

# 'The Roles and Responsibilities of the Clinical Research Nurse & Midwife'

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## BACKGROUND

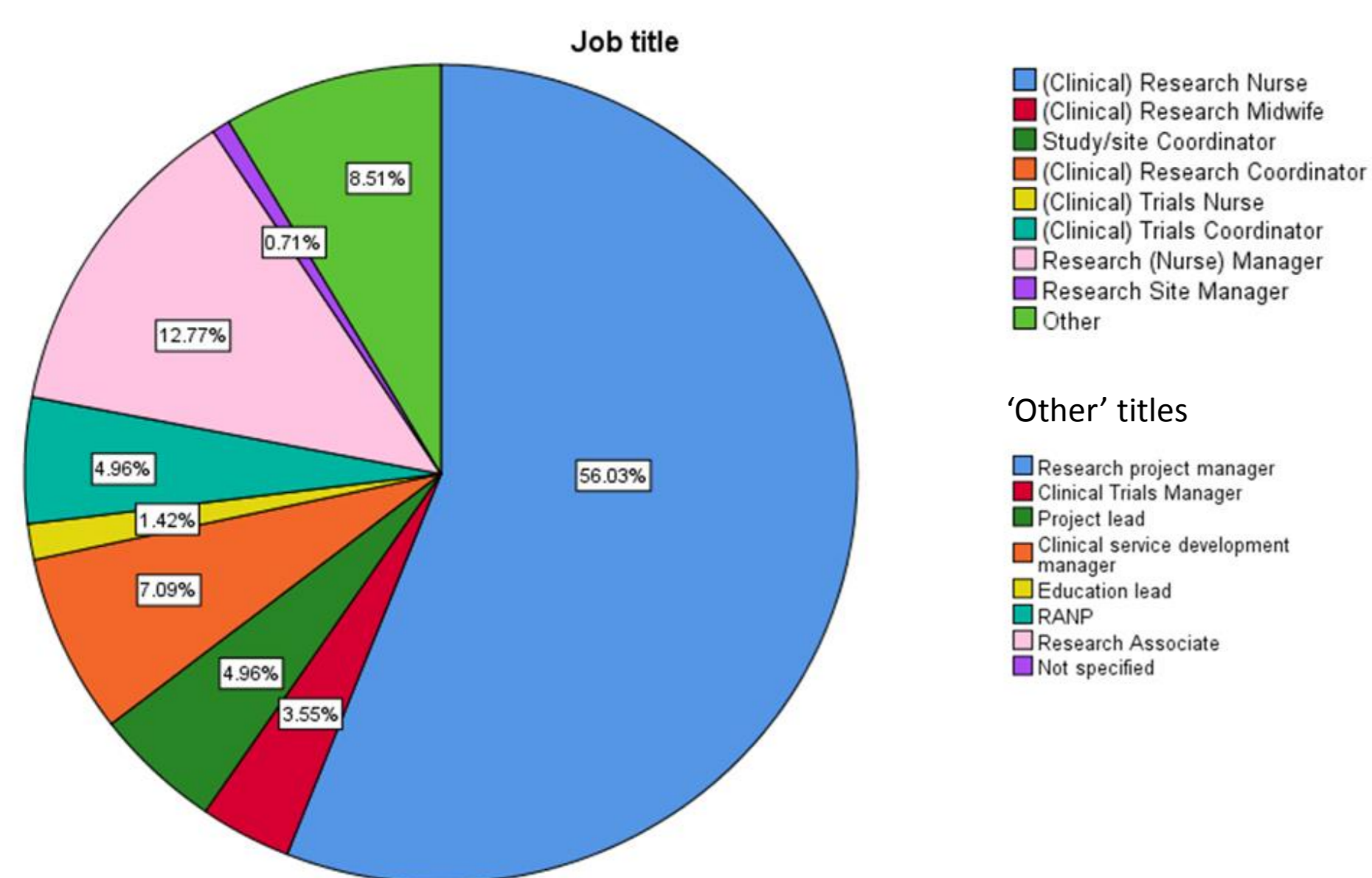
The roles and responsibilities of Clinical Research Nurses and Midwives (CRN) vary between organisations and even from one post to another. A consequence of this inconsistency is an absence of standardised job descriptions, which clearly define the roles and responsibilities for each nursing grade. Furthermore, this impacts on salary, which may not adequately reflect the skills and experience of the CRN. One of the objectives of the IRNN 'Count Me In' study was to identify the primary roles and responsibilities of CRNs in Ireland.

## METHODOLOGY

'Count Me In' was a national survey of CRNs based in a variety of settings (e.g. universities, hospitals, industry, and primary care). The subject population was the entire CRN/M workforce in Ireland. The data collection tool was developed using SurveyMonkey®.

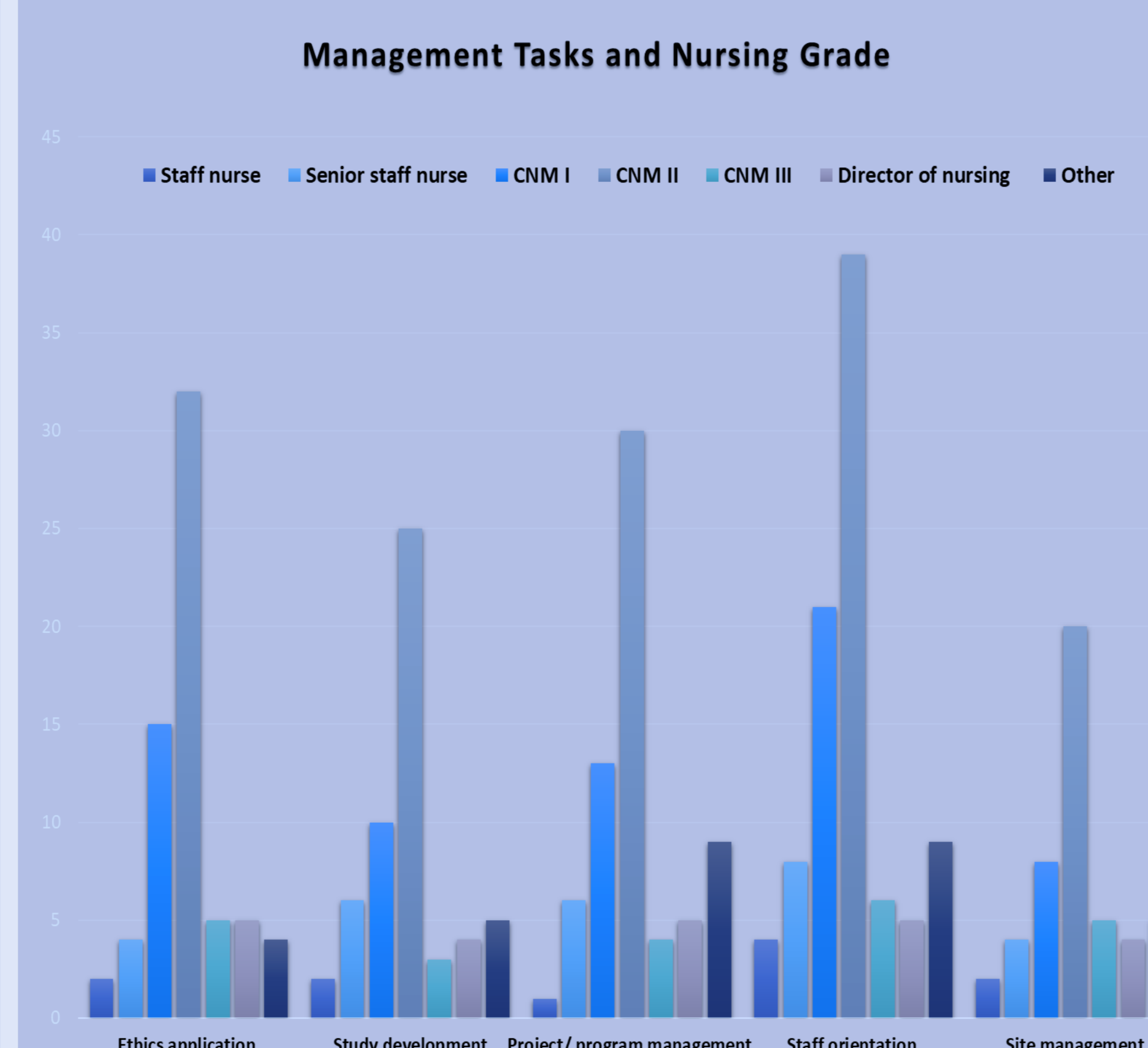
## RESULTS

### Role Title



Previous studies have highlighted the lack of consistency with the role title for nurses and midwives working in a research setting. In this study the majority reported that they used the title Clinical Research Nurse. The 'other' category mainly included management roles such as Research project Manager, Clinical Trials Manager and Project Lead. These roles are usually specific to the organisation or project.

### Roles and Responsibilities



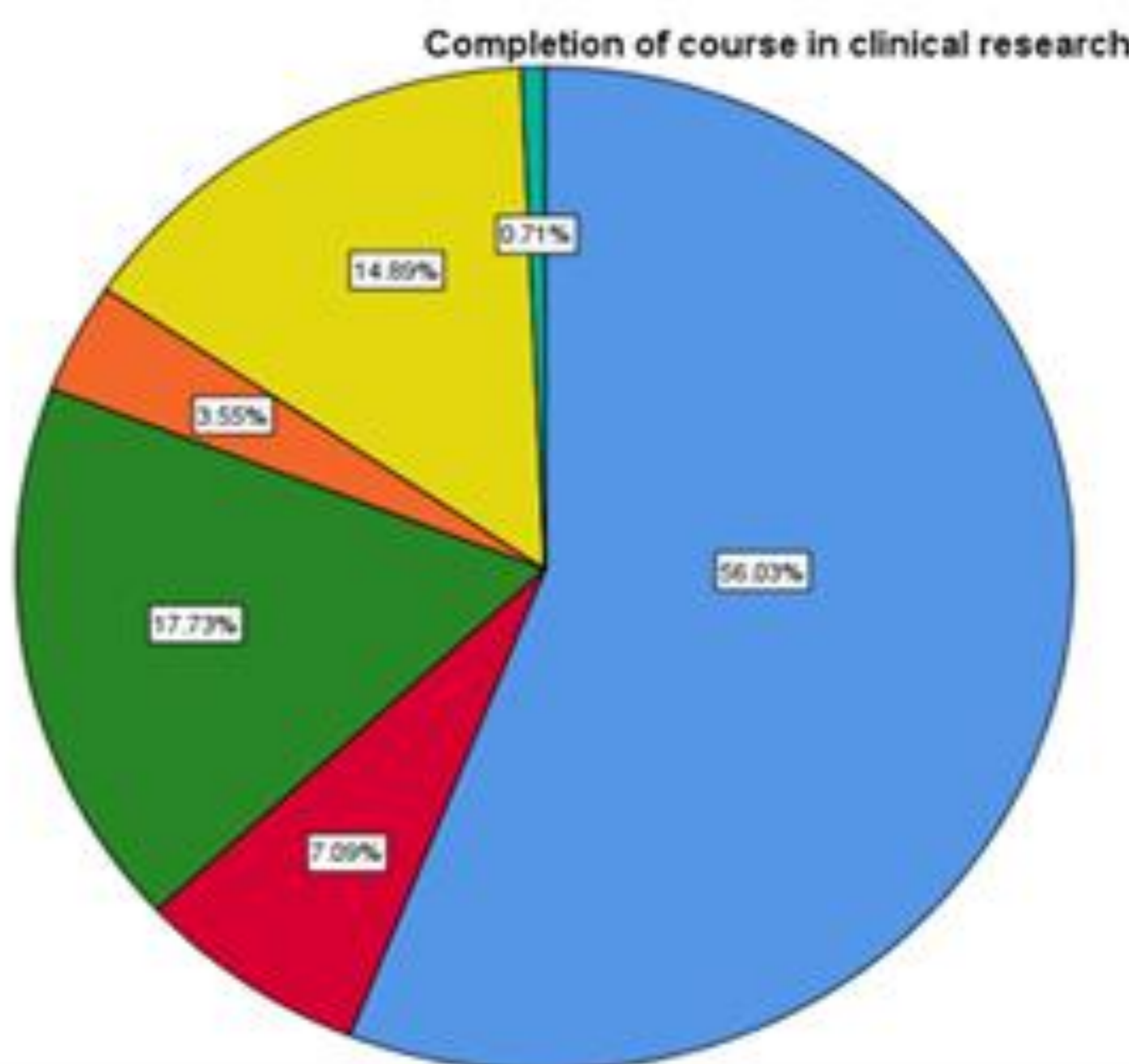
Responsibility	%	Responsibility	%
Participant recruitment	85.5	Study set-up	69.5
Informed consent process	78	*Staff orientation/training	65.2
Adverse event management	78	*Project management	48.2
Study visits	77.3	*Ethics application	47.5
Site file management	77.3	IMP management	44
Case report form completion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

The roles and responsibilities undertaken by CRNs were determined by the setting and type of research. Senior or management duties such as project management, staff orientation and research site management were primarily the responsibility of CRNs employed at CNM and Director of Nursing grade. However it was also evident that in some cases CRNs employed at staff nurse level were undertaking these higher level functions

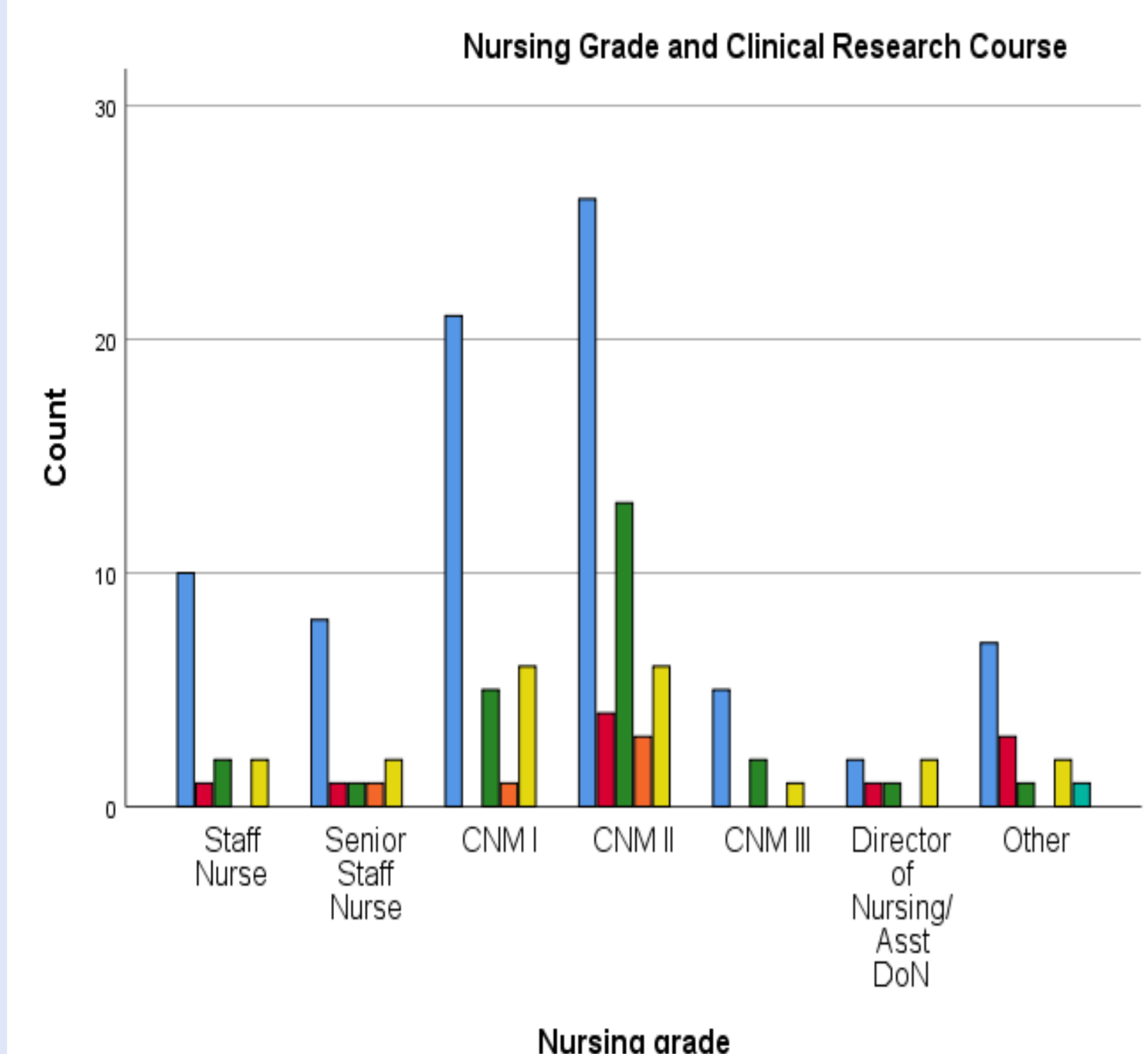
\* Indicates higher level or management functions

### Clinical Research Course

44% of participants had completed a course in clinical research ranging from single modules through to PhD.

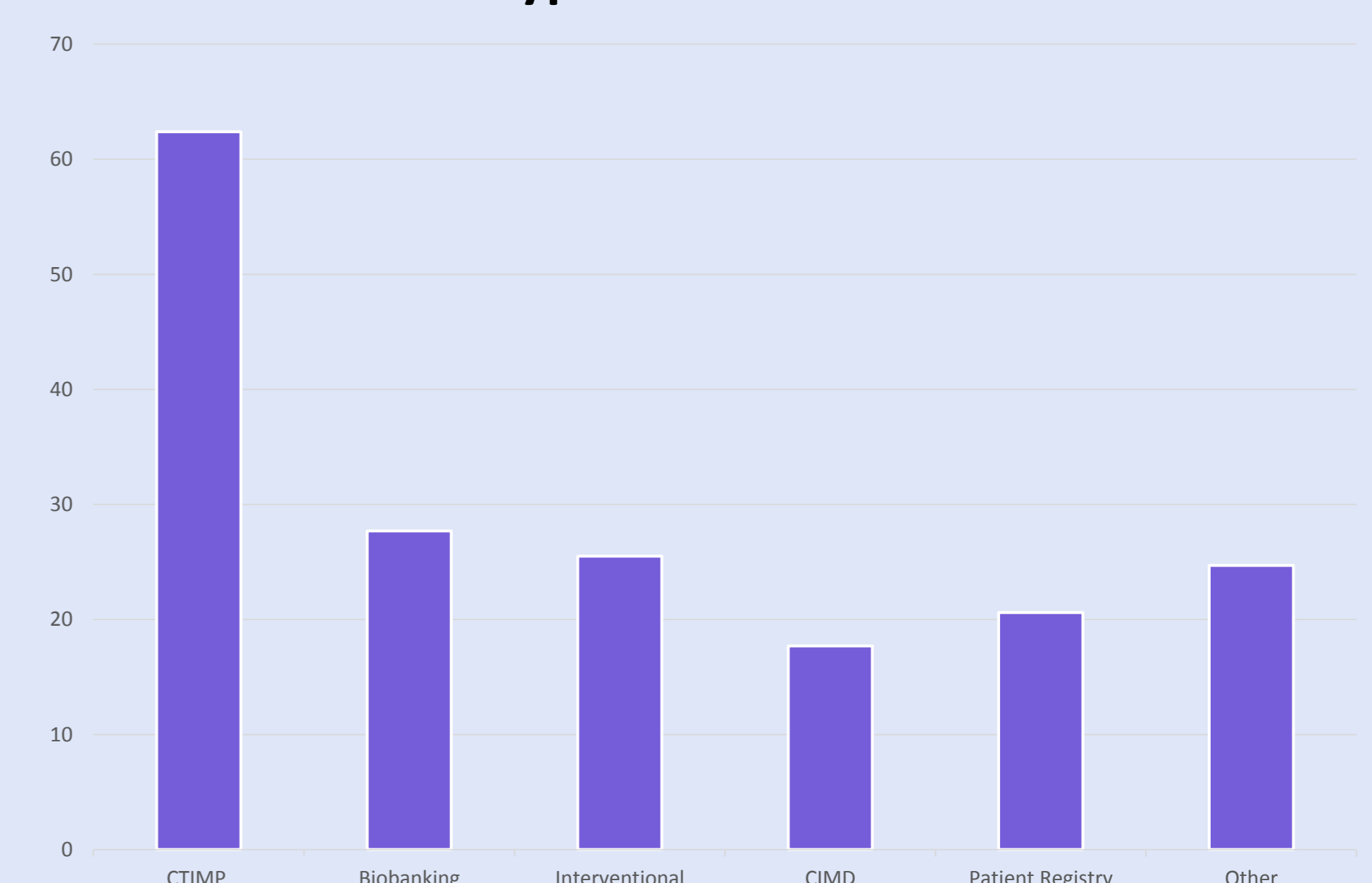


■ No ■ PGCert ■ MSc  
■ Modules ■ PGDip ■ PhD



Less than 50% of CRNs employed at CNM grade had not completed a clinical research course. Currently there is no standardised postgraduate education program for CRNs in Ireland. This is in contrast to nurses employed at a CNM level within recognized specialist areas who would have access to a specialist course. There are diploma and MSc programs in clinical research available in three universities nationally, but it is unclear whether these deliver the bespoke content required for the CRN role.

### Type of Research



Over 60% of CRNs were involved in clinical trials of an investigational medicinal product, although the majority of CRNs reported working across many areas of practice.

The IRNN has developed a competency framework as a tool to aid learning and development for CRNs. The aims of this tool is to enable the CRN to understand more clearly what is expected of them in the personal development needs, provide evidence of achievements to support career development and progression and employ a tool to improve and develop performance.



Reference  
IRNN (2015) Nurse Competency Pack Ver 1 Irish Research Nurses Network Research

## CONCLUSIONS

The role title 'Clinical Research Nurse' is more widely used, however the associated responsibilities have not been defined. Clinical Research nursing is not recognised as a specialist area of nursing which is reflected in the lack of a national post graduate course in this speciality. In some cases CRNs employed at staff nurse level were undertaking higher level functions. Given that there is no established grading structure for CRNs it is not possible to say if these CRNs were inexperienced or employed at a grade that was disproportionate to their skills and level of experience

## RECOMMENDATIONS

- ❖ The development of nationally approved competencies associated with the appropriate nursing and midwifery grades
- ❖ Development of standardised job descriptions detailing the essential requirements for each grade.
- ❖ CRN should be employed at a grade appropriate to their roles and responsibilities, and prior clinical and research experience
- ❖ Sites with sufficient staff numbers should aim for a workforce skill mix from entry level (staff nurse/midwife) through to specialist, advanced practice or management grades
- ❖ CRNs should have access to a post graduate course appropriate to their specialised area of practice