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ABSTRACT

Background: Clinical research nurses (CRN) make a significant contribution to healthcare research within the UK and internationally. However, lack of clarity about their role, and scope of practice renders their contribution within the profession and in the minds of the wider public invisible. This has implications in terms of promoting the role nurses play not only in terms of recruitment, retention, and care of research participants but also as research leaders of the future.

Aim: To examine the perspectives of CRNs in the UK on their professional role identity, in order to inform the professional practice of Clinical Research Nursing.

Methods: Exploratory qualitative design using thematic analysis conducted within a realist paradigm.

Findings: Participants viewed the positive aspects of their identity 'as agents of change' who were fundamental to the clinical research process. Resourcefulness and the ability to guide members of the research team were valued as key to job satisfaction. Successful navigation through the complexity of advice, support, management and leadership tasks related to their role in caring for research patients were role affirming and generated a sense of pride.

However, lack of recognition, clarity of the role and career development opportunities within an identified structure undermined the CRN identity and optimism about progression in the future. Participants reported feeling invisible to colleagues within the clinical community, isolated and excluded from wider nursing groups.

Implications: The study describes UK CRN practice, highlighting the positive benefits and challenges associated with the role, including the need to support professional development to maximise their research contribution. Drawing on international comparators the study makes recommendations to establish well-defined educational, career and promotional pathways that include opportunities for research leadership.

What is already known about this topic

- Clinical research nurses are vital in managing research conduction within the NHS.

- The responsibilities held by CRNs are inconsistent and divergent within and among different countries.

- A coherent job role identity allows nurses to contribute fully to the field, enhance professional outcomes and improve health care service delivery. This is yet to be established in clinical research nursing.

What this paper adds

- Describes the UK CRN job role, and draws attention to its contribution to nursing and clinical research.

- Explores what professional identity means to the CRNs in the UK

- Contribute to the International Association of Clinical Research Nurses (IACRN) efforts to develop the CRN role as a specialty nursing practice internationally, by providing some important perspectives of the UK CRNs on their professional role identity.

INTRODUCTION

Advancements in modern medicine have undeniably contributed to the success of today's society. These advancements have been made possible through scientific inquiry in the form of clinical research. The expansion of clinical research enterprise has resulted in a clear

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need for professionals specialising in clinical research to maintain high-quality research standards and achieve meaningful results. Among these professionals, nurses play a pivotal role (NIHR, 2016). Clinical research nursing is nursing practice with an exclusive focus on the care of research participants. In addition to providing and coordinating clinical care of research participants, they have a central role in assuring participant safety, maintenance of informed consent, ensuring the integrity of protocol implementation, the accuracy of data collection, data recording and follow-up (nih.gov, 2016).

In 2004, the UK Clinical research Collaboration (UKCRC), which is a national partnership of health-related research funding bodies, academic organisations, the NHS, regulatory bodies, the bioscience, healthcare and pharmaceutical industries, and patients was formed with the aim of re-establishing the clinical research environment in the UK. One early recommendation of the UKCRC was to encourage trusts to employ CRNs to manage specific clinical research studies (Gibbs & Lowton, 2012). In 2007, the UK Clinical Research Council recognised CRNs as integral to the success of NHS research. With the introduction of NIHR in England, NHS Research in Scotland, Northern Ireland Clinical Research Network (NICRN) and Health and Care Research in Wales, an explosion in the numbers of clinical research nurse workforce have taken place in the UK (RCN, 2016).

Clinical research nursing is a relatively new and emerging discipline. Clarity on the professional role, responsibilities, standards, training and scope of practice that governs CRN practice is still evolving, as evidenced by wide geographical variations in the job description, titles, devolved roles and career prospects (Hastings et al., 2012; Simpson, 2006; Edwards, 2008; Gibbs & Lowton, 2012). In contrast to traditional nursing roles, the specific clinical activities, competencies and educational requirements for nurses implementing patient care in a research setting are not well- delineated (Bevans et al., 2011). Moreover, CRNs are required to be autonomous and independent practitioners, who

are capable of executing and managing clinical research activities and regulatory affairs, writing research protocols, integrating and applying good clinical practice guidelines, maintaining ethics and conduct of responsible research and research data management (Castro et al., 2011). Current pre-registration nursing programmes and general clinical experiences are inadequate in preparing nurses to take on the CRN role and to practice autonomously within the research field (Sandhu, 2014). In addition, as clinical research has low priority in some NHS trusts, nurses involved in research delivery do not always have the same leadership support or working conditions as colleagues in other nursing disciplines (Crn.nihr.ac.uk, 2015). When making the transition from expert clinical nurse to novice research nurse, CRNs describe their working environment as intimidating and isolating (Stephens-Lloyd, 2004). This process requires transformational and inter-contextual learning that develops from structured training, positive role modeling, supportive mentoring, rich practice experience and an established professional identity (Crigger, 2014).

A national framework to guide CRN professional practice is still absent in the UK (Bowers, 2014). A guidance to formulate local frameworks, *The Competency Framework for CRNs* (2011) was developed by a working group including National Cancer Research Network and Royal College of Nursing (RCN) with plans for revision in 2013. However, the RCN recently confirmed that it has abandoned plans to revise the competency framework (personal correspondence, 6/01/2016), leading to limited guidance available to prepare and develop current CRNs to shoulder their professional roles (McDermott et al. 2014).

Internationally, the United States of America has pioneered the promotion of Clinical Research Nursing as a specialty nursing practice by establishing the first CRN professional organisation, the International Association of Clinical Research Nurses (IACRN) in 2009. Its purpose was to define and validate CRN practice and support nurses involved in research across all specialties (IACRN, 2016).The first organised attempt to scope and standardise the CRN professional practice was also undertaken by the IACRN, thereby obtaining the

official approval of specialty nursing status by the American Nurses Association on 8th August 2016 (Iacrn.memberlodge.org, 2016).

While there are many similarities in the competencies and roles of CRNs in North America, Europe, and the Asia-Pacific region, the difference that does exist between nations appears to be due to variations in the scope of the role (Bell, 2009; Brinkmann-Deney, 2013). For example, within the Indian nursing context, the CRN role is defined by significant and far reaching responsibilities with many nurses taking on the role of principal investigator, whereas, in Italy, the role is more task-oriented and focused on specimen handling and patient monitoring (Brinkman-Denney, 2013). The job scope of CRNs practicing in Australia, Canada, Japan, New Zealand, South Korea, UK and the US falls somewhere in between these two domains (Brinkman-Denney, 2013).

In the United States, the American Nurses Association has recognised five dimensions of clinical research nursing (clinical practice, study management, human subject protection, care co-ordination within research participation, contributions to clinical science as an active research team member) thereby making it a specialty practice; but in reality, CRNs reported performing significantly higher levels of clinical practice activities and significantly lower levels in all other dimensions (Bevans et al., 2011). Catania et al. (2012) report that CRNs' professional skills were being under-used, unacknowledged and limited in Italy, being mostly practical task-oriented and focussing little on protocol assessment, data management, and organisational activities. While post-basic and advanced curricular qualifications are required to handle the complexities and sensitivities of the role, most CRNs in this Italian study sample only had informal preliminary training in clinical research leading to only partially advanced and autonomous practice. At the same time, in Australia, Wilkes (2012) described CRNs as an 'invisible workforce, unrecognised of their existence" with poor working conditions and short-term work contracts. They felt undervalued, uneducated and uncertain in their job positions and lacked a clear career path. They were not listed in the Nursing and

Midwifery database, had no set employment award and had to work on short-term work grants.

Spilsbury et al. (2008) note that CRNs in the United Kingdom lacked professional confidence and were challenged with role conflicts and lack of clinical staff support. Further, this study describes the challenges involved in role transition from nurse to CRN, role conflicts as researcher and nurse, difficulties in obtaining co-operation of non-research staff members and in maintaining their own professional motivation. In contrast, MacArthur et al. (2014) argues that experienced UK CRNs are highly skilled practitioners by virtue of their specialist clinical knowledge and comprehensive understanding of research process and practical issues. However, they also found that despite higher qualifications and rich professional experience, UK CRNs lack a structured career pathway, and many feel that their roles have expanded without appropriate recognition and reward.

Much of the existing evidence base is centred on identifying the professional roles of CRNs within specialties, delineating practice domains, addressing professional issues and challenges and describing role development over time (Gibbs and Lowten, 2012; Bevans et al. 2011). Several of these studies included a mixture of professionals involved in clinical research in its participant group. Consequently, the study conclusions are not exclusive to CRNs. Moreover, most commonly these studies are quantitative and fail to examine in depth the views, experiences, and perceptions of professional identity connected to the role, from the perspectives of the practitioners themselves. This understanding is essential for establishing, defining and recognising their professional role (e.g. Hoeve, 2013; Crigger, 2014; Hurley, 2009). This study therefore attempts to identify how research nurses in the UK make sense of their professional role identity and establish themselves in the unique position as ambassadors of research in nursing and of nurses in research.

METHODS

Design

This study adopted an exploratory qualitative approach using purposive sampling strategy, the characteristics of which are detailed in Table 1. This sampling method enables greater insights into the phenomenon under study by identifying common themes that are evident across a purposefully selected, information-rich, heterogeneous sample of participants (Patton & Patton, 2002).

The National League for Nursing Outcomes and Competencies Model (NLN, 2010) was used as the conceptual framework for this study. It maintains that nurse professional identity is formulated through experiences of: clinical management, leadership, teamwork, and communication including participation in ethical decision-making. To exploit the full scope of practice role, this also needs to include responding to practice challenges, reflection, and evaluation of professional practice and an appreciation of how these align with one's own personal beliefs and values (NLN, 2010).

Inclusion Criteria:

1. Registered with the NMC as a UK nurse,
2. Currently working as a CRN in the UK,
3. Had one- or more years' experience in the CRN- role,
4. Able to communicate effectively in English,
5. Able to give informed consent.

Sample/Participants

All the participants worked full time exclusively as CRNs in an NHS Foundation Trust University Hospital in the South East of England (see Table1). The hospital setting was chosen as it actively participated in a significant number of national and international research studies across fifteen specialties. The CRNs were involved in a wide range of research projects including randomised controlled trials, cohort and case control studies, empirical research, and genome-wide association studies.

The research project was initially presented at the monthly CRN meeting in the hospital, following which twelve out of total eighteen CRNs were identified as eligible to participate. The eligible participants were given the participant information sheet and later individually approached to discuss participation using a fully voluntary opt-in approach. Eleven CRNs consented, while one CRN opted out due to family issues. Thus in total, eleven semi-structured in-depth interviews were conducted in May 2016.

It is interesting to note that of the eleven participants that were interviewed, ten were female (91%) and one was male (9%). The ratio of males to females in the study is reflective of the ratio of males to females in the general population of nurses, where one in ten nurses is male (NMC, 2016). The nursing experience of participants ranged between twelve to thirty-eight years, while research nursing experience varied between two to ten years. The more experienced nurses discussed changes in CRN practice and compared practice challenges over the years, while CRNs with less experience were more interested in the wider scope and opportunities the post offered. Two of the participating CRNs were graduate nurses while the remaining nine had studied to diploma level. Views and opinions on aspects of the CRN role were generally similar and were based more on practice experience than level of education. Practice specialty specific issues were also mentioned; for example, the oncology CRN expressed spiritual distress in the frequent and inevitable deaths of her clients, the stroke CRN expressed the challenges of recruiting participants to clinical trials with tight consenting time windows, within just minutes or hours of alarming diagnoses like cerebral

haemorrhage. In relation to ethnic origin of participants, CRNs from the African continent mentioned that they were conscious of the historical exploitation of black people for research purposes and that these past exploitations may be the reason why the numbers of Black participants in research trials still remains low.

Data Collection

Prior to formal commencement of the study, two pilot interviews were conducted with non-participant CRNs in order to refine the interview process, through familiarity with the format and questions, in addition to exploring different types and degrees of probing best suited to elicit in-depth responses (Gill et al., 2008). Interviews, organised in the workplace, focussed around a number of key areas: professional responsibilities, accountability, training and mentoring influences, the role of communication, team and autonomous working, motivations and job satisfaction. In addition to more philosophical questions connected to the beliefs, values, and attitudes connected to their role, including personal aspirations and scope for future development. Interviews lasted for an average of 43 minutes. Data saturation was considered to have been reached when no new themes or subthemes emerged. Field notes were also made during the interviews which were digitally recorded and transcribed verbatim. The transcripts were later sent to respective research participants by confidential email, to ensure that it accurately reflected what the participant intended to say. All participants confirmed their agreement with the transcribed material and no further amendments or corrections were suggested during this participant validation process.

Ethical Considerations

Ethical approval was obtained from the City University London Senate Research Ethics Committee and the Research and Development Department (NHS Trust) confirmed local agreement for the research site. Participant and data confidentiality and anonymity were maintained according to Data Protection Act 2008.

The research was undertaken as part of National Institute for Health Research (NIHR) funded post-graduate course, by an active CRN. Working as a CRN makes the researcher an insider and member of the professional group. To reduce the unfavourable effects of insider research, the researcher adopted a position suggested by Asselin (2003), that she knows nothing about the phenomenon being studied. Thus, at the beginning of the interview, the interviewer explicitly stated that the participants should respond to questions as if responding to someone unfamiliar with the field of study. Maintaining a disciplined bracketing from participants, on-going reflection on the subjective research process and keeping a reflective research diary allowed the researcher to reduce the negative influences of insider research.

Data Analysis

Following participant validation of the transcribed material, the text was entered into qualitative data analysis software NVivo 10 (QSR International, UK). Using thematic analysis (Braun and Clarke, 2006) conducted using a semantic approach within a realist paradigm, concepts that emerged from the text were identified and linked together. The analytic process involved a progression from description to interpretation where an attempt was made to theorise the significance of the themes and their broader meanings and implications. After initial coding of all transcripts, it was reviewed by the research supervisor, acting as the secondary coder. Following ongoing discussions between the researcher and the two members of the academic supervisory team, the final thematic framework was jointly agreed.

Results and Discussion

The primary themes identified from the data were grouped and synthesised to generate four key categories, which are presented in Figure 1. A summary of the data content within each category is given in Table 2.

<u>**Final Thematic Analysis**</u>

The final thematic map was configured through an iterative process of reading, examining, assimilating and interpreting the preliminary themes and sub-themes in relation to each other and to the wider literature, to establish broad conclusions in response to the research question. This section moves forward from a thematic categorisation of data to an interpretive analysis of the findings. Two dominant themes emerged from the data, composed of three distinct subthemes: **Strengths of CRN identity** (subthemes: **agent of change, navigator, autonomous practitioner)** and **Challenges of CRN identity** (subthemes: **ambiguity, isolation, conflict**). These themes are subsequently discussed and illustrated with extracts from the interviews and annotated with participant identification number.

STRENGTHS OF CRN IDENTITY

Participants expressed great satisfaction in being the **agents of change** in health care, brought about through clinical research:

"We're responsible for setting up trials, identifying and recruiting research patients, co-ordinating the multidisciplinary team regarding the trial, developing good rapport with the patient, their family, the consultants and the study PI and to care for the research patient and study. We collect the study data and also ensure that we get all that information back to

the trial centres correctly and in a timely manner, because all these trials are based on accurate data retrieval. If we didn't have research, then over the last forty years, our standard practices would never have changed. I am completely and utterly committed to my role as a research nurse" (CRN11).

This view recognises that CRNs are able to navigate new pathways for the research patient's disease management and provide and co-ordinate study treatments and procedures that can potentially improve research efficiency, participant safety and the quality of research data (Hastings et al., 2011, Poston and Buescher, 2010). CRNs reported contributing significantly to the collection of data required to establish the evidence-base for medical therapies and practices, subsequently translated in to standard care. The promotion of this role is consistent with the strategic priorities for NIHR CRN workforce (2014), in raising the profile of the profession and demonstrating how through engagement in clinical research, CRNs contribute to improvements in care, practice, and skills.

CRNs identified themselves as **navigators** of the research studies they were responsible for and expressed confidence in being able to guide all other professionals involved in those studies. They stressed how the professional knowledge and experience of being a nurse had supported their research careers, in identifying and solving participant issues in a holistic way. The participants also reiterated the need to demonstrate expert clinical skills, show well-developed critical thinking skills and practice knowledge of regulatory, ethical and scientific aspects of clinical research (IACRN, 2016) to enable them to effectively navigate the research process:

"CRN is the central link that makes it (conduction of research) happen. With research, I find that there needs to be this person who is a Jack of all trades, this person who is multi-talented, multi-skilled, who can pull the team together in order for research to have its data. I think I (CRN) play a very, very important role in that" (CRN 05).

"Research team have confidence that I (CRN) know about the studies, and If they have any questions about what to do with a research patient, they know that I will have an answer from the protocol" (CRN01).

CRNs also greatly valued their identity as **autonomous practitioners**. The specific nature of clinical research necessitated them to take charge of their own practice and work autonomously within the boundaries of the job description, code of practice and study protocol guidance:

"I think there is a lot of autonomy in this role. The responsibility that you have itself by default puts you in a position where you have to take charge of what is happening. You have to be autonomous, you're accountable, you're responsible for a lot of things because, the protocol itself states the responsibility in my role as coordinating the study, to be sure that I manage things" (CRN 05).

Autonomy was perceived as necessary for CRNs to develop effective problem-solving abilities (Roberts et al., 2011). Most participants were advanced in their nursing careers and found this independence essential in their role. Moreover, two participants had assumed the leadership role of principal investigator in studies relating to nursing issues. The PI role was regarded by CRNs to enable professional and personal growth as a researcher and also as an excellent opportunity for career progression. Yet, the number of CRNs acting in principal investigator or co-investigator roles were very limited, with participants identifying the scarcity of nursing-related topics funded by private or government organisations as a possible explanation. There is little discussion available in wider literature to examine the opportunities, effectiveness and challenges of CRNs in the PI role.

The named CRN for each study has a central responsibility for its conduct and ensuring protocol adherence (Poston & Buescher, 2010), with CRNs often managing several such studies concurrently:

"There is an awful lot going on in the role…You'll have different specifics to abide by for each particular study" (CRN04).

Specific job responsibilities within each study are designated to the named CRN by the study delegation log. Unlike traditional nursing roles where pending work can be carried forward to the adjoining shift nurses, CRN tasks cannot be taken over by other staff without research training and study delegation log authorisation (Poston & Buescher, 2010). The person-specific nature of CRN role is crucial as CRNs report that sometimes pressure was exerted on them by hospital managers to cover general nurse shortages on the wards. This raised concerns regarding the protected time available to CRNs to meet their own professional targets:

"I can't do it. Because you have your own work every day, we have deadlines that we need to meet and they (hospital management) don't understand" (CRN06).

This re-allocation of CRNs to frontline care may be an emerging trend within the NHS to combat staff shortages. The impacts of removing CRNs from research duties needs to be further explored as it may compromise the quality of care research participants receive or their ability to deliver high-quality research within established timescales.

CHALLENGES OF CRN IDENTITY

A general lack of understanding of the CRN role **(professional role ambiguity)** was a recurring theme across interviews from CRNs working in all specialties, and posed a

significant challenge in relation to professional progression. Nursing is traditionally associated with health promotion, disease prevention, care in illness and rehabilitation (Taylor, 2008). The place of clinical research as a domain of nursing practice is not clearly visible. Although the role of CRN demands the use of clinical skills and experience from a wide-range of nursing domains, a failure to understand how these are delivered in a research context meant that their role remained a source of ambiguity for professionals across the board ranging from trust management, executive and staff level to service recipient level. CRNs themselves admitted being unsure of their professional role at the beginning of their research career:

"Unless you get good support and training, role transition is a big challenge. You don't know anything when you start" (CRN02).
"They (non-research staff) haven't got any idea what our responsibilities are or even what our job description is" (CRN 04).

In everyday practice, the ambiguity of their professional role sometimes created friction between CRNs and non-research colleagues who held negative attitudes to research in general (Roberts, 2011). Other professionals, especially senior specialist nurses sometimes acted as 'gatekeepers' preventing the CRNs from accessing patients to discuss involvement in research studies. The critical perception of CRNs as 'supernumerary' nurses, or 'clipboard' nurses (Gordon, 2008) detracted from nursing colleagues' potential support for executing research-related clinical activities. A major part of CRN work-time is dedicated to data upload in computerised data capturing systems and the administrative nature of this nursing role was often not appreciated by other nurses and trust management to be an important part of improving evidence-based health care.

Participants had a number of ways of navigating issues in practice, while some CRNs used positive feedback to encourage the non-research colleagues, others actively promoted their role by ensuring participation in the multidisciplinary clinical routines including ward rounds and team meetings. Similar to Merry et al., (2010) these CRNs built effective teamwork with other nursing colleagues by being more visible and engaging in ward-based activities to assist the research patient care. As suggested by Stephens-Lloyd (2004), CRNs themselves must take the responsibility for improving the perceptions their colleagues may have about the relevance of CRN practice.

Participants also expressed feelings of **isolation and exclusion**, especially from the wider nursing community, due to their professional role ambiguity, patterns of lone working, invisibility of research and work objectives that are dissimilar to a conventional nursing role:

*"Our work is mostly isolated, people work in hospital for years and never met a clinical trials nurse and haven't a clue that we exist" (*CRN01*).*

"People outside Research and Development can be extremely challenging – there are barriers when you say you are research nurse- sometimes I am excluded from the clinic- just not allowed to enter" (CRN 04).

"We don't have a nursing directorate that we fell under-nobody took ownership of us- we were just research nurses or trials nurses or whatever title.." (CRN 08).

The issue of isolation is comparable to similar findings in the literature (MacArthur et al., 2006; Gordon, 2008). Establishing a prominent research directorate, providing adequate infrastructure and promoting integration of clinical research staff in to the multidisciplinary team were some solutions identified to overcome separation. In particular, participants highlighted the importance of having nurse leaders who support and promote CRNs as members of nursing team to reduce the perceived isolation experienced by CRNs.

Another hurdle reported were the **professional conflicts** that resulted when consultants (if different to the PI of the study) or advanced nurse practitioners in charge of patients' care felt that their autonomy in decision making and clinical management of patients became restricted, in having to adhere to the research study protocol. Following strict research pathways was not always welcomed by non-research staff and was seen as 'research interference'. The conflict and frustration that resulted between teams were noted as a critical CRN professional concern:

> *" if you are working against each other then it becomes a problem" (CRN08). "....because they would actually sometimes give an impression to the patient that studies are not a good thing, it's as if they own the patients and they would try and prevent the research nurse from talking to this patient about this new study*" (CRN03)

A practical understanding and acceptance of research pathway as an alternative to standard care pathway in patient management, a closer interaction between medical and research teams working towards the same goal of patient well-being would resolve these unhealthy conflicts that CRNs face in practice.

Health professionals' perception of progressive divergence between clinical research and standard health care has been reported to have serious repercussions on the professional practice of CRNs (Bowers, 2014). Sacristan (2015) found that despite their close relationship, clinical research and medical care have become separated by clear boundaries and their integration required researchers, clinicians, health care managers, and patients to re-evaluate the way they understand research, in relation to the potential benefits for present and future patients. CRNs membership in clinical research enterprise was reported as an ongoing struggle to establish the significance and validity of their service within standard care settings:

"Once you establish that we (CRN and non-research colleague) are not enemies here and some of the studies that we have got a drug which is very advantageous to this kind of disease…and you work together, it's good. But it's taking a long, long time" (CRN08).

Participants also reported that PIs occasionally recruited patients by withholding important aspects of trial information. After a fuller explanation by CRNs of the trial process, patients sometimes withdrew from the research. This occasionally resulted in conflict between those delivering direct care and the wider research team. One CRN shared her experience after a patient withdrew following PI's inappropriate consenting:

 "…because you (consultant PI) had not given all the information, I have actually given them (patient) what you might have left out"; I found that the consultant was not happy but obviously I had to be the advocate for this patient" (CRN08).

The negative consequences of an ill-defined professional identity are multi-faceted; leading to inadequate teamwork, role conflicts and poorly defined role objectives and expectations in patient care (Crigger, 2014). As the majority of senior management and general staff are uninformed of the scope of CRN practice (Hastings et al., 2012), it is not surprising that the hospitals that employ them fall short of utilising their specialist knowledge and skills to promote home-grown research projects that could be CRN-led. The CRNs in this study held views similar to Gordon (2008) and Stephens-Lloyd (2004) that the traditional boundaries between professionals continue to be challenged in CRN practice and such challenges often lead to role conflicts, isolation, lack of motivation and poor research line management.

IMPLICATIONS FOR EDUCATION AND PRACTICE

Through engagement with CRNs in a UK NHS hospital, this qualitative study explored the diversity and complexity of factors that are relevant in CRN practice and further described how these factors influenced the construction of a shared professional role identity among

them. The findings from the study illuminate that though CRN's contribution to clinical research is substantial, it is often not recognised by the vast majority of professionals in the health, education, and other sectors.

As noted by Sandhu (2014), participants in this study also reported experiencing transition difficulties to CRN role in spite of their long nursing careers. This implies that it might be beneficial to increase the prior nursing experience requirement for the role from one year to at least three years. Standard nurse training and practice provide little research training and research-based practical experience. Establishing a structured induction programme as well as a well-defined educational pathway for CRNs needs to be developed and widely promoted. This will help to ease the professional role transition challenges and provide confidence to maximise their research contribution. While Jones (2015) argues that an awareness of funded educational schemes is growing among CRNs and in 2013/14 the NIHR (National Institute of Health Research) awarded twelve percent of its total academic training programmes to nurses, most of the participants in this study did not highlight these educational opportunities available to them. Those who undertook them were disappointed in the lack of any remuneration or incentives even after completing higher degrees in research. Also, the existence of popular CRN websites, socialisation sites, professional organisations etc was not mentioned by any participant, which suggests the need for proactively promoting the existence of academic and professional resources in the field to CRNs. This will enable an improved professional identification with global members from the same group and provide CRNs with a platform to address their professional issues.

CRNs in this study expressed concern that nursing students more widely are minimally exposed to clinical research during their clinical placements and practice. A lack of exposure and unfamiliarity to the CRN role means students may not identify it as a potential career role. While a lack of awarenes in the wider nursing profession means, research acitvity is not

discussed as part of patient care. The practice challenges caused by role conflicts pinpoint the need to improve recognition of CRN practice and incorporate knowledge about clinical research and research nursing across the wider nursing profession. Participants in this study mentioned strategies such as organising research induction programmes, open research seminar days, research placements for students and inviting clinical staff to research meetings to improve visibility and acceptance of CRN practice, thereby reducing role conflicts and promoting the nurses role working within and sometimes leading research. Historically clinical research was not included in the specific skills which are practiced and assessed in placement areas (NMC Standards to support learning and assessment in practice, 2008), students cannot work with CRNs as an allocated mentor during placements. While mentoring students is integral to the role and professional responsibilities of all nurses, CRNs felt that these restrictions devalued their expertise as mentors and limited the showcasing of their practice area.

The benefits of clinical research academic roles for patients, service and the individual are multiple and clear: they include improved clinical outcomes, increased treatment options, increased evidence-based care, effective utilisation of resources, increased reputation, income generation and increased engagement with staff (AUKUH, 2010). Yet, the CRNs highlighted potential career stagnation experienced in their research posts, withno structured career development plans for professional progress. Despite undertaking advanced professional tasks or achieving higher research qualifications, career promotion and progression opportunities were very limited. In 2001 Kenkre and Foxcroft, on behalf of the RCN Research Society, mapped out five research career pathways for CRNs, a proposal which is currently archived in RCN Research Society historical initiatives. This has not since been replaced by any similar recommendations. The NIHR funded clinical academic and leadership routes were reported as intellectually demanding, and limited in availability. The

need for establishing clear-cut career opportunities and pathways thus remains a high priority in clinical research nursing.

Clinical Research nursing is a specialist nursing practice in the United States and is recognised as a specialised progression of nurses on the research ladder. Through specialty practice, the CRN makes important contributions to the clinical research process, quality of the research outcomes and most importantly the safe expert care of research participants (IACRN, 2016). The findings of this study argue that CRNs in the UK are also fully engaged in all the domains mentioned in the scope of practice statement for clinical research nursing (NIH, 2009). However, in the UK, CRNS are not recognised as specialist practitioners. NMC (2017) defines Specialist Practice Qualification- nurses as practitioners specialising in areas such as general practice, mental health, children's nursing, learning disability nursing and district nursing. Clinical research is not included here. Further, the NMC states that specialist practice is the exercising of higher levels of judgement, discretion and decision making in clinical care, concentrating on four broad areas; clinical practice; care and programme management; clinical practice leadership and clinical practice development. Though CRN practice can be associated with all these domains, the NMC has not yet specified any standards for specialist CRN practice. It is essential that these gaps are effectively addressed as these nurses contribute heavily to and maintain the excellence of UK's position as a world leader for cutting edge and high impact medical research (NIHR, 2016).

This study puts forward key recommendations as listed in Table 3 that may contribute to address these issues discussed.

LIMITATIONS

A potential limitation of this study is that the findings rely on the individual testimony of subjective experiences in the context of one hospital and may not, therefore, be transferable to all NHS trusts within the UK.

CONCLUSION

CRNs practice globally; they are integral members of the research team who care for a wide range of research participants throughout the life span and across states of wellness and disease, in all settings (IACRN, 2016). Positioning itself within the context of international clinical research nursing, this study focuses on UK CRN practice, highlighting the positive benefits and challenges associated with the role. It makes recommendations that may be of global relevance in CRN practice, to establish well-defined educational, career and promotional pathways that include opportunities for research leadership, enhance role clarity and promote professional recognition. This will facilitate improved research recruitment, the collection of high-quality research data and effective dissemination of research results, which are essential in transforming elemental clinical research questions into evidence-based practices.

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Tables and Figures

Table 1: Participant Details

Partici-pant	Age	Sex	Country of origin	Qualification	Total Years of nursing practice	Years of CRN Practice	Practice Specialty
01	43	F	Zimbabwe	Nursing diploma	12	6	Haematology
02	47	F	India	Nursing and	22	3	Primary care

				midwifery diploma			
03	61	F	Zimbabwe	Nursing diploma	31	6	Breast cancer
04	61	F	Ireland	Nursing diploma	38	10	Oncology
05	54	F	Zimbabwe	Nursing diploma	23	4	Rheumatology
06	52	F	Zimbabwe	Nursing diploma	14	2	Paediatrics
07	60	F	England	Nursing diploma	21	9	Ophthalmology
08	37	M	India	Nursing graduate	15	3	Renal
09	53	F	England	Nursing diploma	32	3	Sexual health
10	53	F	England	Nursing graduate	12	6	Neurology
11	52	F	South Africa	Nursing and midwifery diploma	28	4	Dermatology

Table 2: Summary of data content in each category

Professional Practice			
Job Role and Responsibilities	**Values, Beliefs and Attitudes**	**Ethical Dilemmas**	**Practice Challenges**
• Specified by the protocol	• Research is	• Establish unyielding	• Lack of research

of each research study	fundamental for	ethical standpoints	awareness among
• Initiation, conduction and maintenance of study activities	promoting evidence-based practice	relating to profession	hospital staff
• Research participant recruitment, care and follow up	• Strict adherence to Good Clinical Practice guidelines	• Ensure ethical consenting and recruitment	• Lack of value and respect to CRN role among non-research colleagues
• Disseminate research information to participants and colleagues	• Deep professional commitment to research projects and participants	• Avoid overselling research trials	• Invisibility of research and its contributions
• Facilitate research pathways without variations in trial therapy	• Promote research among management and multi-professional teams	• Avoid pressure on patients to participate in research	• Negativity and anti-research attitude of hospital senior management
• Data collection, storage and transfer	• Dissatisfaction in research not being properly recognised outside research teams	• Research path not to be riskier than standard treatment for participants	• Unrealistic recruitment target numbers
• Safeguarding research data validity		• Avoiding medical jargons and language to promote recruitment while explaining research to participants	• Professional conflicts with unsupportive PIs and non-research colleagues.
• Support and guide research team including PI			• Isolation and alienation from nursing groups
• Monitoring junior colleagues			• Lack of specialist nurse title to support practice
• Lead/attend study meetings			• Practice area specific challenges

Views about the role		
Being a nurse in research	**Communication, Reflection and Autonomy**	**Job scope and security**
• Nursing expertise in patient management, disease pathologies, pharmaceutics, emergencies, data protection, patient advocacy and confidentiality helpful in being a CRN. • Nurse identity foster confidence and trust in research team and patients.	• Highly relevant in practice • Goal-directed, situation-oriented and professional communication necessary • Regular reflection is necessary to refine practice • CRN practice is guided by research protocol and they autonomously manage participant caseloads.	• Leadership role exists in research oriented trusts, but sparse and difficult to obtain • Limited career progression opportunities and poorly identified career pathways limits practice scope • CRNs mostly felt secure in the job and preferred to stay in the local trust despite low career progression. This was due to good work relations with research colleagues and family commitments forcing to avoid distant commute.

Influencing Factors		
Prior nursing experiences	**Training and induction**	**Team and management support**

• Extensive prior nursing experience is recommended • One year post qualification entry requirement not deemed enough to meet practice demands. • Good organisational, social, strategising, time and work management skills are essential.	• Structured research training and induction programme is of paramount importance • Positive induction experience included friendly and approachable research team and management, assigned mentor, supervision, work shadowing. • Negative induction experiences: Lack of designated work space, inadequate training, high expectations from PIs and managers to deliver immediate results in terms of recruitment.	• Very supportive and encouraging research management, maintains good rapport with CRNs • Hospital management lacked appreciation and understanding of CRN practice • CRNs were frustrated in being treated as 'supernumerary nurses' required to cover general nurse shortages in the trust, thus overlooking their responsibilities and challenging work deadlines.

Personal Implications		
Motivations and rewards of the job	**Being a CRN**	**Image as CRN**
• Regular work pattern and no shift work • Autonomy, independence, intellectual challenge and inspiring nature of the job • CRN role ideal to progress in academic, research and	• All participants were completely satisfied being a CRN • Finds value in being a 'change agent' and the supportive link between all personnel involved in research • Satisfaction in forging strong and	• Personal: Perceived themselves as specialty practitioners by virtue of professional expertise, designated responsibility and accountability required of the role. Discontent in this

clinical career pathways .	resourceful work relationship with patients and being available to them as and when required.	expertise not being acknowledged by the nursing profession and wider health sector.
		• Patients: Recognised and valued CRNs as experts in the field.
		• Non research staff: CRNs felt undervalued, misrepresented, misunderstood and overlooked by non-research colleagues. Lack of recognition was felt as a trust-specific issue and not generalisable.
		• Trust management: Lack of knowledge, understanding and respect to research activities and personnel involved in it. Not having nurse researchers as leaders at top executive and management positions was mentioned as unhelpful.

Figure 1: Key categories and corresponding themes

- Roles and responsibilities
- Values, beliefs, attitudes
- Ethical dilemmas
- Practice challenges

- Being a nurse in research
- Role of reflection, communication and autonomy in practice
- Job scope and security

Professional Practice

Views about the role

CRN IDENTITY

Influencing factors

Personal implications

- Prior nursing experience
- Training and induction experience
- Team and management support

- Motivations and rewards of the role
- Being a CRN
- Images as CRN- Personal, patients, non-research staff, trust management
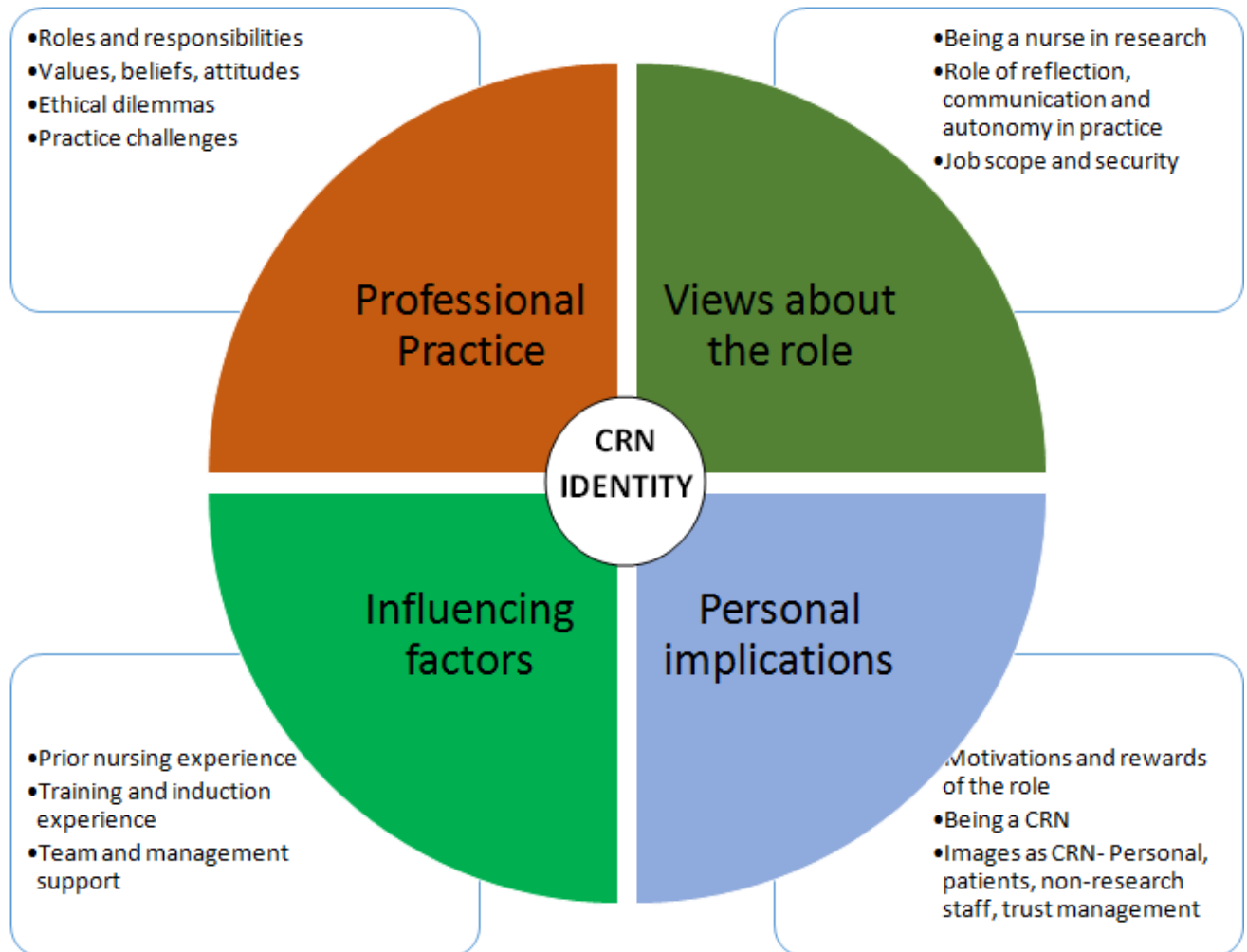
Table 3

<u>Key recommendations of the study</u>

- Improving training capacity for the CRN workforce by providing access to accredited training.

- Raising the status of CRNs to specialty practitioners to enhance service delivery and to extend and expand their scope of practice, thereby improving the health outcomes of research participants.

- Developing CRN practice educator post to tackle the role transition and training challenges surrounding CRN practice. The CRN practice educator could be a promotional role for advanced CRNs to train, guide and support new CRNs to progress through clinical, academic and research pathways.

- The development of a sustainable and easily accessible 'how-to' toolkit and web-based resource to support the implementation of CRN workforce initiatives including inductions and student placement preparation.

- To incorporate clinical research to student nurse practice placements.

- To promote CRNs as principal/co-investigators in clinical research studies wherever appropriate.