

Spotlight on clinical research nursing

Deirdre Hyland and Mary Clarke Moloney discuss the changing environment of clinical research nursing in Ireland

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.¹

Clinical research is vital to provide the evidence to support improving standards of patient care, by investigating prevention strategies, treatments and the methods of patient care delivery. It offers economic, social and direct healthcare benefits. With these benefits in mind Irish governments over the past 10 years have invested significantly in the area of clinical research in Ireland. This investment has primarily focused on the development of various dedicated clinical research facilities, located in Dublin, Cork and Galway.

These centres aim to provide facilities and human resources in the form of qualified and suitably experienced staff to support both investigator-led (academic) and industry-led clinical trials. Research funding, primarily channelled through the Health Research Board, has also supported the establishment of a number of clinical trial networks including the All Ireland Co-operative Oncology Research Group (ICORG), the Dublin Centre for Clinical research (DCCR) and the recently launched HRB Clinical Research Co-ordination Ireland (HRB-CRCI).

These investments have been successful in increasing Ireland's visibility internationally and have attracted a greater number of grant funded and industry led projects, giving patients the opportunity to engage in clinical research and in some cases access treatments that would not be available outside the clinical trial setting.

The increase in clinical research activity nationally and improved organisational structures have had a direct impact on what has been, until now, a relatively

invisible area of nursing: clinical research nursing. This article puts the spotlight on clinical research nursing in Ireland, discussing the roles and responsibilities associated with that position. If Ireland is to maximise outputs from its infrastructural investment it must acknowledge the vital role clinical research nurses will play in implementing and co-ordinating clinical trials to optimise research efficiency, ensure participant safety and deliver on high quality research data.

Role of the clinical research nurse

The role of the clinical research nurse (CRN) is complex and multifaceted and, although considered integral to the clinical research team, there is no standard definition of the role. CRNs are expected to maintain the skills and professionalism they attained during nurse training and practice, and apply them in an environment that is not directly concerned with patient care or recovery, but rather with discovering improved practices or treatments to apply to large patient groups, or making new scientific discoveries. Research nurses tend to be employed outside traditional reporting structures, and may not be embedded within the nursing services of their institution.

How does one become a research nurse? Many nurses will attest that it happens more by accident than design, as there is, to date, little formal structure or career pathway for CRNs. A nurse may respond to an advertised vacancy due to general interest or curiosity, may be recruited directly from specialised practice, or may simply be in the right place at the right time when a need arises. Most CRNs 'learn on the job' and gradually acquire the knowledge and skills required. However, there is an increasing range of education programmes and resources available to help the nurse transition to this area of practice, supported by collaborative networks and groups such as the

Irish Research Nurses Network (IRNN see: www.irnn.ie).

The number of nurses working in clinical research in Ireland is an unknown entity. This is partly attributable to the lack of a defined grade or job description within health services and universities. It is further confounded by the diversity of the role, the lack of an agreed role title, variability of contracts and geographical dispersion.^{2,3} Even within healthcare and academic institutions research nurses are often unaware of other nurses working in similar posts. The IRNN has established the most definitive contact list for CRNs in Ireland, but acknowledges the list is incomplete. In November 2015, there were more than 180 names on this list.

Despite aspirations to integrate research into health services,⁴⁻⁷ and recommendations that research nurses should be embedded into HSE supported posts in hospitals⁵ most CRN posts depend on grant and/or commercial funding. There is little formal recognition or definition of the role, and no security of tenure.

The *Report on the Role of the Nurse or Midwife in Medical-Led Clinical Research* published in 2008² confirmed this lack of visibility, with the role of CRN largely unknown. Responsibilities associated with the role were seen to be diverse depending on the study setting, the type and stage of studies being done, and the composition of the research team. This is not unique to Ireland, and corresponds with international literature on the CRN role.⁸⁻¹⁰

Since the publication of the NCNM² report, little has changed for CRNs at infrastructural level. While some CRN posts are located within clinical research facilities, they are associated with relatively short-term contracts and outside of such facilities there is limited job security as most CRNs are employed on a project-by-project basis.¹¹ However, CRN networking and education has progressed

considerably, as has collaboration between research facilities and other research sites.

Despite the contractual issues outlined above, CRNs enjoy the role and find it a good source of job satisfaction. Positive aspects of the CRN role include its location at the centre of the research continuum. CRNs continue to interact with patients and can still utilise their nurse and midwife clinical practice skills: nurses are still nurses, bringing to the role a commitment to holism and patient advocacy.²

CRNs enjoy the challenges and autonomy associated with the role, which, by being intellectually demanding, encourages personal development and the thirst for new knowledge. Gibbs and Lowton contend that the ultimate reward for CRNs is the knowledge that research to which they contribute may lead to improved healthcare now and in the future.³ CRNs are also very well placed to carry out their own research, either as part of a research team or as an independent investigator.^{2,9}

Responsibilities

"Clinical research nursing is nursing practice with a specialty focus on the care of research participants in which nursing care delivery parallels the process of clinical research study implementation."¹²

Clinical research projects vary in size and complexity, from simple, once only, patient encounters to complex or intensive studies lasting many years. The role assumed by the research nurse, and associated responsibilities, will vary depending on the type of study being undertaken, the structure of the study team, and the expertise the nurse can bring to the study management process. CRN responsibilities centre on providing and co-ordinating clinical care, ensuring participant safety, maintenance of informed consent, protocol implementation, and collection and storage of accurate complete data. In addition to utilising core nursing competencies the CRN must develop skills in phlebotomy, management of biological samples, data and document management, project co-ordination, and much more.

Although the principal investigator retains ultimate responsibility for any study, it is the CRN's responsibility to coordinate day-to-day study management. To fulfil this role CRNs require a comprehensive understanding of the study disease area and also an extensive knowledge of the research process and research-related legislation. Brinkman-Denney¹³ believes that the collaborative competencies demonstrated by CRNs make them crucial to the management of research protocols in the clinical setting.

Core to the CRN responsibility is patient advocacy. Patient advocacy is integrated into all nurse education programmes and is reflected in the Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives.¹⁴ In addition to this core nursing responsibility, CRNs are further obligated to advocate for the research participant under the legislation that underpins clinical trials. The EU clinical trial directive (2001/20/EC) 15, transposed into Irish law as SI 190 of 2004,¹⁶ makes guidelines for good clinical practice a legal obligation in Ireland for all trials of investigational medicinal products. ICH Good Clinical Practice¹⁷ is an international ethical and scientific quality standard, comprising 13 core principles, for the design, conduct and recording of research involving humans.

Adherence to good clinical practice provides international assurance that:

- Rights, safety and confidentiality of participants in clinical research are respected and protected
- Data and reported results of clinical investigations are credible and accurate.

To meet the requirements each CRN must have up-to-date training and certification in good clinical practice before they can be involved in clinical research activity and also must be "qualified by education, training, and experience to perform his or her respective task(s)".¹⁷

Advanced areas of responsibility undertaken by research nurses include:

- Research project management
- Development of study protocol and associated study documents
- Ethics and/or regulatory submissions
- Budget assessment and negotiation
- Feasibility assessment
- Grant applications and management of funds
- Reporting studies and result dissemination
- Nurse-led research.

Future

Ireland has increased its ability to be involved in clinical research projects with the development of clinical research facilities. Once the newly funded HRB-CRCI is established it will facilitate the harmonisation of practices for the conduct of research in Ireland, which it is hoped will attract and 'home grow' a greater number of clinical research projects. This increased activity will result in a need to develop a critical mass of CRNs with the appropriate training and experience to work on delivering these projects.

This growth will offer both opportunities

and challenges for clinical research nursing. Some of the challenges that need to be addressed have been mentioned in this paper. These include standardising grades, job descriptions and competencies associated with clinical research nursing, while the level of training needed and the provision of that training also require discussion.

The projected increase in clinical research activity in Ireland presents an opportunity to highlight the value nurses bring to the research team and to promote and develop this emerging nursing specialty. The biggest challenge, however, is the integration of health services research, and consequently clinical research nursing, into mainstream health service provision.

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