their former professional role as registered nurses. To avoid reality shocks, the development of clear competence pathways for nurses to become clinical research nurses, including introduction, mentorship and continued support, is necessary. Making their professional title more homogeneous, nationally and internationally, would facilitate role identification and comparisons in research.

KEYWORDS
clinical research nurse, clinical study coordinator, clinical trial nurse, interviews, nurse, professional development, qualitative content analysis, registered nurse, role, transition

1 | INTRODUCTION

Studies have reported on the important role of the clinical research nurse (CRN) in clinical studies. Yet, there is no international consensus about the competencies and tasks related to the role. The role of CRNs is yet quite unexplored in Sweden, but previous studies have shown that CRNs' tasks vary, ranging from study-specific tasks (e.g., blood sampling and other study-related procedures) to developing study protocols and presenting study results (Backman Lönn et al., 2019). The effect of lacking a clearly defined professional role on registered nurses (RNs) who are becoming CRNs has only been briefly explored. Further studies may clarify their challenges and could provide an opportunity to reach a consensus about the CRN role.

2 | BACKGROUND

CRNs bring important skills and knowledge to the clinical research setting. Pick et al. (2011) described CRNs' role as especially important with regards to patient security and the quality of trial results. In Sweden, the CRN's role has been insufficiently explored, and there are no formal guidelines about the work tasks associated with the role. Various job titles are used, including study nurse, study coordinator and clinical research nurse. In the frame of this paper, all these titles are referred to as 'clinical research nurse (CRN)'.

Regarding the role and tasks of CRNs, a study conducted in England by Spilsbury et al. (2008) reported difficulties in role transition from ward-based clinical nurse to CRN. A ward-based nurse has a professional responsibility to care for patients. For a CRN, this obligation extends to ensuring that studies are well conducted and that ethical standards are met while simultaneously guaranteeing study participants' safety and well-being (Spilsbury et al., 2008). Ethical issues that can arise and create tensions for CRNs were studied in the United States by Larkin et al. (2019). They reported that CRNs at times experienced dilemmas, such as tension between the nursing and research perspectives as well as conflicting allegiances to multiple stakeholders. A study conducted by Hemingway and Storey (2013) showed similar results: balancing the professional responsibilities of the RN with the work tasks of the CRN involves complex decision-making, and maintaining that balance can lead to personal, professional and ethical dilemmas. For example, it is important for a CRN to maintain objectivity when gathering study data, which requires a different approach than working in a ward. These dilemmas concern the relation to the patient/participants as well as the CRN tasks related to the study requirements. Studies exploring CRNs' tasks and skills have been conducted in Australia by Wilkes et al. (2012), in the United States by Ehrenberger and Lillington (2004), in the United States and Canada by Nagel et al. (2010) and in Italy by Catania et al. (2012) using validated questionnaires. In summary, the results show that CRNs' tasks vary from country to country and between contexts, ranging from purely practical tasks to involvement in the design and implementation of study protocols and management of the study results. Their results also highlight that CRNs with higher levels of education were involved in more advanced tasks in the study process. Nagel et al. (2010) reported that the CRNs rated the informed consent process as one of the most important aspects of their work.

Regarding CRNs' education around the world, a US study by Mori et al. (2007) showed that courses in good clinical practice (GCP) and federal regulations around research were commonly attended. Within this infrastructure, CRNs were viewed as experts in combining patient care and research tasks. The authors concluded that there was an emerging need for a professional organization to facilitate CRNs' education and certification, and that this would benefit research in the United States. Scott et al. (2013) investigated CRNs' educational and career pathways and identified barriers such as limited finances, limited time and unclear employment and career advancement opportunities. The results also indicated that varying job titles could have a negative influence in pursuing clinical research nursing as a career. Scott et al. (2013) also reported great interest in improving CRNs' education in the area of research. Similar results were presented by Rickard et al. (2011), who reported that, even for the nurses who wished to continue working in research in Australia, the lack of clear career pathways, support and a structured organizational environment were deterrents.

There is a lack of research on the education, competence and skills required for the CRN role in Sweden as well as on Swedish CRNs' working experiences. Currently, no Swedish register or statistics exist regarding the number of RNs that are working as CRNs. The education needed to become a RN in Sweden was officially established in 1993, requiring 3 years of education with a greater focus on research and research methodology and leading to the degree of Bachelor of Science. Nursing care is the RN's specific expertise and involves both scientific knowledge and clinical work with patients based on a humanistic view of human beings. Swedish RNs are independently responsible for their clinical decisions and should follow the nurses' ethical code to offer people more opportunities to improve, maintain or regain their health. Once the bachelor's degree is obtained, RNs in Sweden have the option of specializing by completing a year-long master's degree (Backman Lönn et al., 2019). However, currently, there is no master's degree or advanced course that allows specializing in clinical research.

Consequently, RNs who become CRNs in Sweden have varying titles (e.g. clinical trial nurse and clinical trial/research coordinator). Furthermore, there are seldom any demands on specific

competencies stated in the job applications other than expressing a special interest in the research or medical field. Several of the employees working as CRNs are not even RNs but have other professions such as assisting nurses or biomedical analysts. Some have only undergone limited training consisting of 1- to 2-day courses in GCP or 3- to 5-week courses in clinical research (i.e., 5 to 7.5 ECT/credits). These courses have been developed in collaboration with pharmaceutical companies, healthcare organizations and universities.

The lack of specialist education among Swedish CRNs is problematic since the clinical research process is complex and requires specific competencies and skills throughout the different study phases. For instance, CRNs are involved in protocol assessment and planning, participant recruitment, informed consent management, handling of investigational products, protocol implementation and evaluation and data management (Backman Lönn et al., 2019). Their role, however, also requires professional performance, including ethical reasoning (Backman Lönn et al., 2019).

To date, only a few studies are available on Swedish CRNs' contributions, competencies, skills and roles. Arrigo et al. (1994) studied European and Swedish CRNs engaged in oncology research and found that they lacked education in oncology and research methods, were rarely involved in study design and their tasks were mainly patient related (e.g., basic patient care, information presentation, drug preparation and administration, monitoring of toxicities, data management and follow-ups). Höglund et al. (2010) showed that Swedish CRNs could experience moral distress after having ethical discussions with the principal investigator (PI), which resulted in struggles to follow their own judgement. Arrowsmith et al. (2016) identified differences between the transition process of newly graduated and experienced nurses, with the former striving to shape a role identity and the latter aiming to reshape their identity. While recently graduated nurses' experiences of the transition into their professional roles have been thoroughly investigated in the literature, research on experienced nurses' transition into other roles and specialties, including higher academic roles, is scarce (Arrowsmith et al., 2016).

2.1 | Theoretical framework

Role transition, in general, is explained by Nicholson's transition model (Nicholson,1984), which describes how the interaction between individuals and social systems/organizations affects each other. The four phases of transition, including career changes and new work roles, are described as *preparation*, *encounter*, *adjustment and stabilization*. Preparation refers to how well-prepared people are for changes in work roles, including their expectations and motivation as well as organizational introduction and socialization (Nicholson, 1984). Inadequate preparation can lead to reality shock, which has been described as a reaction to the conflict between school-bred values and work values or as a disparity between expectations and reality (Arrowsmith et al., 2016). The encounter phase occurs within the first weeks in the new settings, the outcome of which depends on both individuals' confidence and competence to implement the skills required for the new job, relating to their own beliefs as well as culture (Nicholson, 1984). Afterward, the adjustment occurs to facilitate personal and role development. Changes in the work nature and new demands are absorbed to change the person's frame of reference, values or other identity-related attributes. Role development varies in relation to the limitations and possibilities the role entails, and depends on the person's expectations of the role (Nicholson, 1984). Lastly, stabilization takes place when the tasks pertaining to the new role are acquired and organizational demands are met (Nicholson, 1984).

Beyond the theory of general transition described above, role transition among nurses was explained by Duchscher and Windey (2018). They described three aspects of nurse role transition: doing, being and knowing. Initially, doing is prominent, as nurses are trying to orient themselves in a new role, which requires mastering different tasks and responsibilities along with meeting their own expectations in the new professional role. Thereafter, being is prominent since nurses begin to feel more comfortable with the responsibilities and competencies required for the role while also rapidly developing critical thinking and feeling more proficient. Lastly, knowing refers to establishing a distinction between their and others' roles as well as developing expertise and critical thinking about work organization, their tasks and competence skills. According to Duchscher and Windey (2018), the transition into a new role takes time, and how well this process evolves depends on how well it is facilitated. Therefore, we find it crucial to investigate how formerly ward-based RNs experience their transition into their new role as CRNs with the ultimate goal of supporting their professional development.

3 | THE PRESENT STUDY

3.1 | Aim

The study aimed to explore Swedish RNs' experience of transitioning into the CRN role.

3.2 | Design

The present study followed a qualitative approach. Interview data were collected in Sweden and analysed using inductive qualitative content analysis as described by Graneheim and Lundman (2004). The present report adheres to the EQUATOR guidelines for reporting research, following the Consolidated Criteria for Reporting Qualitative Research (COREQ), a 32-item checklist for interviews and focus groups (see Appendix S1; Tong et al., 2007).

3.3 | Sample

In an attempt to obtain an overall picture of the phenomenon of interest, purposeful sampling was conducted. RNs working as CRNs were

invited to participate in the study. Participants had different lengths of employment and came from various settings, such as different sizes of hospitals from southern, middle and northern Sweden, ensuring a variety of experiences and backgrounds. General information about the study along with an invitation to participate in an interview was sent by email through professional networks. Thereafter, an oral invitation was directed to a convenience sample of CRNs that fulfilled the inclusion criteria. All the invited CRNs were interested in participating; detailed study information was sent to them via email. Then, a time and place for the interview were arranged.

Malterud et al. (2016) developed a model for assessing the appropriate sample size in qualitative interview studies. Information power, which is the core concept of the model, accounts for items such as a narrow or broad study aim, dense or sparse sample specificity, use of any established theory, strong or weak quality of the dialogue, as well as whether the analysis strategy is based on the case or cross-case analysis. We believe the present study has a narrow aim, dense sample and employs inductive analysis. The quality of the dialogue was strong, even though the interviewer was not very experienced. The quantity and depth of the data were judged as satisfactory. Therefore, based on Malterud's model and suggestions (Malterud et al., 2016), we assume that our sample offers satisfactory information power.

3.4 | Data collection

Semi-structured interviews were conducted to gather data on the experience of becoming and working as a CRN. A pilot interview was performed with one of the participants to test the interview guide and changes were made after (see Table 1). The pilot interview was still included in the analysis since it provided very interesting data.

The interviews addressed five major topics: transitioning into the CRN role, experiencing working in a new role, experiencing ethical dilemmas and experiencing organizational and professional issues related to the role. Open-ended questions were used, with supplementary, follow-up questions, if needed. The interviews were conducted by the first author during the spring of 2017 and lasted from 50 to 100 min. The interviews were audio recorded digitally and transcribed as soon as possible. The setting for the interviews was chosen by the participants; five were interviewed face-to-face in a quiet room away from their workplace, while one interview took place in a breakfast meeting room at work. Four participants chose to be interviewed through Skype using a webcam. During the interviews, the interviewer showed empathy and active listening. At the end of each interview, the interviewer reflected on and summarized what was said to ensure that nothing was misunderstood.

3.5 | Ethical considerations

This study followed the ethical principles of the Declaration of Helsinki, which highlights respect for participants, doing no harm and voluntariness of participation. The study was approved by the regional ethics review authority (Dno 2017/67–31). Special attention was given to ethical considerations and the protection of privacy due to the first author's work as a study coordinator and the fact that many CRNs are familiar with one another. The researchers,

TABLE 1 Semi-structured interview guide

How did you experience the first initial phase working as CRN?	Follow-up questions if necessary: How did you become working as a CRN? What kind of education, work experience, introduction and support did you have/get?
How do you experience your role today?	Follow-up questions if necessary: How do you experience that other personnel and the study team perceive your role?
How do you experience your role from an ethical perspective?	Follow-up questions if necessary: Have you experienced any ethical issues in your work as CRN? If so, how did you manage it?
Describe management and the organization around your role as CRN?	Follow-up questions if necessary: How is your role as a CRN organized within your work unit? Do you have an individual plan for competence development? Do you experience any leadership included in your role?
Describe your career prospects based on the role that you find yourself in today?	Follow-up questions if necessary: what opportunities for your own development do you see in the future (e.g., any interests in own research)?

therefore, provided both written and oral information to participants, emphasizing that participation was voluntary. The participants also had time to think and ask questions about participation since the scheduling of interviews was done days before they took place. All participants signed an informed consent form before the interview took place.

3.6 | Data analysis

After audiotaped interviews had been transcribed verbatim, qualitative content analysis was conducted as described by Graneheim and Lundman (2004) and Graneheim et al. (2017). Inductive analysis means that no theory or template was used to code or understand data. The qualitative content analysis deals with both descriptive, manifest content (i.e., the visible and obvious) and latent content (i.e., the interpreted, unspoken meanings of what was said in the interviews). Initially, the level of abstraction and interpretation is low, and gradually it becomes higher on thematic levels. Interpretation in the qualitative tradition is often referred to as hermeneutics, even if hermeneutics is a scientific method on its own. Interpretation involves explaining, reframing and making sense of or showing an understanding of a person's experience. It is also a part of a recontextualizing process moving from manifest to latent content (Graneheim et al., 2017), whereby the researcher must make sense of both the words used and the person who said them.

Initially, the transcribed interviews were read repeatedly and analysed line by line. Meaning units, that is, phrases that answer the aim, were selected and condensed (i.e., shortened by removing words that the researcher did not consider meaningful, but still keeping the core content intact). Thereafter, the condensed meaning units were interpreted and given descriptive labels/codes, which could be a short sentence or a few words, still with a low level of abstraction and interpretation. The codes were then compared on content and levels of abstraction and discussed. Based on similarities and differences, the codes were sorted into groups with the same messages or content and formulated into similar levels of abstraction and interpretation (Graneheim et al., 2017). These groups were given tentative category labels describing their content. The categories were then analysed and sorted hierarchically, which sometimes meant that they were divided into two or three categories or abstracted and merged with another category with similar content. Finally, the categories were arranged in a hierarchy and their labels were refined to fit into the system of categories and logical abstraction (Graneheim et al., 2017). An example of the analysis process is given in Table 2.

To ensure credibility, the first two interviews were analysed and discussed together with co-authors for data triangulation and agreement on the coding scheme, in accordance with recommendations by Graneheim and Lundman (2004). The research group also discussed the preliminary findings, including the labelling of new codes and tentative categories as well as how they should be sorted. Further analysis of the categories resulted in a refinement of the category system, and, lastly, themes going through the categories were identified and included in the final results. No software was used for the analysis.

3.7 | Validity and reliability/rigour

Triangulation of coding of the first interviews took place in order to reach an agreement. The interviews and analysis were conducted in Swedish language. Although the results reported in the article were translated to English, the underlying latent meaning was preserved; the interpretations and translation have thoroughly been reflected on and discussed by the research team. Reflexivity refers to the researchers' awareness of themselves as a part of the collected data. In this study, the pre-understanding of the CRN's role needed reflection, since the first author has a background as a study coordinator. A pre-understanding of the research can also be an advantage for data interpretation, thereby increasing trustworthiness. To strengthen the credibility, dependability and reflexivity of this study, the interviews were performed by one researcher, following a semi-structured interview guide. The various steps in the analysis were discussed by the research team to evaluate the interpretation, coding and categories and themes (Graneheim & Lundman, 2004).

3.8 | Findings

Ten participants were interviewed. All were women aged 35 to 65 years. They had worked a minimum of 5 years as RNs before

TABLE 2 Example of the analysis

Meaning unit	Condensation	Category	Subtheme	Theme	Main theme
It was like a new world, I did not get any-thing when attending my first a GCP course and thought, 'Oh dear, what is this?' Later on, I could under-stand more of the new terminology	Initially a new world but later I understood more of the new terminology	(New) Terminology	Trying to orientate oneself in a new field	Unclear professional identity	Challenging transition

becoming CRNs, a role they had been performing for at least 2 years. Six of the participants were working in research units, whereof only one was working part-time. The other four worked in wards and part-time as CRNs (Table 3).

The RNs described experiencing reality shock when they started working as CRNs; that is, it was a challenging and transforming experience they remembered very well. The main theme, a challenging transition, was developed from the four subthemes highlighting that the CRN role defied their previous nursing role and expectations. They experienced an unclear professional identity, extended professional mandate, increased professional status and growing ethical consciousness in their new role. Entering this new world influenced the CRNs' professional identity, mandate, status and ethical consciousness. The main theme contains themes, subthemes and categories, which are presented below along with examples. Categories are integrated into the text describing the subthemes. An overview of the results is given in Table 4.

3.9 | Unclear professional identity

An unclear professional identity was reflected in the 'Trying to orientate oneself in a new field' and 'Struggling for role identity and recognition' subthemes. Even if a participant had extensive experience as a RN, the role of CRN posited new challenges.

3.9.1 | Trying to orientate oneself in a new field

The transition from RN to CRN was described as entering a completely new world in which they had to reorientate themselves, sometimes leading to feelings of confusion. For instance, the new role presented them with new terminology, which they did not initially understand.

It was like a new world. I did not get anything when attending my first GCP course and thought, 'Oh dear, what is this?' Later, after a while and after attending the second GCP, I could understand more of the new terminology. (CRN #1).

The nurses' struggle to orient themselves in a new world also implied loneliness and seldom having anyone to ask for help or gain information from. Despite their established identity and extensive work experience as RNs, they felt lonely and inadequately prepared to join the research process. Insufficient introduction and orientation to the new work environment were frequently mentioned in the interviews. This situation caused feelings of insecurity at first, but their experiences as RNs were helpful as they created new routines and proceeded with the new tasks.

The practical skills of being a nurse were helpful in making me feel secure and face the challenge of learning about the research process and the new terminology. (CRN #3).

Many of the CRNs struggled initially and indicated that more support or mentorship would be helpful. Some participants expressed that they appreciated it when they were trained and mentored by experienced CRNs. Others described how, in the absence of such support or mentorship, they searched for it by networking with other CRNs and research staff. Such support was highly valued and perceived to facilitate their accommodation to the CRN's work and new role.

The first time and the first study, I was almost crying; there was nobody to ask locally besides the investigator. The assignment and rules were unclear, and it wasn't until later that I attended a GCP course. Regardless, we did try to help each other, we clinical research nurses. (CRN #6).

3.9.2 | Struggling with role identity and recognition

The participants felt alone and struggled with role identity and recognition. They experienced that other personnel, including the manager of the ward/unit, had little or no knowledge about the CRN's work tasks and responsibilities. Therefore, they developed their own strategies to inform and explain their role to their colleagues,

TABLE 3 Participants' work experience

Participants	Work time	Size of the hospital, location[a]	Workplace	Years working as CRN
#1	Full-time	A, Mid Sweden	Research unit	>10
#2	Full-time	A, Mid Sweden	Research unit	<2
#3	Part-time	A, Mid Sweden	Hospital ward	>3
#4	Part-time	A, Mid Sweden	Hospital ward	>10
#5	Full-time	A, Mid Sweden	Research unit	>20
#6	Part-time	A, Mid Sweden	Research unit	>10
#7	Full-time	B, Southern Sweden	Research unit	>3
#8	Full-time	B, Northern Sweden	Hospital ward	>5
#9	Full-time	A, Northern Sweden	Hospital ward	>20
#10	Full-time	B, Northern Sweden	Research unit	>20

[a]A, Hospital with up to 300 beds; B, University hospital with >300 beds.

TABLE 4 Results in categories and themes on various levels

Main theme	Themes	Subthemes	Categories
Challenging transition	Unclear professional identity	Trying to orientate oneself in a new field	Terminology Loneliness Mentorship
		Struggling for role identity and recognition	Information Conflicts Organizational culture
	Extended professional mandate	Engaging in new work	Dedication Empowerment Work satisfaction
		Appreciating independent work	Freedom Responsibilities Informal leadership
	Increased professional status	Progressing in competence	Respect Trust Learning
		Collaborating in networks	Expertise Support Acknowledgement
	Growing ethical consciousness	Managing double responsibility	Study protocol Patient security
		Dealing with ambiguity	Patients vs. participants Ethical guidelines Informed consent

who had limited understanding and respect for their work, to defend their position and avoid and manage conflicts.

We try to be more transparent; we have joint meetings and sometimes meetings with our boss, so we can tell him what we do. (CRN #1).

CRNs in ward settings reported that conflicts with other personnel often occurred. They experienced that their nurse colleagues were envious and occasionally expressed frustration towards them and their specific role in the unit/ward.

I had to answer, defending myself for working as a clinical research nurse, to those nurse-colleagues who believe that nursing work can only be in a ward setting. (CRN #7).

The organizational settings and culture surrounding their work role mattered since it influenced the work atmosphere and, by extension, their motivation at work.

I have so much to do in my ordinary work role as a nurse, so even if the agreement is that I work part-time as a CRN, no one replaces me as a ward nurse. This makes me feel divided and it makes it hard to prioritize research studies, especially when there aren't enough staff. (CRN #3).

3.10 | Extended professional mandate

An extended professional mandate was demonstrated by the 'Engaging in new work' and 'Appreciating independent work' subthemes. The participants found that working as a CRN was very positive and rewarding. The feeling of being an important member of the study team and contributing to the development of health care led to role satisfaction.

3.10.1 | Engaging in new work

The participants expressed their engagement with and dedication to their new work and role. All participants felt that it was rewarding to be a part of a research team working towards the same goal and to evaluate new treatment strategies.

I feel valuable; I feel like I really make a difference, coming from the departmental work and being a little tired of it and then getting to come and work with research and meet healthy volunteers. It is incredibly stimulating. (CRN #8).

The CRNs indicated that being acknowledged for their special competence and their opinions extended their professional mandate and was rewarding and empowering. As their knowledge increased, they felt motivated by the opportunities for individual development.

I can come up with my own ideas and I get backed up at once, and that spurs me on even more. (CRN #7).

Working in an environment that led to individual professional development and working among colleagues or doctors who appreciated their work engaged the CRNs and improved motivation and work satisfaction. Many indicated that it was their desire for professional development that had led them into this new and satisfying role.

If I do not feel that I am developing in my work, if I am stagnating, then I will leave. It must attract me. (CRN #7).

It was the principal investigator and I, with some other doctors, we worked as a team and that was fun. (CRN #9).

3.10.2 | Appreciating independent work

The participants appreciated the independence they had in their work. They enjoyed the freedom they had to plan their work hours, vacation and performance of their duties in the studies, which differed from their work as nurses in wards. They not only expressed it as freedom with responsibility but also implied that their work occasionally extended into evenings and weekends when the study required it.

It is independent work; I am doing the work as I want based on the frameworks and rules. It doesn't matter how I do it, when it is done, only that it is done, so I plan the work as I want to. (CRN #1).

They felt a responsibility to perform specific patient-related study tasks, but were often also unofficially taking a broader responsibility for the overall study and its coordination. Even if the broader role was not formally delegated to them, they sometimes took charge of their own initiative.

Although it is the physician/investigator's responsibility, we see that it depends on us, the whole process and how it is driven. I will screen the patients in advance also. They have a brief conversation with the doctor then come out and meet us, and we go through the study and patient information together. (CRN 2).

This independent work was described as governed by 'informal leadership', which the CRNs appreciated since they felt that other research staff, such as the PI, felt secure and trusted their expertise and ability. They frequently emphasized the importance of their work, for example, their involvement in procedures for clinical studies and, thus, their contribution to the quality of those studies.

It's largely an informal leadership, you are a coordinator, both for physicians and nurses, since it is I, who plans the work, agendas, meetings and who takes the decisions (CRN #7).

3.11 | Increased professional status

An increase in professional status was demonstrated by the 'Progressing in competence' and 'Collaborating in networks' subthemes. The participants experienced increased professional status, especially in relation to the doctors. They felt respected and trusted, and that they were developing in their role through increased learning.

3.11.1 | Progressing in competence

The participants described how they gained competence and thereby increased their professional status as CRNs. Through their previous experience as nurses, they had developed a broad knowledge as well as special interests in various fields of health care, such as endocrinology, oncology, urology, haematology, medicine and surgery. They felt that they were also respected and trusted by physicians because they had this experience. They were often asked for their opinions regarding study protocols and study issues such as feasibility and ethics. This promoted their higher status in relation to other staff members and nurses.

In the medical group we have a high status as CRNs, I mean, they come to us—they do not have the same track of protocols even if it is their own studies—we are the ones they come to with questions such as, what was it?, when should this be done?, when should the doctor's visit be?, and what should I do now? (CRN #1).

The participants had a positive view of the continuous demands placed on them and of the opportunities for learning. They had new responsibilities and did not initially understand the terminology and procedures; therefore, they had to seek new knowledge and learn more, thereby becoming increasingly competent. Finding suitable courses to increase their knowledge was something they did on their own initiative; no competence plan was available.

For the moment I am attending a course in nursing science in my free time. I still need to strengthen my knowledge in this field, so my goal is to seek a specialist education, but it is on my own initiative. (CRN #2).

3.11.2 | Collaborating in networks

Collaborations with research teams or professional networks accentuated the participants' expertise. They met people with similar knowledge of the topic and procedures and felt that they themselves were assets and experts. The participants, therefore, appreciated networking and travelling to meetings and conferences, further expanding their knowledge and expertise.

Participating in networks with other CRNs gives me a broader picture and keeps me up to date on the latest in that field of research. (CRN #3).

The new role required them to seek support from colleagues and collaborators. When they became CRNs, the nurses found that the work atmosphere became more interesting, and their role expanded from that of an individual nurse to being part of a research team. They also became involved in various inter- and intradisciplinary networks, which led to national and international collaboration. These external collaborators were often their only source of support.

I had some support from my PI, otherwise it was just a new assignment in work. I had no support from the ward staff, my colleagues. Going on study meetings therefore gave me a lot. (CRN #9).

Collaboration with others led to a feeling of acknowledgement, thereby improving their professional status. The CRNs had opportunities to participate in networking and conferences worldwide and felt that their expertise was acknowledged and valued much more highly than their expertise as nurses in clinical wards.

I've just been to a European meeting with all the other sites and got to meet my colleagues in the same study, so it was awesome!

Then you realize, 'this is how it's supposed to be'… more networking and more collaboration and more closeness to each other…, then it's much easier later, when you are back home in your own office, to call when you need help with any problem. (CRN #7).

3.12 | Growing ethical consciousness

A growing ethical consciousness was demonstrated by the 'Managing double responsibility' and 'Dealing with ambiguity' subthemes. In the participants' view, their main obligation as CRNs was to protect and preserve the research participants' interests and rights.

3.12.1 | Managing double responsibility

The participants described how, as CRNs, they had to manage double responsibilities, including following the study protocol while simultaneously prioritizing patient security. Both tasks were considered equally important. They strove to protect the patients in all study procedures, from beginning to end. They also ensure that the researcher/PI and other personnel followed the protocols, which was not always easy. They were passionate in declaring that the patients always had to come first as something that is essential in their vocation.

Maybe it's because we are drilled in our basic profession as nurses to always prioritize the patient's well-being… We're including the patients and we must take care of our patients who participate with their bodies and lives; they must be respected (CRN #4).

When they tried to manage this double responsibility, the CRNs were sometimes challenged by some investigators who had different priorities.

We are involved in ethical issues. When we receive a study request it goes first to one of our doctors or the head, they make an assessment then send the study request to us so we can read and reflect on it. It has happened that we have said no to such requests. For some studies, we ask, does it make sense to expose our patients to this? Some issues in some studies cannot be justified even if it is approved by the ethical review board. (CRN #5).

A moral obligation to do right by the patients was expressed by many of the participants. They often described themselves as more sensitive to patient issues than PIs and other research staff.

It must be conducted in the right way. It's my role to make sure that the study participants are feeling secure and well looked after. (CRN #6).

3.12.2 | Dealing with ambiguity

Related to their growing ethical consciousness, the participants also had to deal with ambiguities. For example, they could find it challenging to treat the patients as participants and participants as patients, roles that are sometimes intertwined.

Sometimes the researcher gets so eager to collect data for his/her research that he/she forgets that we are dealing with people, for example, to collect more blood, then I remind him/her—this is not what the protocol says (CRN #8).

Another ambiguity concerned the views on ethical guidelines. The participants indicated that ethical issues always arise when dealing with research and volunteers, but they felt that nurse education and training, grounded in ethical principles and guidelines, was an important fundament to rest on and made them more secure in handling ethical problems and dilemmas. They found that it was helpful to have learned about ethical guidelines theoretically in addition to taking courses in good clinical practice.

Oh, it is hard; like, for example, today there was a patient who wanted to withdraw their participation in a study, and I had to bite my tongue, bite my tongue and prevent myself from trying to convince him to stay although I thought otherwise. I mean, according to the ethical guidelines, they always have a right to withdraw without having to explain themselves. (CRN #2).

Several participants highlighted ambiguity around the informed consent process as challenging their ethical consciousness. The patient's right to say no became increasingly important for the CRNs over time. Initially, they were keener to comply with the PI's instructions and desired to include as many study participants as possible.

The hardest ethics issues are related to the process of consent; it took me approximately 5 years to feel comfortable in that process, with informing people in such a way that I am sure that I am not convincing them to participate. This was always a concern and still is, but I am now feeling more secure in the way I inform the patient. (CRN #5).

4 | DISCUSSION

The results showed that RNs entered a new world when they took on the CRN role, which entailed new dimensions both in their professional role and identity and in relation to their working context and atmosphere.

While transitioning to the CRN role, the study participants first experienced reality shock, with signs of confusion related to new tasks, terminology and regulations, since they were novices in the research field. This was something they had not been introduced to or expected, leading to an experience of disparity between expectations and reality (cf. Arrowsmith et al., 2016). Similar descriptions of reality shock have been identified among newly graduated nurses when they enter the workforce and experience a conflict between their student training and professional role (Kim, 2020). Our results showed that the feeling of confusion was overcome in a relatively short time. That is, within a couple of years, after attending GCP courses and being involved in several research studies, CRNs adjusted and felt they had achieved enough knowledge to feel secure in their new tasks and role. Mentorship/support from other CRNs also made them feel more secure. According to Kim (2020), the professional development of skills and self-concept is an ongoing process

where nurses' thoughts and feelings about themselves as a nurse are positively related to satisfaction with their clinical practices and professional competence. Additionally, according to Nicholson's transition theory (Nicholson, 1984), adjustments to a new role depend on personal characteristics, role requirements and organizational settings. With this in mind, despite extensive experience working in wards as RNs, the transition to the CRN role was vividly remembered by the participants as a radical transition in their professional role, where they had to adjust to new work tasks, organizational settings and professional skills. The results imply that the unclear role, lack of introduction and lack of competence plan affected the transition from RN to CRN. For instance, initially, the nurses followed the PI's instructions and study protocols, but they later began to contribute their own professional ideas and opinions as they started to feel more secure in their role. This is consistent with the adjustment and stabilization phases proposed by Nicholson (1984). Duchscher and Windey (2018) refer to this period as the stage of being, in which nurses were aware of the work organization and could rely on their own skills more easily. Therefore, the experiences narrated by the participants were diverse and probably reflect several phases in the transition process.

Many of the challenges the new CRNs experienced in their transition processes, such as unclear identity and ethical dilemmas, could be reduced if a clear definition of their professional role was established, facilitating formal consensus about their tasks and duties as suggested by Duchscher and Windey (2018). Furthermore, as stated in several other studies (Bevans et al., 2011; McCabe et al., 2019; Ness & Royce, 2017), education in the form of residence and mentorship programmes is needed for new CRNs to be clear about their role and competence. There is also a need to recognize the CRN role as a specialty. Formal education and clear competence guidelines and role definition can contribute to establishing the CRN role, thereby facilitating CRNs' professional development and transition into a new professional identity. Moreover, such changes may also create a potential career pathway in the nursing profession, which is currently lacking in Sweden and many other countries.

All participants experienced that they were acknowledged by the doctors, but not always by nurse colleagues. Other studies showed how RNs' searching to gain recognition from themselves and others during the work role transition leads to experiences of extreme emotional upheaval (Arrowsmith et al., 2016). Nicholson (1984) described that nurses use strategies to adjust to the new role in new organizational social settings, which was confirmed by our findings that CRNs needed to inform other staff and colleagues about what they were doing and how the studies were progressing. This also became a strategy to motivate and involve other staff to perform specific duties in current research studies. However, they felt quite invisible among other ward staff, something Höglund et al. (2010) also reported. On the one hand, the CRNs in our sample found their work to be rewarding, which overcame the drawbacks of the role (e.g., feelings of loneliness and lack of support). The support varied in the different organizational settings where they worked. For example, CRNs working in ward settings seemed to struggle more to combine ward and research duties. The participants expressed appreciation for the support and introductions provided by colleagues who worked as CRNs. Most advice otherwise came from the PI, who often only told the CRNs what to do. The importance of building different networks, such as CRN networks, and collaborating with other study teams in the context of multi-centre studies was emphasized as these were supportive and reduced feelings of loneliness. Similar results regarding benefits and drawbacks were presented by Rickard et al. (2011), who suggested building organizational structures to overcome feelings of isolation and not being recognized as CRNs.

Our results demonstrate challenges and highlight the necessity to better educate and support the CRNs, as well as to work towards a consensus regarding their professional titles and competence descriptions. Many CRNs in Sweden are included in the national organizational structure for research, which aims to improve the quality of clinical research, and this may be a natural way to develop such competence descriptions and work for a unified title. As Bryson (2014) highlights, expectations on professional development, striving for movement to a higher level of achievement and competence as practitioners are common feelings among health personnel. Many of the CRNs in our study described a higher level of achievement and competence, experienced freedom and were respected and trusted for their knowledge by the research staff. These feelings were most strongly related to feeling rewarded for their work, fairness, a manageable and controlled workload and a sense of being part of a community, which is also in line with Bryson's (2014) findings.

The work as CRNs gave the participants an opportunity to combine the field of special interest with caring. The combination of achieving and being a part of developing new knowledge while still interacting with patients motivated them to become CRNs. This is in line with Scala et al.'s (2019) report on a desire among clinical nurses to engage in clinical research. Common reasons were their personal desire to learn more and contribute to improved health care. Our participants described that they were thankful and inspired to become CRNs. They had already developed compassion, were engaged in caring and desired professional development. Such motivational orientation, as explained by Nicholson's theory (Nicholson, 1984), predicts a positive transition process and further development in the CRN profession. The present results also showed that all participants had attended short courses in GCP, yet they expressed a need for further education in research, economics and data management, which was also reported by Mori et al. (2007). Presently, the Swedish health care system is struggling with keeping competent RNs with extensive experience in their profession due to a lack of optimal work conditions and possibilities for professional development. Clarifying a potential career pathway for these RNs to become CRN's would be beneficial for the Swedish health care system, for the quality of the clinical research conducted in Sweden as well as for the nurses' professional development.

Former education in ethical guidelines, both for nursing and research, was described to give a solid ethical ground when the CRNs

had to address ethical issues, but it was sometimes challenging to manage double responsibilities; that is, following the procedures in the study protocols despite knowing about other treatments that could benefit the patients more and giving patients placebos, for example. Our results show that CRNs have a big ethical responsibility to ensure that the study participants have understood the PI's information, to provide more information if something is unclear and to guarantee that the informed consent process is accurate. According to good clinical practice, it is the PI's responsibility to ensure that each eligible study participant is given the study information, is participating for the right reasons and understands the information before signing the informed consent. However, in practice, this becomes CRNs' responsibility. This occasionally created ethical dilemmas for the CRNs in our study. Similarly, Höglund et al. (2010) and Larkin et al. (2019) reported that CRNs were responsible for making judgement calls regarding patients' suitability for the trial, which was challenging for them. Challenges and ethical dilemmas could be prevented with better ethics education, formal delegation in the studies and by having repeated ethical discussions regarding the informed consent process, for example, in the research team.

4.1 | Limitations

The transferability of these results is subject to certain limitations. First, our sample was small. However, the participants were from different contexts with diverse clinical research experiences, which contributed to the richness of interviews and in-depth qualitative data for analyses (Malterud et al., 2016). Additionally, the researcher's background knowledge could have influenced the interviews. However, the use of interview guides, audiotaped interviews and a structured method to analyse data code scheme with supervisors ensured effective data collection and analysis. Still, the interviews were performed by a novice researcher with limited experience conducting interviews, which could have negatively affected data collection in terms of listening or reflecting and following up on responses by using probing questions in a correct way to get more data. However, a positive aspect is that all authors participated in all parts of the analysis and reflected on and discussed the results until a consensus was reached (Graneheim & Lundman, 2004). Analysis involving several researchers is a strength of this study since researchers' different backgrounds can contribute to the appraisal of data and a greater understanding of the studied phenomenon (Malterud et al., 2016). Although some time has passed since data collection, which could be a limitation, this is the most recent study about Swedish CRNs' role. Dissemination of our findings will allow comparisons with results from other countries. However, as with all qualitative studies, the results reported here should be understood in their context. It is essential to consider the participants' characteristics and the context in which data were collected when generalizing the results.

5 | CONCLUSION

The results imply that RNs who become CRNs have needs that are both distinct from and overlap with those of their former professional role as ward-based RNs. They also imply that CRNs, overall, seem to be satisfied with their work, but some of their experiences regarding skills, education and organizational structures require improvement, such as an appropriate introduction to the CRN role. Ethical challenges need ongoing discussions in the research teams. The need to develop clear competence pathways for nurses to become CRNs, including mentorship and support, was prominent. For research purposes, making their professional title more homogeneous, nationally and internationally, would make comparisons easier. This result can be considered and of use in the field of nursing, research and health organization. CRNs' need for education and support was highlighted. Overall, the results could be used to strengthen the role of CRNs, thereby improving the quality of clinical studies conducted in Sweden. Providing customized education and support to RNs who wish to transition into the CRN role would improve their competence. A suggestion is to offer mentorship and introductory training as well as courses on the research process, ethics, project coordination, leadership and communication to avoid reality shocks and other struggles.

AUTHOR CONTRIBUTIONS

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE*): (1) Substantial contributions to conception and design, acquisition of data or analysis and interpretation of data; (2) Drafting the article or revising it critically for important intellectual content. *http://www.icmje.org/recommendations/

ACKNOWLEDGEMENTS

We would like to thank the participating clinical research nurses for willingly sharing their experiences and taking the time to be interviewed.

FUNDING INFORMATION

Funding for the study has been received by Region Vasternorrland, Sweden.

CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

PEER REVIEW

The peer review history for this article is available at https://publons.com/publon/10.1111/jan.15397.

DATA AVAILABILITY STATEMENT

Data available on request due to privacy/ethical restrictions. The data that support the findings of this study are not publicly available since the data consists of information that could compromise research participants' privacy and consent.

ORCID

Beatrice Backman Lönn https://orcid.org/0000-0002-9033-1297

REFERENCES

Arrigo, C., Gall, H., Delogne, A., & Molin, C. (1994). The result of the EORTC oncology nurses study group survey. *Cancer Nursing*, *17*(5), 429–433.

Arrowsmith, V., Lau-Walker, M., Norman, I., & Maben, J. (2016). Nurses' perceptions and experiences of work role transitions: A mixed methods systematic review of the literature. *Journal of Advanced Nursing*, *72*(8), 1735–1750. https://doi.org/10.1111/jan.12912

Backman Lönn, B., Olofsson, N., & Jong, M. (2019). Translation and validation of the clinical trial nursing questionnaire in Swedish: A first step to clarify the clinical research nurse role in Sweden. *Journal of Clinical Nursing*, *1–10*, 2696–2705. https://doi.org/10.1111/jocn.14855

Bevans, M., Hastings, C., Wehrlen, L., Cusack, G., Matlock, A.-M., Miller-Davis, C., Tondreau, L., Walsch, D., & Wallen, G. (2011). Defining clinical research nursing practice: Result of a role delineation study. *Clinical and Translational Science*, *4*(6), 421–427. https://doi.org/10.1111/j.1752-8062.2011.00365x

Bryson, D. (2014). The developing professional. *Journal of Visual Communication in Medicine*, *37*(3–4), 107–111. https://doi.org/10.3109/17453054.2014.981798

Catania, G., Poire, I., Bernardi, M., Bono, L., Cardinale, F., & Dozin, B. (2012). The role of the clinical trial nurse in Italy. *European Journal of Oncology Nursing*, *16*(1), 87–93. https://doi.org/10.1016/j.ejon.2011.04.001

Duchscher, B. J., & Windey, M. (2018). Stages of transition and transition Schock. *Journal for Nurses in Professional Development*, *34*(4), 228–232. https://doi.org/10.1097/NND.0000000000000461

Ehrenberger, H. E., & Lillington, L. (2004). Development of a measure to delineate the clinical trials nursing role. *Oncology Nursing Forum*, *31*, 64–68. https://doi.org/10.1188/04.ONF.E64-E68

Graneheim, U. H., Lindgren, B.-M., & Lundman, B. (2017). Methodological challenges in qualitative content analysis: A discussion paper. *Nurse Education Today*, *56*, 29–34. https://doi.org/10.1016/j.nedt.2017.06.002

Graneheim, U. H., & Lundman, B. (2004). Qualitative content analysis in nursing research: Concepts, procedures and measures to achieve trustworthiness. *Nurse Education Today*, *24*, 105–112. https://doi.org/10.1016/j.nedt.2003.10.001

Hemingway, B., & Storey, C. (2013). Role of the clinical research nurse in tissue viability. *Nursing Standard*, *27*, 62–68. https://doi.org/10.7748/ns2013.02.27.24.62.e7113

Höglund, A. T., Helgesson, G., & Eriksson, S. (2010). Ethical dilemmas and ethical competence in the daily work of research nurses. *Journal of Health Care Analysis*, *18*, 239–251. https://doi.org/10.1007/s10728-009-0126-z

Kim, J. S. (2020). Relationships between reality shock, professional self-concept, and nursing students' perceived trust from nursing educators: A cross-sectional study. *Nurse Education Today*, *88*, 104369.

Larkin, M., Beardslee, B., Cagliero, E., Griffith, C., Milasaszewski, K., Mugford, M., & Witt, E. (2019). Ethical challenges experienced by clinical research nurses: A qualitative study. *Nursing Ethics*, *26*(1), 172–184. https://doi.org/10.1177/09697330177693441

Malterud, K., Siersma, D. V., & Guassora, A. D. (2016). Sample size in qualitative interview studies: Guided by information power. *Qualitative Health Research*, *26*(13), 1753–1760. https://doi.org/10.1177/1049732315617444

McCabe, M., Behrens, L., Browning, S., Vessey, J., & Williams, M. (2019). The clinical research nurse: Exploring self-perceptions about the value of the role. *American Journal of Nursing*, *119*(8), 24–32. https://doi.org/10.1097/01.NAJ.0000577324.10524.c9

Mori, C., Mullen, N., & Hill, E. (2007). Describing the role of the clinical research nurse. *Research Practitioner*, *8*(6), 220–228.

Nagel, K., Gender, J., & Bonner, A. (2010). Delineating the role of a cohort of clinical research nurses in a pediatric cooperative clinical trials group. *Oncology Nursing Forum*, *37*(3), 180–185. https://doi.org/10.1188/10.ONF.E180-E185

Ness, E., & Royce, C. (2017). Clinical trials and the role of the oncology clinical trials nurse. *Nursing Clinics of North America*, *52*(1), 133–148. https://doi.org/10.1016/j.cnur.2016.10.005

Nicholson, N. (1984). A theory of work role transitions. *Journal of Administrative Science Quarterly.*, *29*(1984), 172–191.

Andrew Pick, Alan Liu, Victoria L. Drew, James McCaul. (2011). The role of the research nurse. Nursing Times 107: online edition, 26 april

Rickard, C., Williams, G., Ray-Barruel, G., Armit, L., Perry, C., Luke, H., Duffy, P., & Wallis, M. (2011). Towards improved organisational support for nurses working in research roles in the clinical setting: A mixed method investigation. *Collegian*, *18*, 165–176. https://doi.org/10.1016/j.colegn.2011.07.002

Scala, E., Patterson, B., Haas Stavarski, D., & Mackay, P. (2019). Engagement in research. *Journal for Nurses in Professional Development*, *35*(3), 137–143. https://doi.org/10.1097/NND0000000000000538

Scott, K., White, K., & Roydhouse, J. (2013). Advancing the educational and career pathway for clinical trials nurses. *Journal of Continuing Education in Nursing*, *44*(4), 165–170. https://doi.org/10.3928/00220124-20121217-38

Spilsbury, K., Petherick, E., Cullum, N., Nelson, A., Nixon, J., & Mason, S. (2008). The role and potential contribution of clinical research nurses to clinical trials. *Journal of Clinical Nursing*, *17*(4), 549–557. https://doi.org/10.1111/j.1365-2702.2006.01872.x

Tong, A., Sainsbury, P., & Craig, J. (2007). Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*, *19*(6), 349–357. https://doi.org/10.1093/intqhc/mzm042

Wilkes, I., Jackson, D., Miranda, C., & Watson, R. (2012). The role of clinical trial nurses: An Australian perspective. *Collegian*, *19*(4), 239–246. https://doi.org/10.1016/j.colegn.2012.02.005

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Lönn, B. B., Hörnsten, Å., Styrke, J., & Hajdarevic, S. (2022). Transitioning to the clinical research nurse role – A qualitative descriptive study. *Journal of Advanced Nursing*, 78(*11*), 3817–3829. https://doi.org/10.1111/jan.15397