‘COUNT ME IN’ STUDY REPORT

The Irish Research Nurses Network (IRNN) National Clinical Research Nurse/Midwife Workforce Survey

Carole Schilling & Deirdre Hyland

This study was funded by a grant from the Health Research Board (HRB) to IRNN, and supported by the RCSI Clinical Research Centre

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National Clinical Research Nurse/Midwife Workforce Survey

Published August 2019

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TABLE OF ABBREVIATIONS

CRC ..... Clinical Research Centre

CRF ..... Clinical Research Facility

CRNs ..... Clinical Research Nurses and Midwives

DCCR ..... Dublin Centre for Clinical Research

HRB ..... Health Research board

IRNN ..... Irish Research Nurse Network

NUI ..... National University of Ireland

PI ..... Principal Investigator

RCSI ..... Royal College of Surgeons in Ireland

1 INTRODUCTION

The Irish Research Nurse Network (IRNN) is a voluntary group that provides resources and professional support to Clinical Research Nurses and Midwives (CRNs) and that advocates for the creation of a formalised career structure and pathway for CRNs. This is necessary in the absence of a national approach to the employment of CRNs, the lack of integration of CRNs into mainstream health services, and the need to include the research nurse resource in future clinical research infrastructure development.

IRNN was formed in 2008, but was built on the foundation of a previous CRN network called the Irish Research Nurses Association. That group had been set up by a small group of CRNs who felt they needed peer support in an unfamiliar area of practice. It ceased to function within a few years of forming, primarily due to the difficulties associated with a lack of research infrastructure or forums. The award of infrastructure funding from the Health Research board (HRB) to the Dublin Centre for Clinical Research (DCCR) in 2008 included provision for CRN networking and support, which was seized with enthusiasm. Within 6 months the first national conference of CRNs took place, and in just over a year an NUI approved certificate programme for CRNs was up and running. This was made possible through the creation of a Director of Nursing post within DCCR. Although located in one of the affiliated clinical research centres (CRCs) this person had protected time to dedicate to supporting CRNs in Dublin and, ultimately, nationally. In addition, the affiliated clinical research facilities and centres – in Dublin and nationally, accepted that networking and professional development activities were a legitimate function and supported their CRNs to represent sites on the IRNN committee.

DCCR funding for these functions ended in 2014, and was not replicated in subsequent funding calls. The IRNN has continued to function, and indeed flourish, but depends on the dedication and commitment of a small core committee. Numerous committee members have come and gone over the past 11 years, and many have struggled to balance commitment to IRNN activities with the demands of their work and family life. This carries the risk of a loss of corporate memory and if pivotal members of the IRNN committee find they can no longer commit there is no certainty that IRNN can continue to function. It is therefore unrealistic to expect a voluntary group, with no formal supports or administrative personnel, to be responsible for the professional practice of this specialised group of nurses and midwives. Should the IRNN cease to function, the support, collaboration and networking between CRNs nationally may be compromised. Furthermore, CRNs have no formal representing body and in the absence of the IRNN the 'voice' of CRNs may not be heard and their needs may not be considered in the future development of the clinical research infrastructure.

The IRNN has built a strong reputation as a supporter of not only CRNs, but other research team members also and the annual conference attracts speakers and delegates from across the clinical research community. This led the HRB to provide increasing levels of funding for the annual conference and other IRNN activities. In 2018 IRNN received funding from the HRB to support the professional development for research nurses and midwives in Ireland over a three year period: 2018 – 2021. The grant is administered through the RCSI. Included in the grant was a commitment to complete a survey to measure and describe the Clinical Research Nurse and Midwife (CRN) workforce in Ireland. Due to the urgency placed on compiling data about CRNs in Ireland it was stipulated that the project should be completed during the first year of the grant. This report summarises the study findings and makes recommendations for the increased recognition of the research nurse workforce.

This study aimed to collect data from the entire CRN workforce, and while it is not possible to state concisely to what extent this was achieved, we are satisfied that it is the most comprehensive study of the Irish CRN workforce to date. Due to the imperative to complete the project within an extremely tight timeframe we were limited in the scope and depth of data collected, but the findings will be beneficial in identifying areas for further exploration.

1.1 Background to the study

'Clinical research nursing is nursing practice with a specialty focus on the care of research participants. In addition to providing and coordinating clinical care, clinical research nurses have a central role in assuring participant safety, ongoing maintenance of informed consent, integrity of protocol implementation, accuracy of data collection, data recording and follow up'

http://clinicalcenter.nih.gov/nursing/crn/crn_2010.html

When advocating for increased recognition of CRNs, and a more structured, professional model of employment, IRNN faced a major hurdle. We could not, despite over 10 years of activity, say how many CRNs were working in Ireland, and what the main challenges were. We knew that, within the network created by IRNN, there were issues in relation to employment terms and conditions, limited opportunities for career progression, and migration in and out of employment due to the temporary or short term nature of contracts. However, we also knew that there were cohorts of CRNs that had not engaged with IRNN, either by choice or because they were unaware of the network. While the number of CRNs working in Ireland is unknown it is estimated to be in the region of 200. Many CRNs are based in hospitals or established clinical research facilities/centres (CRF/Cs), but they are usually employed through universities. CRNs may also be employed by commercial organisations or medical research charity groups. Within the IRNN membership, only a few CRNs were employed through hospitals, on HSE contracts.

CRN job titles, roles and responsibilities and terms of employment may vary between organisations and even from one post to another. A consequence of the lack of standardisation

is an absence of job security. Furthermore, there is little professional support and no clear or defined career pathway for CRNs. The contribution of CRNs to the conduct of clinical research is acknowledged in reports and research strategy documents (over the years). However, a review of the literature revealed that there is little empirical data pertaining to the role of CRNs in Ireland. The exception is a report commissioned by the HRB that was published in 2008: 'Report on The Role of the Nurse or Midwife in Medical-Led Clinical Research' (NCNM 2008). The researcher, Sarah Condell, completed an intensive study that included:

a) A literature review of the international experience of the nurse and midwife role in medical led research
b) Site visits to international research facilities
c) Consultation with nurses/midwives currently in the role in Ireland (individual and focus-group interviews) (N=41)

The main findings of the study, which corresponded to international literature on the role of the CRN at that time were:

- Lack of visibility – the role of the CRN is largely unknown
- The CRN role is diverse - depending on setting, type & stage of study, composition of research team
- Professional development is self-determined rather than standardised
- There is a lack of opportunity for role progression
- Large variance in contracts, conditions and entry criteria
- Lack of consensus as to engagement with nursing and midwifery

Positive findings about the role in Ireland were:

- Tasks within the role cluster around the centre of the research continuum
- The role utilises nurse/midwife clinical practice skills
- Role itself is good source of job satisfaction
- Potential to build nursing & midwifery research in parallel with medical-led research

Condell made a number of strong recommendations, some of which provided a remit for IRNN activities, but many of which needed national commitment and resources:

- Need to establish a career pathway for clinical research nurses and midwives
- An agreed role title with a profile outlining professional responsibilities and competencies
- Established employment grades

    - Newly developed CRFs should lead to standardisation and regularisation of CRN contracts
- Increased understanding of the role of the research nurse
    - A profile of what the role entails and its contribution should be provided to key stakeholders
- Alliances with nursing & midwifery management and academia should be encouraged
- Access to appropriate orientation, education and training required

Anecdotally there has been little progression in these areas since this report was published over a decade ago. However, there has been significant investment in clinical research facilities (CRFs) and research infrastructure in Ireland, in some cases supporting the creation of CRN roles. This study provides a timely opportunity to measure the impact of these developments on the CRN role.

The IRNN have completed a number of surveys of members, primarily aimed at assessing their needs in relation to IRNN activity and support. A survey completed in 2010 attracted 41 responses and reaffirmed the need for IRNN to advocate for increased visibility for CRNs, integration with nursing services in affiliated hospitals, and assist with HR issues. In addition members wanted IRNN to provide continuing professional development and updates, and to share information, experience and support. While IRNN tries to meet all these needs it should be emphasised that these resources were commenced when there was a funding model that supported CRNs in certain CRFs to dedicate time to IRNN activities. The loss of HRB funded CRN posts has led to increasing pressure on committee members to fit IRNN obligations into an existing workload or to spend their own time and resources on IRNN activities. Without centralised support and resources this will not be sustainable.

The most recent survey of IRNN members (54 respondents) was published on the IRNN website in 2018 (https://irnn.ie/initial-report-2017-2018-irish-research-nurses-network-survey-research-nurses-midwives/). It reaffirmed findings of previous studies – variations in job title, roles and responsivities, and in terms and conditions of employment. 63% of respondents reported that they were on fixed term or temporary contracts, suggesting that little progress had been achieved. This led IRNN to consider completing a more comprehensive survey of the entire clinical research nurse and midwife workforce in Ireland.

In the period since the Count Me In study commenced an additional report, ‘Future Investment in Clinical Research’, was published by research stakeholders in Ireland. The steering committee for the report was coordinated by Clinical Research Development Ireland (CRDI), and included a representative of the IRNN committee. The report strongly endorsed the need for highly trained and specialist clinical research staff to underpin success of an integrated Irish clinical research system. “Long term funding for clinical research roles would enable the development

of secure career pathways and the retention of such staff". The report decries the anomaly whereby nurses and midwives have to resign from their permanent posts with health services in order to take up a post in clinical research. It recommends that CRF/Cs should be embedded in hospitals, with the same level of services and supports as other hospital departments, and that CRNs should be either directly employed by the hospital, or seconded without loss of benefits, to work in the CRF/C. This would not only provide security of tenure, and staff retention, but "would also facilitate a gradual cultural change in the present perception of research as a clinically irrelevant activity".

It is anticipated that the Count Me In study will provide data to further the justification of this argument, and the realisation that the availability of a skilled, confident and permanent CRN workforce will contribute to the success and reputation of clinical research in Ireland.

1.2 Study Rationale

The 'Count Me In' study was a national survey of Clinical Research Nurses and Midwives (CRNs) based in a variety of settings (e.g. universities, hospitals, industry, and primary care) in Ireland. The individuals and organisations approached for data collection were determined by the work location of known CRNs and research services, and the networks of research services known to the researchers.

When engaging with stakeholders about the needs of CRNs the first question IRNN representatives are asked is 'How many research nurses are there in Ireland?' We were unable to answer that question. IRNN has been successful in building up a membership consisting of approximately 100 CRNs nationally, but we are aware that many research nurses have not engaged with the network and may not even be aware of the supports available to them. There are also groups of CRNs – e.g. Oncology Research nurses – who have not fully engaged with the network as their needs are met by Cancer Trials Ireland and the Oncology nurses association. However, there is a move towards integration of cancer research into CRFs, and at local level CRNs find their paths cross, providing opportunities for mutual support. In order to advocate for CRN recognition and support this survey attempted to incorporate all groups of CRNs.

On completion of the survey participants in the study were invited to register on the IRNN database, and directed to the separate survey link for that purpose. On completion of the Count Me In study this CRN database will be retained by IRNN as a live register of research nurses and midwives. This will be in adherence to the General Data Protection Regulations (GDPR), and individual data will not be shared without explicit consent. Participants will be able to self-register via the IRNN website and can also request for data to be removed or amended at any time. Administrative access to the database will be controlled by selected members of the sitting IRNN committee.

2 STUDY AIMS, OBJECTIVES AND ENDPOINTS

2.1 Aim of the study

The primary aim of the study was to describe the clinical research nurse/midwife workforce in Ireland

2.2 Primary Objectives

- To discover how many nurses/midwives are employed specifically in clinical research nurse or midwife posts in Ireland
- To describe terms and conditions of employment, such as security of tenure, employment grade and career pathway available
- To identify the primary roles and responsibilities of CRNs in Ireland
- To develop a database of clinical research nurses/midwives for future contact (optional)

A secondary objective of the study was to create a national CRN Database. This will be retained securely on the IRNN website and will be accessible to authorised member of the IRNN committee and website support personnel only. It will be used to track CRN employment trends and to advocate for issues of concern to CRNs such as security of tenure, clarity about employment grades and opportunities for professional development and career progression.

During the study the database was held by the researchers, with no other access permitted. Upon completion of this study the CRN Database will be maintained as a live dataset on a secure database managed by IRNN. To ensure accuracy CRNs will self-register and can later submit a request to the administrator to have their data amended or removed. CRNs will have access to their own data only, and the list will not be publicly available. The control of this data will be transferred to selected members of the currently elected IRNN committee, who will be identified on the IRNN website. Details of how the data will be managed will be available on the website.

2.3 Study Endpoints

- The completed and returned surveys
- Consent for personal data to be held on the CRN database

3 STUDY DESIGN AND METHODOLOGY

3.1 Study Design

This was a quantitative, descriptive study of the CRN workforce in Ireland. The study population was the entire CRN workforce. Based on existing knowledge of staffing levels in CRFs and other research units it was 'guesstimated' that there are approximately 200 CRNs working in Ireland. However, the actual number of CRNs is a known unknown. Therefore an enrolment target could not be set, but the intention was to achieve contact with all members of this population, and to include as many as possible in the study.

3.2 Inclusion and Exclusion Criteria

Participants were considered eligible for inclusion in the survey if they fulfilled the following criteria:

- A nurse or midwife on the active register of An Bord Altranais agus Cnáimhseachais (Nursing & Midwifery Board of Ireland)
- Currently employed in a clinical research role and/or setting

Participants were considered ineligible if any of the following criteria are met:

- Their role involves an 'element' of clinical research, but is not the primary focus or responsibility*
- Nurses/midwives completing nurse led research for an academic award (i.e. nurse researchers)

*There was considerable debate about whether nurses or midwives employed in another role but who became involved in clinical research as part of their role should be included. However, as these nurses held a substantive post (usually within the HSE) that was not directly impacted by research activity, and which had security of tenure in its own right, it was not deemed appropriate to include them.

3.3 Data Collection Tool

A survey is considered the most appropriate method to gather basic data from a large number of participants over a short duration. A data collection tool was developed using Survey Monkey® to collect a minimal data set based on the outlined objectives. Questions were designed to explore variables associated with the survey objectives and as identified in previous studies and literature. There were 10 questions in total, although three of these related to eligibility criteria and consent for retention of data stored on the separate CRN database. A mixture of closed questions and Likert scales were used to capture data. Where appropriate

questions had optional sections or 'other' comment boxes to collect responses that may not have been anticipated by the researchers.

A participant information leaflet was provided to each potential participant. To ensure confidentiality was protected consent to participate was assumed by the return of the completed survey and every effort was made to ensure that answers to questions would not identify the respondent's research site or the specific area of practice. Before finalising the data collection tool advice was sought from the statistical support services of the organisation, and the tool was reviewed for reliability and validity by content experts and by local research nurses. An external researcher with knowledge in this area was asked to review the questionnaire and evaluate whether the questions effectively captured the objectives under investigation, and the survey was pilot tested by a small number of local CRNs, who were asked to complete the survey and provide feedback on usability.

Due to the short timeframe for collecting and analysing data a deliberate decision was made to collect high level data only and to avoid straying outside strict parameters. It was anticipated that the data collected will inform future, more detailed studies. In retrospect, it is evident that there was scope to ask supplementary questions, but the pragmatic approach taken did result in the delivery of the project on time and within budget.

3.4 Participant recruitment

Previous efforts to conduct surveys of IRNN members using Survey Monkey® had a limited success with a lower than expected response rate. A more direct approach was taken with this survey. The study was promoted on IRNN website, at educational workshops and networking events. During the development stage of the project 'consent to contact' forms were completed by attendees at the IRNN conference (in November 2018) and at other appropriate gatherings. These lists included CRNs who provided their email addresses for the survey and employers of CRNs who were willing to pass on the survey within their organisations. In addition the project manager established contact with other known employers of CRNs, including achieving commitment from a HSE gatekeeper to circulate the survey to HSE employees. Collaborators on the HRB grant to IRNN, such as Cancer Trials Ireland and Clinical Research Coordination Ireland (CRCI), also committed to circulating the survey links.

Data collection commenced on 28th January 2019 and was closed on 15th March. A variety of methods were used to circulate the survey:

- Using SurveyMonkey® the survey link was sent to individual email addresses on the contact lists compiled during the set up stage
- Details of the survey were posted on the IRNN website, and information shared via the members' newsletter and twitter

- IRNN 'Champions' in research sites and organisations circulated the survey links to CRNs locally and via their websites
- Hard copies of the survey were available for distribution locally or at research events if preferred – to be returned anonymously to researchers
- Weekly recruitment numbers were posted on the IRNN website and tweeted from the IRNN account @Irish_rnn.
- The use of SurveyMonkey® to circulate the data collection tool meant that the researchers did not know the identity of respondents, but periodic automated reminders were circulated as above.

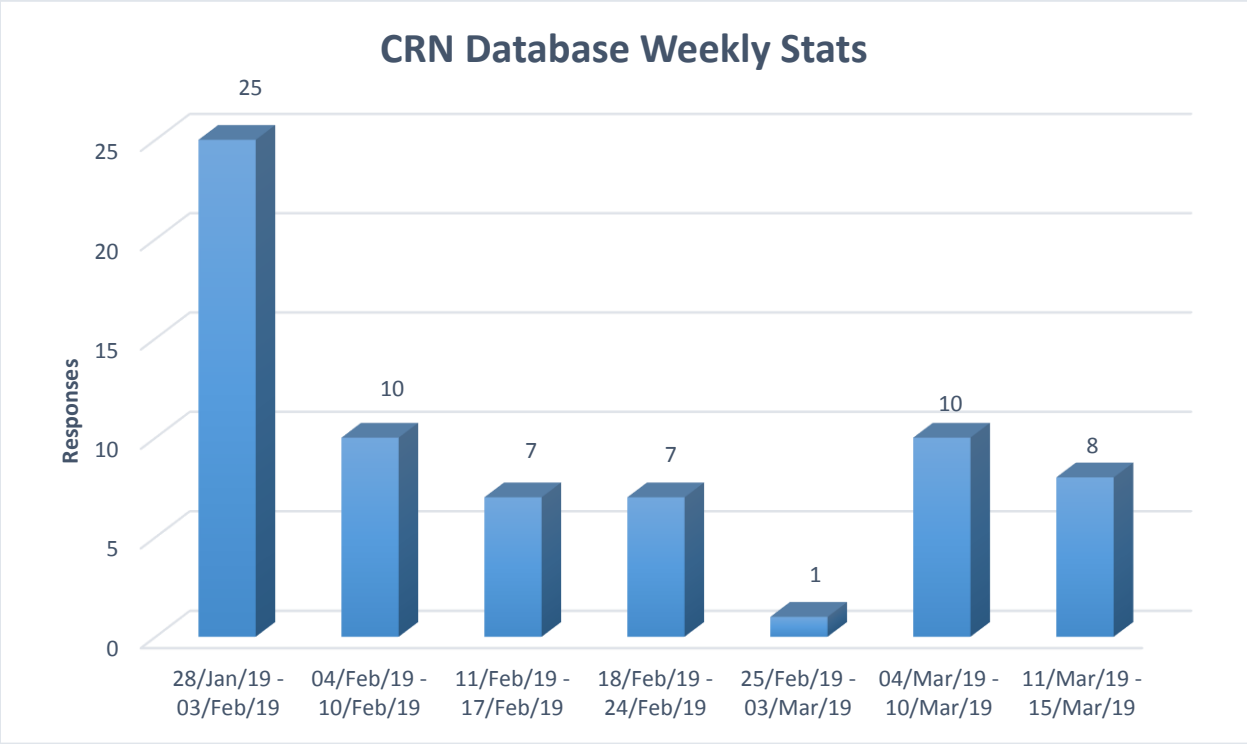

Figure 1: Weekly participant recruitment

As was expected the response in the first week was very good. This was partly due to the level of promotion and engagement with stakeholders during study set up. By weeks 4 and 5 responses had dropped significantly, suggesting that the majority of CRNs had already participated. At week 5 we sent reminders to everyone which resulted in an increase in responses for week 6.

A total of 143 responses were received. This is almost three times more than previous studies in this area, which recruited 41-54 participants. As previously stated it was not possible to define the population size and recruitment target, and therefore not possible to estimate the response

rate, but it seems reasonable to claim that this cohort is highly representative of the total population.

When assessed against the inclusion and exclusion criteria two respondents were deemed ineligible, therefore a total of 141 participants were included in the data analysis.

On completion of the survey participants were given the option to proceeding to a separate database to provide contact details for future contact and retention of information on the CRN Database. This information was not linked to individual survey responses. 60 participants availed of this option. This data was retained securely by the researchers during the study, and will be transferred to the custody of the IRNN committee, and maintained as a 'live' database of research nurses and midwives in Ireland. This database is being developed in compliance with requirements of GDPR. CRNs will have the option of having their data altered or deleted on request.

4 STATISTICAL ANALYSIS AND DATA MANAGEMENT

4.1 Statistical Analysis

Data were collected using SurveyMonkey®. The majority of respondents used the web links provided to complete the survey electronically. Five CRNs submitted hard copies of the completed survey, and these were entered into the SurveyMonkey database by the study project manager and verified for accuracy by the Principle Investigator (PI). As required by the ethical approval for the study hard copies of the survey form were destroyed following entry into the database and verification of accuracy.

During the data collection stage the study team created a database for analysis, using IBM SPSS Statistics, Version 25. Variables were derived from the survey questions and response options provided. When provisional data in SurveyMonkey® was reviewed additional variables were identified in relation to some questions – e.g. from answers given when the 'other' option was chosen. Advice was provided by the RCSI Data Science Centre before the database was finalised.

4.2 Data Management

Data from the surveys completed on-line were printed in hard copy, numbered, and entered into the SPSS database by the project manager. A maximum of 20 completed surveys were entered per day to reduce the risk of error. A data entry log was maintained to record the date on which surveys were entered. Where there was a conflict between answers provided to questions the project manager and PI reviewed the completed survey together and agreed on the most accurate interpretation (logic checks). The PI carried out quality review of a minimum of 10% of the entered data to check for discrepancies between the hard copy and the entered data. Any discrepancies were corrected and the date of change was recorded on the data entry log. On completion of the study report the hard copies of survey forms will be scanned to the electronic study file and paper copies destroyed. The scanned copies and SurveyMonkey® responses will be destroyed once all data accuracy has been verified. This is expected to be no later than July 2019. Data entered in the survey database are now anonymous and cannot be linked to the participant, therefore requests for information to be withdrawn is not possible. The study data will be deleted once the researchers are satisfied that all data analysis has been performed and no further interpretation of the data is necessary. This is expected to be no later than December 2019.

SurveyMonkey® was also used to design a CRN database that was separate to the survey responses. When a participant consented to providing identifiable data, they were granted access to a link to a separate Database in SurveyMonkey® and were asked to provide the

following information:

- Name
- Job title
- Place of work
- Contact number
- Email

The IRNN Committee are in the process of commissioning a secure database that will house this information. Until then it will be retained securely by the researchers. Following transfer of the data to the IRNN database, and verification of accuracy, the raw data in SurveyMonkey® will be deleted. This is expected to be no later than September 2019. The IRNN committee will have control of the CRN Database, and retain it as a live record of CRNs in Ireland, with their consent. The website developers have confirmed that the database will comply with GDPR. A data protection impact assessment was completed to identify and mitigate any potential risks. Data privacy statements will be available for review by those registering on the database.

4.3 Ethical considerations

4.3.1 Human Subject Involvement

The participant population consisted of clinical research nurses and midwives who fulfilled the inclusion/exclusion criteria and who were willing to complete the survey. In the interests of data minimization identifiable or sensitive data regarding personal characteristics such as age, gender or ethnicity were not collected. Participants could consent to provide contact details for inclusion in the CRN Database, but this was not linked to their survey responses. This data is identifiable but does not contain any sensitive information.

It was possible that colleagues and staff members associated with the investigators may feel undue influence to complete the survey. The researchers acknowledged this and, whilst anxious to encourage participation, endeavoured to assure staff members and colleagues that participation was voluntary, and the survey data would be completed and submitted anonymously.

4.3.2 Ethical approval

Advice was sought from the RCSI ethics committee as to whether the survey would require ethical review prior to commencing. Due to the fact that the survey will generate a report and publications to a wide audience, ethical approval was required.

The submission of the survey protocol and participant information leaflet was made at the end of November 2018 for review at the ethics committee meeting scheduled for December. A

response letter was received from the ethics committee in early January 2019. Clarification questions in relation to the validation methodology and data protection were raised, and answered. As an institutional requirement, a data protection impact assessment was also completed to ensure that all measures to safeguard and protect personal information relating to participants and the investigative team were in place.

On receipt of approval from the DPO the application was deemed approved by the REC. There was a requirement that electronic data was to be saved on a secure, password protection section of the REC website, and that any hard copies of data and identifiable subject information should be scanned to this location and destroyed once source data verification is complete.

4.4 Participant Information and Consent

A participant information leaflet (PIL) was provided electronically to all email recipients, and was also available in pdf format on the IRNN website. To ensure confidentiality implied, rather than explicit, consent was obtained, with consent deemed to be valid through the voluntary completion of the survey. To ensure participants had received the PIL they were required to answer a question to that effect before commencing the survey.

As study data was not linked to individual respondents there was no facility to remove data following submission. On completion of the survey participants had the option of exiting the programme or opting in to the CRN Database, where they could provide contact details for retention by IRNN. The PIL made it clear that this was optional, that their contact information could not be linked to their survey responses, and that they could have their data amended or removed at any time.

5 RESULTS

5.1 Demographics

141 CRNs were included in data analysis. As previously stated, this represents three times more CRNs than previous studies and surveys, and we are confident the results are generalizable to the population. Regional distribution of respondents broadly reflected the locations of CRFs and Cancer Clinical Trials Units nationally. The majority of CRNs were based in Leinster (60.4%), followed by Munster (27.3%), Connacht (11.9%) and just one response from Ulster (0.7%). It is not possible to state whether the low response rate from Ulster indicates a lack of clinical research in the border counties, or a failure on our part to establish contact with CRNs in these areas.

CRNs in Leinster & Munster were more likely to work in a hospital site than in a CRF, while CRNs in Connacht were primarily located in a CRF. When these data were combined there was a relatively even distribution of CRNs who were based in a hospital setting compared with those located in a CRF, just under 47% and 44% respectively. Work location was not necessarily the same as the employing institution. For example, CRNs employed by a PI or research organisation/network may work in a CRF/C or hospital setting. The distribution of work locations are outlined below:

- Hospital setting: 46.81%
- Clinical Research Facility/Centre: 43.97%
- Primary Health or Community Setting: 4.26%
- Other: 2.84%

Figure 2 shows the distribution of employers of CRNs. A majority of CRNs (38.3%) were employed by a clinical research facility, with an additional 7.09% reporting that they were employed by a university. The researchers were surprised to find that 24.11% of CRNs were employed through the HSE, as IRNN had not previously engaged with this cohort. IRNN members are primarily employed through CRFs or by investigators. We did not attempt to elicit area of specialist practice, as in the small world of research it would have potentially identified respondents, but we consider it possible that CRNs employed through the HSE are mainly oncology research nurses whose contracts are with the HSE, although their salaries are reimbursed by Cancer Trials Ireland.

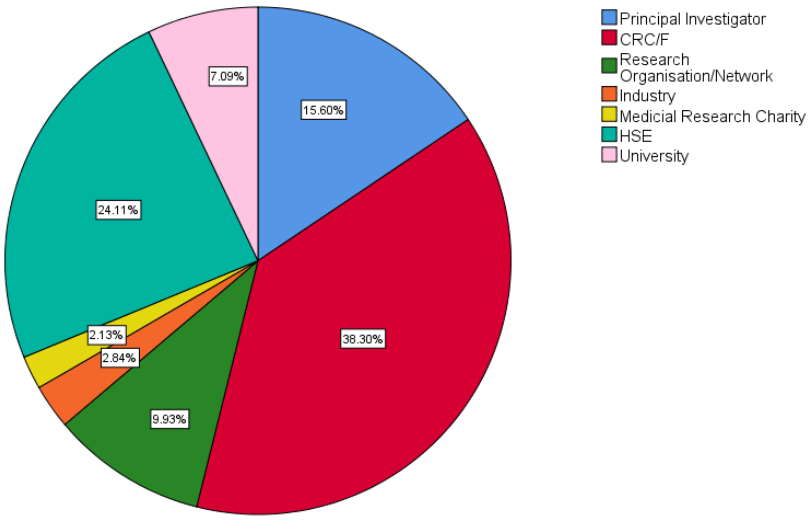

Figure 2: Employers of Clinical Research Nurses or Midwives

5.1.1 Length of time in current post (Table 1)

46.1% of respondents were less than 2 years in post while 25.53% were between 2-5 years in their current role. 14.18% of respondents held their current CRN post for 5-10 years, with 14.18% (N=20) in post for more than 10 years. Considering that many CRFs and research units are in place for 10, 20 or more years it we might expect to see more of a skill mix, or an even distribution of novice to experienced staff. This could be seen to reflect the lack of permanency and security of tenure associated with the CRN role, and implies that the strong investment in research infrastructure over the past decade has not impacted on the longevity and security of CRN posts, or supported the development of a large cohort of skilled, experienced research support staff.

Table 1: No. of years in post

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	<1 year	40	28.4	28.4	28.4
	1 - 2 years	25	17.7	17.7	46.1
	2 - 5 years	36	25.5	25.5	71.6
	5 - 10 years	20	14.2	14.2	85.8
	>10 years	20	14.2	14.2	100.0
	Total	141	100.0	100.0	

When we compared length of time in post with employer, this theory was reinforced. CRNs working within the HSE or directly for the investigator were more likely to be in post for 2 years or more (58.82% HSE; 72.72% PI) compared to CRF/C (55.55%) and university (30%). The study did not explore length of service within organisations, nor did it ask about previous clinical

research experience prior to taking up the current post, which would in hindsight have been useful data to have collected. Due to the short duration of some research contracts CRNs can move from one post to another within or between organisations.

5.1.2 Role title

Previous studies have highlighted the lack of consistency with role title for nurses and midwives working in a research setting. In this study 56% reported that they used the title Clinical Research Nurse, with the next most frequent title that of Research Nurse Manager (12.77%). These were followed by 'Other' at 8.51%, Research Coordinator (7.08%), Clinical Trials Coordinator and Study/site Coordinator at 4.96% respectively, and Clinical Research Midwife (3.55%). The category of 'other' included Clinical Trials Manager (n=4), Research Project manager (n=2), Project Lead, Clinical Service Development manager, Education Lead, Research Associate and Research Advanced Nurse Practitioner (1 of each). There appeared to be more inconsistency in the managerial role titles. This could be due to the that they are positions usually developed to meet the specific needs of a particular CRC/F

5.2 Terms and Conditions of Employment

5.2.1 Salary scale

Despite the fact that almost half of respondents were less that 2 years in post, a majority of 60.28% reported that their salary scale was at Clinical Nurse Manager (CNM) 1 or CNM 2 level, with less than 20% reporting that they are employed at staff nurse level (Figure 3). While this might be attributed to the responsibilities of the role it also indicates a possible disparity between clinical research experience and employment grade.

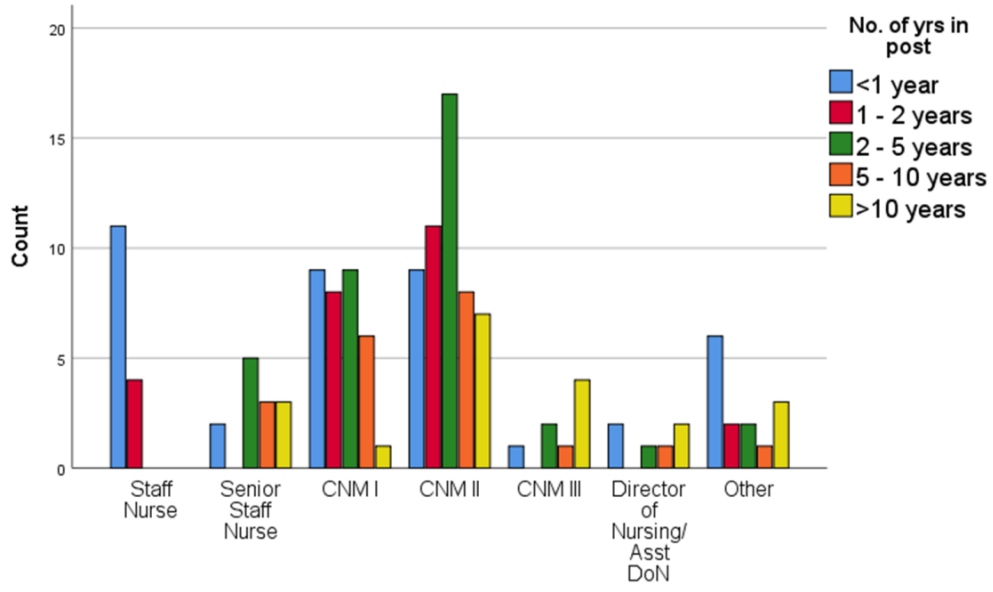

Figure 3: Years in current post compared to nursing grade

The lack of information about prior research and/or clinical experience makes it difficult to establish whether CRNs are being paid at a level commensurate with their knowledge, skills and experience. Data did, however, demonstrate that CRNs bring to the role impressive academic qualifications (see section 5.3), but also found that employment grade did not equate to job security (Figure 4). With the exception of CRNs in post for more than 10 years, the majority of CRNs were on fixed term or temporary contracts. When we compare contract type across grades it is evident that seniority does not denote security, with the minor expection of those at director of Nursing level.

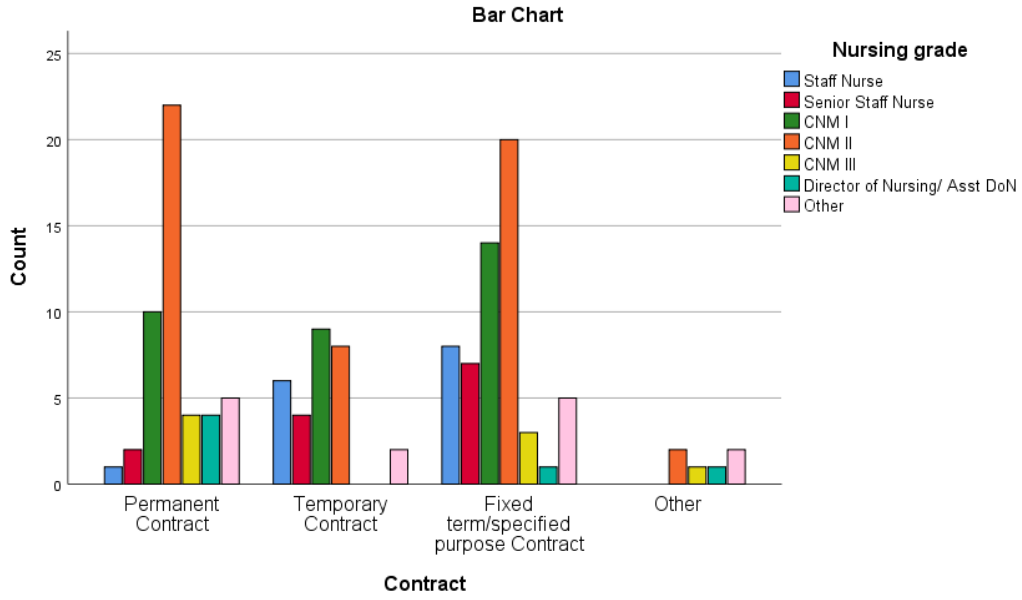

Figure 4: Contract type by nursing grade

5.2.2 Security of tenure

When we looked at the correlation between the type of contract and employer (Figure 5) we found that 72.2% of CRNs employed by CRFs and 81.81% of CRNs employed by a PI were on either a fixed term or temporary contract. Fixed term and temporary employees are likely to have no regular salary review, with the majority on fixed salaries, which can be stopped abruptly when research funding runs out.

It emerged that of 34 respondants employed through the HSE, 76.47% (n=26) were on permanent contracts compared to only 22.22% (n=12) of CRNs employed by a CRF. This is a significant difference which demonstrates the disparity between employers of CRNs. Furthermore CRNs on permanent contracts are more likely to be on an incremental scale or have regular salary reviews.

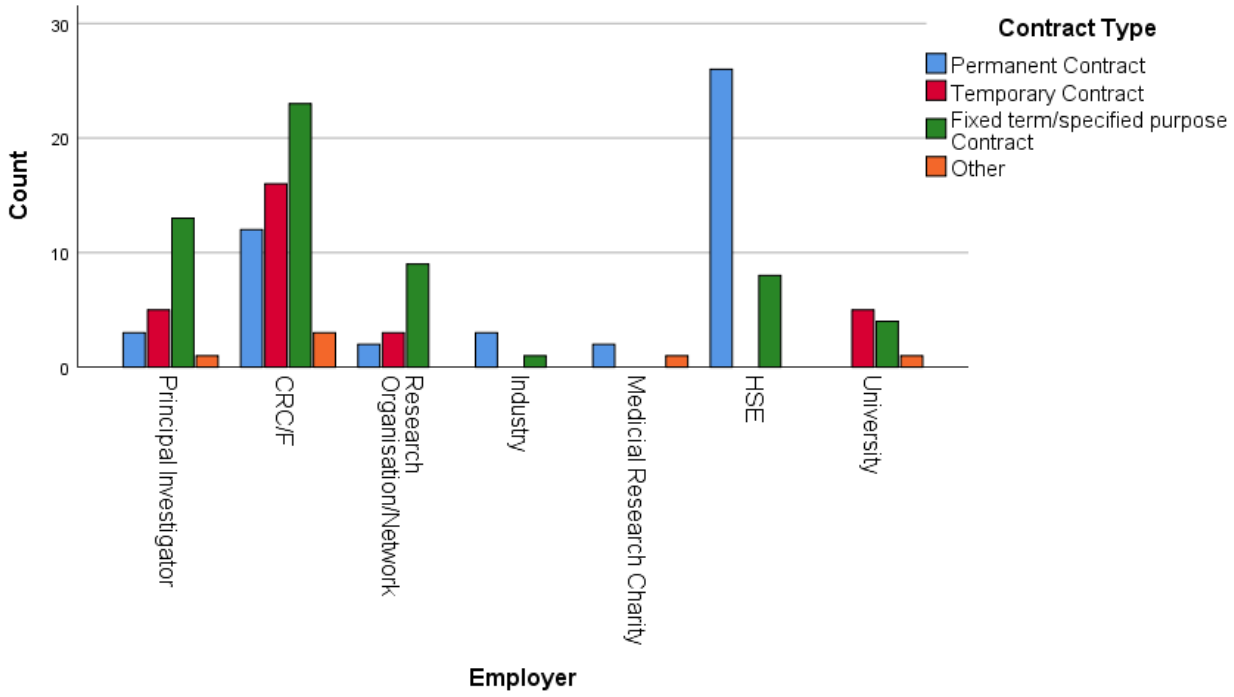

Figure 5: Contract type by employer

5.2.3 Salary review

Regardless of the lack of permanent posts overall, 55.3% (n=78) reported that they were on an incremental salary scale while 44.7% were not. Of the latter group (N=63), 20 reported that their salary was never reviewed, including a CRN 20 years in post. 15 reported annual salary review and 5 biennial. Of the remaining responses, 7 were on fixed salary, 6 said 'at managers discretion', 4 'at contract renewal' and 3 reported that they were on the top of their payscale without an avenue for further progression. 2 had their salary reviewed on request and 1 reported three monthly review. As many of these research contracts were temporary and short term the review period may not be problematic, but the data does highlight the ad hoc and inconsistent approach to CRN contracts.

5.3 Academic Qualification

All participants were required to be registered with NMBI, and therefore all had a professional qualification, in nursing and/or midwifery. Nurses and midwives graduating in Ireland since 2013 hold a BSc, while this was awarded for nurse training in the UK some years prior to that. The survey did not ask for length of time as a registered nurse or midwife, another variable item that may have been useful during data anaylsis. A number of survey items explored engagement in continuing professional development and atainment of academic qualifications.

We asked about the highest level of academic qualification attained:

- 54.61% of respondents had completed a Postgrad Diploma or MSc. programme
- 2.84% had been awarded a PhD.
- 31.2% of respondents had not received a major academic award (BSc, MSc,PhD)

Only 10 respondents (7.1%) reported that they had not undertaken any third level education. This demonstrates a commitment to learning and illustrates the high level of education and qualification of research nurses and midwives in Ireland. Access to post graduate courses for CRNs, in the form of funding or study leave, is at the discretion of the employer, but many research grants do not include contingency for course fees for CRNs wishing to further their knowledge.

The survey did not explore in detail completion of short courses or in-service training, although we did ask if participants had completed a course in clinical research. The distribition of responses is reported in Figure 6. 56% of participants had not completed a clinical research course, and the remainder report engagment at levels from single modules through to PhD. Over 100 CRNs completed some or all of the Postgratuate Certificate course for CRNs in RCSI from 2009 – 2015. The loss of centralised support for this programme made it unsustainable, and the fact that less than 18% report that they completed a postgraduate certificate in clinical research implies that some of these CRNs are no longer working in clinical research. Furthermore it highlights the difference between CRNs and nurses employed in other recognised specialities within the HSE. Nurses employed at a CNM level would have access to a specialist course whilst this is not the case for CRNs. There are Diploma/Msc programmes in clinical research available in three universities nationally, but it is unclear whether these deliver the bespoke content required for the role of CRN.

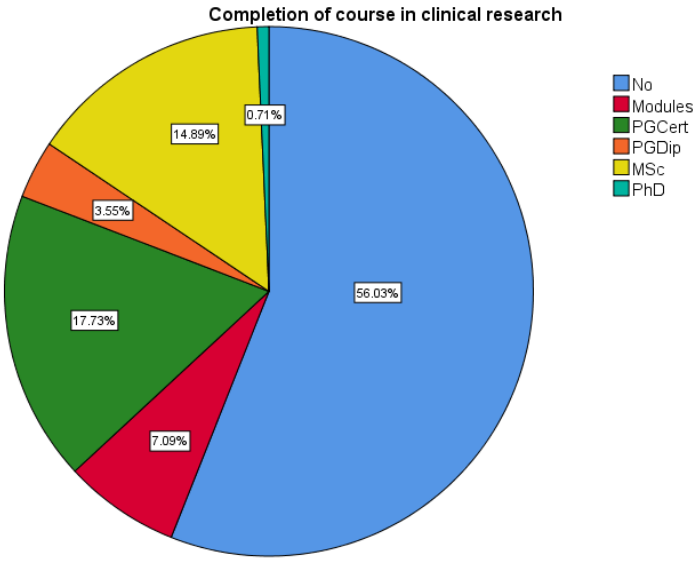

Figure 6: Completion of course in clinical research

5.4 CRN responsibilities.

The roles and responsibilities undertaken by CRNs were determined by the setting and type of research that they were involved with. Senior or management duties such as project management were primarily the responsibility of CRNs employed at Clinical Nurse Manager (CNM) and Director of Nursing grade. However in some cases CRNs employed at staff nurse level were undertaking these higher level functions. Table 2 presents a summary of the tasks and responsibilities most commonly undertaken by CRNs.

Responsibility	%	Responsibility	%
Participant recruitment	85.5	Study set-up	69.5
Informed consent process	78	*Staff orientation/training	65.2
Adverse event management	78	*Project management	48.2
Study visits	77.3	*Ethics application	47.5
Site file management	77.3	IMP management	44
Case report form completion	73.8	*Study development	39
Sample processing	70.9	*Research site management	34

Table 2: CRN Responsibilities **** Indicates higher level or management functions***

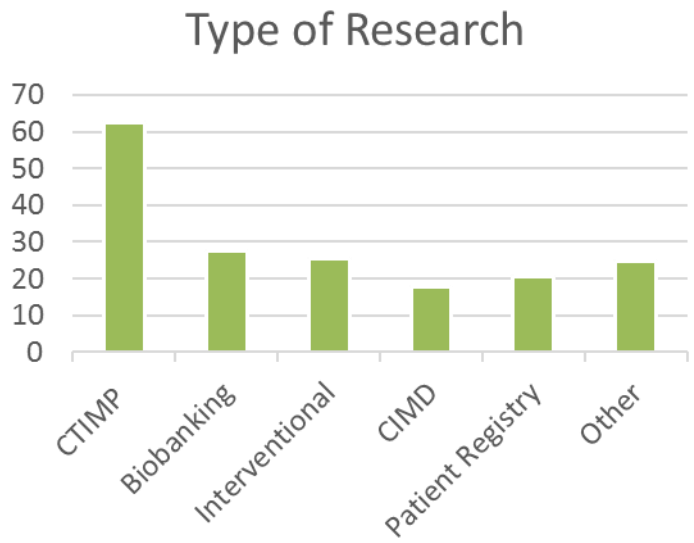

Table 3: Type of research

The types of research respondants worked on are reported in Table 3. Over 60% of CRNs were involved in clinical trials of investigational medicinal products, and some nurses worked on two or more types of study. The majority of CRNs reported working across many areas of practice.

These functions may have been performed under the supervision of a PI only, by a CRN working in isolation from other CRNs, or the CRN may have worked in a well resourced CRF or research unit, supported by colleagues and mentors.

It is not possible to comment on the competence of the individual CRNs to perform the reported tasks, or the level of supervision and support they receive. This depth of information was beyond the scope of the 'Count Me In' survey, but suggsts topics for future research. The IRNN has developed orientation and competency packs for use by CRNs that are usful tools for accessing skills and competencies, but these are most useful where there are experts and role models available to guide practice.

5.5 Satisfaction with the role

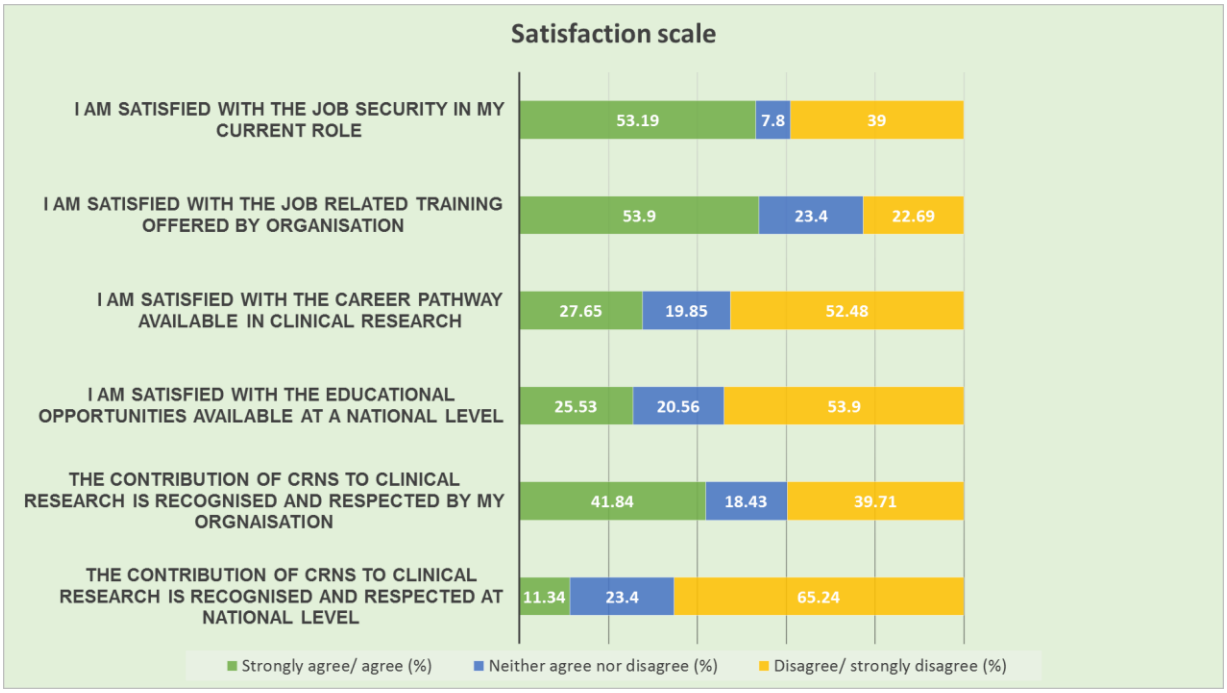

Table 4: CRN Satisfaction

The final section of the questionnaire looked at the overall level of satisfaction of CRNs within their role. A series of statement were provided and participants were asked to indicate their level of agreement on a scale from 'Strongly Agree', 'Agree' or 'Neither Agree or Disagree' to 'Disagree' and 'Strongly Disagree'. In Table 4 we have merged Agree/Strongly Agree, and Disagree/Strongly Disagree.

Despite the fact that a significant portion of respondents were not on permanent contracts, 53.19% reported that they were satisfied with their job security in their current role. A closer

look at this result shows that 88.23% of CRNs employed through the HSE were satisfied with job security compared to 36.28% of those employed in a CRF, 27.27% of those that were employed directly by a PI, and just 25% of CRNs employed by or through a university. This illustrates that security of tenure is still a significant problem for the majority of CRNs employed outside of HSE settings.

53.9% were satisfied with training in the role received locally, but a similar number expressed dissatisfaction with the educational opportunities available to them nationally, with only 25.53% expressing satisfaction in that domain. This again highlights the non-availability of a specialised course in clinical research coordination and management, and the lack of dedicated funding for CRN education and development. 65.2% of participants reported that part of their role was to provide orientation and training, which is likely to include support of other CRNs.

When faced with the statement 'I am satisfied with the career pathway available to me' less than 9.22 strongly agree and 18.44 agreed. 19.85% did not agree or disagree. 26.24% disagreed with the statement while a similar percentage strongly disagreed (52.48% in total). The need for a career structure and pathway for CRNs is well documented, most prominently in the report commissioned by the HRB in 2008 (NCNM 2008) but it would seem that CRNs continue to be a low priority in terms of career progression within this specialist area of practice. CRNs with higher academic qualifications were less likely to be satisfied with their career options than those with no third level qualification or with a BSc. (Figure 7). 25% of those with an MSc, and none with a PhD, expressed satisfaction with opportunities for career progression.

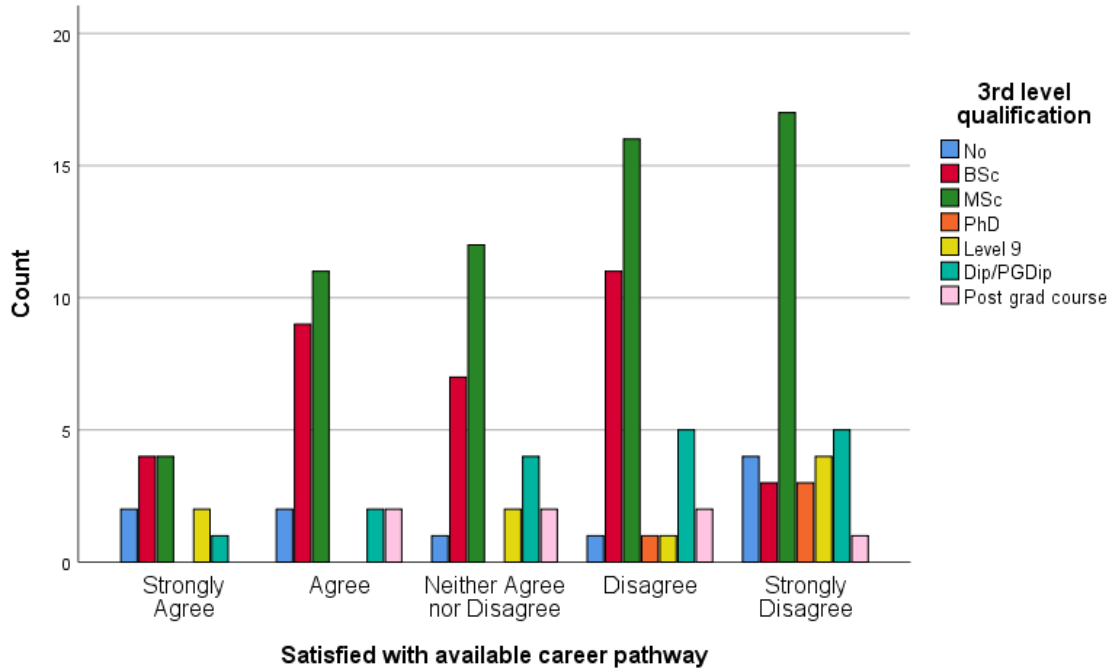

Figure 7: Satisfaction with career pathway by highest academic qualification.

The final survey questions asked participants to rate the recognition and respect given to CRNs within their organisations and nationally. Opinions about whether the contribution of CRNs is recognised and respected within individual organisations were evenly divided between satisfaction and dissatisfaction, but a mere 11.34% believed that the contribution of CRNs to clinical research is recognised and respected nationally. This is a damning indictment of the treatment of CRNs who are at the coalface of research, supporting the conduct of safe, high quality research, and ensuring that the rights, safety and wellbeing of research participants is respected.

5.6 Free text comments

Participants were given the option to add free text comments before exiting the survey. These can be reviewed in Appendix 1. The overriding themes that emerged were related to career pathway and job security. There was also a call for restoration of a formal programme of education for CRNs, and opportunities for professional development.

"I feel strongly there should be a career pathway, that having completed 1-2 years we should be in a permanent role, and there need to be increments. I have over 20 years' experience in research (previously employed by PI) and in order to secure a fixed purpose contract I had to accept a drop in salary." **Participant 38**

"I would be a lot happier in my role if there was more job security and recognition. Research is one of the most important aspect of modernising the health system, however its staff are not respected or acknowledged." **Participant 3**

"I would like to be recognised by my success to date. There is no opportunity for promotion. I have proven my capabilities time and time again and it still isn't recognised. I do the exact same job as my colleagues and they are on the HSE CNM2 grade." **Participant 58**

A number of respondents felt their contribution was undervalued, and that there was little awareness of what the CRN does:

"*In my experience management would not know role or duties you perform within a clinical research study."* **Participant 28**

"It can be a very unclear role in our organization. There is a lack of support and understanding of the research nurses role from all members of the MDT" **Participant 65**

"The role of the research nurse is undervalued by PI and hospital management and also within the 3rd level institutions, it is refreshing to see that this survey identifies the difference between nurse led research and a research nurse working within the clinical trial framework." **Participant 88**

Salary level and lack of increments was also problematic, with experienced CRNs stating that they had taken pay reductions to start in a new post despite previous experience or when returning from abroad:

"My biggest annoyance is the HRB funded salary set in the post I will start next week. Post looks very interesting but one should progress as in other parts of nursing not take 1/3 less salary with no negotiation" **Participant 117**

"I have recently returned to the country after gaining further qualifications and strong experience in oncology research. I have found if I want to continue to work in this area of healthcare, my only current employment options are short term contracts outside of the HSE. I believe the service I work in (early phase oncology trials), and would ideally hope to remain in, is a critical service to oncology patients. However without job security or the possibility of HSE investment in cancer research in the future I am not sure how long I can continue to work in this field. At present in Ireland there is a very limited and unsure career path for oncology research nurses" **Participant 48**

"I worked in research for 6 year in Australia and found that the opportunities there were far greater" **Participant 107**

Conversely, others commented on the frustration associated with new, inexperienced nurses/midwifes being offered posts at a salary that did not reflect their lack of experience:

"New staff can start on the same salary with no experience or training, they will ultimately make a lot of mistakes and learn on the job, but this is not good for the quality of the research outcomes. For example it could be a year of poor data collection or poor blood processing or poor patient monitoring etc." **Participant 44**

"Another thing I found unfair was a 3rd year graduated Registered Nurse being given a CRN job at CMN II salary, that was in-experienced in nursing and in general!" **Participant 43**

Comments also reflected that CRNs enjoyed the role despite the challenges:

"The role as a clinical research nurse is a fantastic job which I personally love. However the biggest problem and reason for nurses not choosing this career path is the lack of job security" **Participant 116**

"Instability of job security is a pain when seeking a mortgage etc. just for doing a job you enjoy" ***Participant 43***

Finally, some respondents commented on what needs to happen in the future:

"Formal recognition of the role is required with associated bench marking. Terms of employment need to dramatically improve for some CRNs. Formal training for CRNs should be reinstated as a way to support career progression and CPD" **Participant 41**

"*The infrastructure needs to be in place for the role to develop and succeed i.e. administrative staff, dedicated pharmacy staff, flexibility to employ staff to meet data entry deadlines etc."* **Participant 109**

"I would love if the CRN was recognised as a specialist role. There should be advancement to Advanced Nurse Practitioner level" **Participant 21**

"It would be great to see recognition of research nursing as a specialty within nursing and increase the awareness of it as a career pathway" **Participant 1**

6 DISCUSSION

This study was completed to a tight timeline and was by necessity limited in scale and depth. Nevertheless, it provides the most comprehensive examination of the research nurse and midwife resource in Ireland to date, and provides data that can be used for planning the future resourcing of clinical research. It also provides very real challenges for employers and research stakeholders, who for too long have failed to address the problems faced by CRNs in relation to terms and conditions of employment, professional development and career progression, problems which were previously highlighted over 10 years ago.

6.1 Investment in Clinical Research

It cannot be denied that there has been significant investment in clinical research infrastructure in Ireland during the past decade, but it remains to be seen what the legacy of this investment will be. Funding comes and goes, and the lack of continuity can result in wasted effort as well as wasted money. Clinical research nursing, as a specialist area of nursing practice, received a significant boost during the DCCR funding cycle, both through the creation of networked CRN posts across the affiliated CRFs, and the availability of a specialized postgraduate certificate course, that provided unique content about all aspects of the study coordinators role. A crucial element of the DCCR funding was the appointment of a national Director of Nursing, who, while continuing her own role in a CRF, had protected time to dedicate to CRN support. Funding for these functions was not continued beyond the lifetime of the DCCR grant, however, and not only was the course no longer viable, but network CRNs, many of whom had been facilitated to complete the postgraduate certificate, found that their posts were no longer funded. CRNs either left or were reallocated to other contracts. This cyclical approach to research strategy needs to be replaced by long term investment in a sustainable research infrastructure.

6.2 Role Longevity and Career Progression

In this study findings in relation to length of time in post confirmed that CRNs do not, or cannot, stay in the same post for many years. While the skill mix of clinical research staff was not explored, statistics in relation to length of service suggest that there may be a concentration of less experienced staff overall. An alternative interpretation is that CRNs have worked in clinical research for longer periods, but the nature of their contracts meant that they have had to change to new contracts or investigators depending on the available work. Free text comments demonstrated the frustration experienced by CRNs, with some stating that they were actively seeking opportunities outside of research or, indeed, the nursing profession.

The obvious dissatisfaction with opportunities for career progression found in the study points to the need for a more formal, structured approach to the employment of CRNs. The time has come to address this long-standing issue. With the exception of pharmaceutically sponsored trials funding for clinical research ultimately comes from the Department of Health or other government departments. It should be possible for funding bodies and the HSE to find solutions to this challenge. The survey results support the need for CRNs to have secure, permanent contracts of employment, ideally through, or strongly affiliated with, the HSE, regardless of who ultimately funds their salary. It is no longer acceptable for CRNs to have piecemeal contracts that depend on the good will of an employer for salary review or extension of contract.

Anecdotally we also know that having to recruit and employ appropriately skilled CRNs for research projects is a huge source of frustration for investigators and can lead to delays in study start up. It would not be a massive investment to create permanent posts for CRNs in the CRFs and research units affiliated to hospitals, or employed by external agencies but located in hospitals. This model is already in place for the cancer trials units located throughout Ireland. This model would provide a far stronger base for clinical research than the current structures. A more integrated staffing model would also counteract some of the complications that arise in relation to the health research regulation and the clinical indemnity scheme.

Not all of the problems associated with career progression are related to funding – they can also be attributed to the staffing models implemented within CRFs. Despite the fact that the newer CRFs all received government funding through the HRB there was no standardised approach to employment grades or skill mix. The established model of employment of nursing staff within healthcare services enables employment of nurses and midwives on the pathway from staff nurse/midwife (starting at an increment scale commensurate with experience, and with annual incremental progression), to senior staff nurse/midwife, clinical nurse specialist or clinical nurse manager, and finally advanced nurse practitioner or senior nurse management (Director of Nursing) grades. This model was not adopted for CRFs, and it was deemed acceptable that in some sites all CRNs were initially employed at staff nurse/midwife level while in others all were employed at CNM 1 level, regardless of their years of experience or clinical expertise. This is not meant to infer that staff were not qualified for the posts they were given – or were overqualified – but rather than there needs to be consistency and transparency across CRFs, particularly where they have the same funding stream. The availability of a continuum for career progression could be a mechanism to increase satisfaction of nurses and midwives commencing a career in clinical research.

6.3 Professional Development

The NCNM report (2008) noted that CRNs are forced to take responsibility for their own professional development, and our findings echo this and also suggest that the only realistic route for career progression is to leave the specialist area of practice., or move to a management role This highlights the key discrepancy in the model for funding clinical research in Ireland. The primary purpose of research funding is to support scholarship and research output, and many of those carrying out the studies are on a trajectory to PhD and post-doctorate rewards. Academically, they are supported by lecturers and department heads, at considerable expense. However, true infrastructure also needs a firm foundation that supports practical and clinical aspects of research projects, and the CRNs that provide support for the day to day running of studies, providing 'how to' expertise, and acting at the interface between clinicians, scientists and patients, are still deplorably undervalued. This also applies to other research staff who occupy support or service roles, rather than holding student or lecturer posts.

The knowledge and skills associated with the role of the CRN, while not unique to the profession, differ from the theory covered in an academic research course. The role focuses more on the practical day to day issues and logistics associated with running a study, and on ensuring that the rights, safety and wellbeing of research participants is respected. This was recognised in 2008, both by the provision of funding for this purpose, and in the recommendations of the NCNM report (2008). The development of an accredited postgraduate certificate programme that addressed all aspects of clinical research coordination and management was innovative, and its value went beyond the needs of CRNs only. The repercussions of the loss of this programme can be seen in the fact that a significant proportion of CRNs have not completed a specialised course in clinical research. It is vital that appropriate educational opportunities are available to CRNs and other core clinical research staff.

While IRNN contributes to the training and professional development of CRNs in Ireland through the provision of study days and seminars, conferences and other resources, the provision of formal programmes of education is not within its scope. An educational programme that covers the coordination and management of clinical research projects needs to be available at institutional and/or national level. Given the size of the research community in Ireland this would not necessitate providing a resource that is replicated across all sites, but rather a shared resource or coordinating function that could support clinical research education nationally.

6.4 Recognition of CRNs

Our study found that CRNs do not feel that their role is recognised or respected nationally. as previously mentioned, the support provided to research nurses under the DCCR funding stream included the appointment of a Director of Clinical Research Nursing to support and represent CRNs across the networked research infrastructure. The availability of this function led to the revival of a CRN network, the inauguration of an annual research conference, and the provision of the postgraduate certificate programme. The loss of this resource loss created challenges in ensuring continuity and sustainability of the IRNN. Experience has shown that committee members eventually have to prioritise their work or family commitments, leading them to withdraw from the IRNN committee. IRNN have been very fortunate in obtaining funding to support its activities, but would readily admit that management of this resource places additional burdens of responsibility for what is essentially a voluntary activity. The availability of a dedicated CRN National Lead and associated resources would alleviate this pressure.

7 LIMITATIONS AND RECOMMENDATIONS

7.1 Limitations

The main limitation of this study was the imperative to gather and report this data within a short timescale. This impacted on the depth and scale of the data collected, but also highlighted themes which provides indicators for possible future research. We do not believe the time constraints limited the success of participant recruitment. There is no advantage to a long data collection window for a study such as this, and the enthusiasm of the IRNN committee, and engagement with research partners and stakeholders, maximized engagement of CRNs in the project. We are confident that the data collected strongly represents CRNs in Ireland. When analysing the data it was apparent that the findings would have been strengthened by including some more questions about years of clinical experience and research experience prior to the CRNs current role. There is also scope for further exploration of the professional support available not only to CRNs but to research nurse managers. Is it appropriate to be carrying out clinical duties in CRFs that do not have formal links with the services of their co-located hospital?

7.2 Recommendations

- Clinical research nurses and midwives in CRFs and research units should be employed as core staff, and allocated to investigators as appropriate to the needs of the study
    - Depending on the study the associated costs may be covered the institution or reimbursed by sponsor as research income.
- CRFs and research units with sufficient CRN staff numbers should aim for a workforce skill mix from entry level (staff nurse) through to CNS/CNM and Advanced Nurse Practitioner or Director of Nursing grade.
    - Annual increments or salary review should be mandatory
    - CRNs employed at staff nurse level should be supported by more experienced colleagues and have a realistic expectation of career progression based on competency and experience.
- Nationally approved competencies associated with the appropriate nursing and midwifery grades should be developed in addition to standardised job descriptions detailing the essential requirements for each grade.

- CRNs should be employed at a grade appropriate to their roles and responsibilities, and their prior clinical and research experience

- CRNs employed through universities should hold permanent posts, with all the entitlements and benefits afforded other grades of permanent staff

- The HRB and Department of Health should enter negotiations about the status of CRNs and consider either:

    - Agreed numbers of CRNs employed through the HSE with salary funded by DOH +/- HRB +/- academic institutions OR

    - CRNs employed through academic institutions with salaries funded as above but holding honorary contracts with the HSE to enable seamless research activity and access to nursing education and professional support in their affiliated hospitals.

Note 1: *in reality a combination of these models will be necessary, and there will still be demand for temporary and fixed term contracts in some circumstances. However ongoing rolling temporary contracts should not be maintained.*

Note 2: *Representatives of CRNs must be included in any discussions and decisions about the future status and career pathway of CRNs*

- CRNs should be supported in accessing educational programmes appropriate to their specialized area of practice and continuing competency

    - CRNs are currently unable to access professional training on HSELAND as they do not have a formal hospital affiliation

- A national CRN support function should be established to

    - Provide professional support and advice for CRNs

    - Source or develop training and education resources specific to CRN needs, in particular a specialist CRN programme.

    - Maintain the CRN database

    - Support IRNN in its activities

Note: *The person or persons assigned this function requires access to support such as IT, technology enhanced learning, administration and finance, in either their academic institution or from the research infrastructure, and would need an appropriate budget to achieve targets.*

7.3 Recommendations for future research

As previously indicated the priority for this study was to provide high level data about the CRN workforce in Ireland, and there is scope for in-depth exploration of aspects of the role. Areas for further research include:

- Development of a recommended career pathway for CRNs, from entry level through to advanced practice and/or management

  Note: This requires urgent consideration. It could be completed as a follow up to the current study.

- The skills and competencies associated with roles undertaken by research nurses:
  - Are there different levels of competency?
  - Are these skills and competencies unique to nurses and midwives or are they equally applicable to other research team members?
  - The barriers and enablers to CRN careers: Why do they stay and why do they leave?
- Supports provided to novice CRNs and other research team members

8 CONCLUSION

In completing this study we sought to describe the clinical research nurse and midwife resource in Ireland. The number of CRNs in Ireland remains unknown, and, while IRNN intends to establish a CRN database, this will be a voluntary register, and IRNN does not have the authority or the resources to mandate its use. A rough estimate informed us that there are in the region of 200 CRNs in Ireland, and the inclusion of 141 eligible participants in this study assures us that the findings are highly representative of the CRN workforce in Ireland.

There is evidence that the work environment for CRNs has improved with the establishment of CRFs, but many of the issues described in the HRB funded NCNM report (NCNM 2008) are still evident. The lack of standardisation of terms and conditions of employment, a clear or defined career pathway and support for professional development all contribute to an absence of job security and migration between roles and ultimately into alternative areas of practice. This results in a loss of expertise within the research community, and the need to constantly recruit, orientate and train new entrants into this area of practice.

The IRNN, operating on a voluntary basis, has demonstrated commitment to the professional development of CRNs, and is appreciative of the funding provided to support its activities. However, there is little evidence of a strategic approach to implementing the changes required at infrastructural level, or that research leaders truly appreciate the extent of the problem. This report provides an opportunity to acknowledge and address these anomalies.

The clinical research infrastructure in Ireland continues to benefit from considerable investment, and the HRB is now engaging in the development of the organisation's next Strategic Plan, which will cover the period 2021 – 2025. As part of the strategic planning development process, the HRB plans to consult with a wide range of external stakeholders. The voice of clinical research nurses and midwives has patently not been heard in previous strategies. It is essential that they are included in consultations for this strategy, and that representatives of research sites and IRNN are part of the discussions and solutions.

9 REFERENCES

NCNM (2008) *Report on the Role of the Nurse or Midwife in Medical-led Clinical Research*. National Council for the Professional Development of Nursing and Midwifery, Dublin 7

10 ACKNOWLEDGEMENTS

We would like to thank the following individuals and groups, without whom this project could not have been completed:

- The IRNN Committee, and the project steering committee, for their support in planning and completing this study
- Clinical research nurses and midwives in Ireland, for taking the time to complete the survey and for encouraging others to take part also
- Employers and representatives of research organisations, for promoting the study and encouraging staff participation, in particular
  - Clinical Research Coordination Ireland
  - Cancer Trials Ireland
  - HSE Champions
  - Managers of Clinical Research Facilities
- RCSI Clinical Research Centre, for providing a base of operations for the project

- Finally, special thanks to the Health Research Board, who have shown commitment to the future development of clinical research nurses and midwives in Ireland through the provision of funding for this project. We hope that the results and recommendations will provide a framework for the employment of CRNs within the national research infrastructure, and that the findings of this study will inform the next HRB Research Strategy.

‘COUNT ME IN’

THE IRISH RESEARCH NURSE NETWORK (IRNN)

NATIONAL CLINICAL RESEARCH NURSE/MIDWIFE WORKFORCE SURVEY

AUGUST 2019