

**Preliminary piloting and validation of a questionnaire identifying basic clinical skills  
practised by research nurses**

Authors: Kirkpatrick, S., Harding, S., Pollard, K., and Tacchi, P.

Corresponding Author

Mrs Suriya Kirkpatrick

Senior Cancer Research Nurse

North Bristol NHS Trust

Southmead Hospital

Westbury-on-Trym

Bristol | BS10 5NB

Telephone.

Email: [suriya.kirkpatrick@nbt.nhs.uk](mailto:suriya.kirkpatrick@nbt.nhs.uk)

Dr Sam Harding,

Senior Research Associate

North Bristol NHS Trust

Southmead Hospital

Westbury-on-Trym

Bristol | BS10 5NB

Telephone 0117 41 43957

Email: [sharding.jb@gmail.com](mailto:sharding.jb@gmail.com)

Dr Katherine Pollard

Senior Research Fellow

Faculty of Health and Applied Science

University of the West of England

Bristol, BS16 1QY

Telephone 0117 32 81125

[Katherine.Pollard@uwe.ac.uk](mailto:Katherine.Pollard@uwe.ac.uk)

Paula Tacchi

Nurse Consultant

Clinical Research Network: West of England

Whitefriars

Lewins Mead

Bristol BS2 1NT

Telephone 0117 34 21375

[paula.tacchi@nihr.ac.uk](mailto:paula.tacchi@nihr.ac.uk)

### Abstract:

Clinical research nurses (CRNs) need to be competent in both clinical and research skills. In the last 10 years there has been increasing focus on developing the research competencies of CRNs. Employers however, use the nurses registered status as an proxy measure of the nurses clinically competence to perform their duties. The true extent of what clinical skills are practiced by CRNs in a large NHS trust is unclear and there is a lack of validated measures to obtain this information. By using a mixed methods approach of questionnaire and semi-structured interview, we aimed to develop, pilot and validate a questionnaire to identify CRNs self-reported confidence with clinical skills.

Keywords: Clinical Research Nurse, Clinical Skills, Competence, Questionnaire research

### Key points:

1. The clinical research nurse plays a vital role in the research teams successful delivery of a project
2. Maintaining clinical competencies may be challenging for the clinical research nurse
3. Currently no measures of which clinical competencies are needed, or if they are practised by the clinical research nurse
4. A measure of clinical competencies for clinical research nurses has been developed

### Reflective questions:

- Think about the essential clinical skills required to carry out your role
- Consider how often you practise these skills; how would you evidence reaching competence in them?

- Think about how clinical research nurses could maintain their competence in basic skills if these skills are not practised regularly.
- Consider the challenges clinical research nurses' face that may lead to them becoming clinically deskilled.

## Introduction

The United Kingdom Clinical Research Collaboration (UKCRC) defines the clinical research nurse (CRN) as “A nurse who is employed principally to undertake research within the clinical environment” (UKCRC 2007, p32). The role was formalised in 1977 when the Royal College of Nursing (RCN) published its guidance on research ethics for CRNs (Royal College Nursing 2009, p2). This has led to nurses carrying out their own and others’ projects, and undertaking all elements of the research journey including; collecting data, writing and reviewing research protocols and commissioning research. The CRN is not the same as a 'nurse researcher', where a CRN works on projects related to patient care, and treatment, the nurse researcher is generally part of an academic career path allowing the nurse to undertake postgraduate educational qualifications (Jones 2015).

The CRN plays a vital role in the research team ensuring a study’s success, as they are experts in combining patient care with the research process (Mori, Mullen and Hill 2007).

The range of these expertise can include; data collector, lab technician, counsellor, mediator and expert according to the needs of a particular study. Despite the extensive nature of the role of the CRN, individuals often have to learn on the job with little supervision or guidance (Stephen-Lloyd 2004; Calvin-Naylor, Jones, Wartak, Balckwell, Davis. Divecha et al, 2017).

The RCN published the “competency framework for clinical research nurses” in December 2008 and revised it in October 2011 (Royal College Nursing 2011). The framework provides the basis for establishing the training and development needs for research staff. Whilst this framework focuses heavily on research competencies there is little mention of clinical competencies. It does however state that “the competencies presented in the document focus only on those skills unique to the role of CRNs, “Clinical skills are assessed through

different processes” (Royal College Nursing 2011 p.8), however these processes are not clear. The RCN (2011) recognises the complexities of the roles of CRNs, which make it challenging to provide a one size fits all competency frameworks for CRNs but the framework offers a useful starting point for developing local competency guidelines.

This potential for decay of clinical skills is increasingly recognised across medical, nursing and allied health professionals (Maehle, Cooper, Kirkpatrick, 2017). A major concern for managers is that whilst the role of the CRN is expanding and CRNs take on more research activity, they are doing less clinical work, consequently becoming deskilled, suffering from skill fade/decay and become less competent in carrying out clinical skills. CRN managers are therefore facing a challenge with the training and development of their CRNs when the true extent of clinical skills practised is unknown.

It is the experience of the authors of this paper, that within the NHS CRNs have clinical experience, that basic clinical skills have been mastered and that they are competent to carry out tasks such as; measuring temperature, pulse, respiration, electrocardiogram, oxygen levels, cannulation, venepuncture and administration of specific treatments.

However, to date, no research has been found to support this assumption. It is therefore unsurprising that there are no known measures to identify what clinical skills are believed to be essential to the CRN role, and as such it is difficult for research managers to ensure relevant training is provided and competence is appropriately reviewed. This study aimed to develop a questionnaire that could be used to establish what clinical skills are practised by CRNs.

## **Method**

A mixed methods approach using a questionnaire and semi-structure interview was adopted in order to capture specific information relating to clinical skills and CRNs' views about clinical competency. The use of these two methods allows complimentary data to be gathered. The questionnaire provides information on what skills are being used, as well as reliability of responses. The face validity and acceptability of the tool was explored via the interviews.

### *Ethical Issues*

Ethical approval was obtained from the University of West of England.

### *Sample selection*

The potential research population included all professionals working under the banner of 'clinical research nurse' employed in a clinical research role. There were approximately one hundred and twenty CRNs employed within the recruiting trust. As a pilot study, fifteen participants randomly selected using Stattek.com (2018) were invited by email to complete an online survey twice with a gap of two weeks between administrations. According to Connelly (2008), extant literature suggests that a pilot study sample should be 10% of the potential population; fifteen people were approached to allow for people to decline the invitation.

Not all participants completed the online questionnaire twice; however those that did were asked if they were willing to participate in a follow-up interview.

### *Data collection*

There were two phases to the data collection. Firstly, the development and administration of an on-line questionnaire and secondly interviews. The method of developing the

questionnaire is presented below, followed by that of the interview schedule. This mirrors the pattern experienced by the participants.

### *Developing the questionnaire*

The questionnaire was developed using pre-existing knowledge of clinical skills that registered nurses in one NHS Trust are known to practise. This was independently assessed by the lead CRN of a large acute NHS Trust and by members of the Trust training and development department.

The list of clinical competencies were grouped into four distinct sub-scales, each relating to the level of expertise required to perform the skill. The four sub-scales were; basic, intermediate, advanced and clinically specific. The categorising of the skills was undertaken by the hospital trusts training department and was informed by the trust protocols.

Fourteen skills were categorised as basic, seven as intermediate, and two as advanced (Table 1). Clinically specific skills, such as those in oncology (administration of intravenous cytotoxic medication, care of the peripherally inserted central catheters (PICC line), and patient education on the effects of chemotherapy) and renal (care of the Hickman line, haemodialysis) were included and respondents were given an opportunity to add other clinically specific skills relevant to their practise.

Respondents were asked to rate their level of confidence, frequency of applying the skill and how essential to their role they felt each skills was. This was done using standardised formats. The responses for how confident the CRN was in performing the skill included; not at all, moderately or very; to rate how frequently a skill was applied the choices were weekly, monthly, 1-2 times a year or never; and to establish if respondents thought that the skill was essential to the role the response options were either not at all, moderately or



very. Responses were assigned value, and each individual's responses within each skill category (basic, intermediate, advanced) were totalled to result in an overall score for each category.

#### *Development of the interview guide*

A semi-structured interview schedule was constructed to focus the discussion on user experience of completing the questionnaire and to ensure that acceptability of the content to the CRNs. The researcher invited respondents who completed the questionnaire twice (N=8) to a face to face interview. Five questionnaire respondents agreed to participate in an interview, but due to clinical commitments interviews with only three CRNs were undertaken.

#### *Data Analysis*

##### *Questionnaire*

SPSS for Windows Version 19 was used to analyse the questionnaire responses.

Establishing reliability requires that a questionnaire is both stable and internally consistent (Bryman 2008). To assess stability, individuals' responses to each administration of the questionnaire were compared using Spearmans' rho ( $\rho$ ); an acceptable level of correlation was set at 0.8 (Oppenheim 1992). This analysis was undertaken with each skill and for overall scores.

The internal consistency of each of the scales was assessed by means of Cronbach's alpha coefficient.

##### *Interview*

Relational content analysis was undertaken with the transcriptions from the three interviews (Kaid 1989).

## Results

Section one of the questionnaire explored demographic data (Table 1). Of the 15 people invited to take part in this pilot study, 14 responded to the first administration of the questionnaire. One of the 14 respondents did not complete the full questionnaire and their data was their removed from analysis, leaving a sample of 13. Eight respondents completed the questionnaire a second time, but one participant only completed section one and therefore their data were not used in the validation process. The 7 people who did not complete the questionnaire on the second occasion volunteered reasons such as; work/time demands, and the need to have a computer to complete the questionnaire.

**Table 1 Demographic Data**

	Directorate	Job Title	Band	Full Time/Part Time
Administration 1 n=14	1 x Medical 2 x Surgical 6 x Musculo skeletal 4 x Neuroscience 1 x Core clinical	7 x Clinical Research Nurse 3 x Senior Research Nurse 3 x Nurse 4 x Other	6 x 7 5 x 6 3 x 5	8 x Part Time 6 x Full Time
Administration 2 n=8	1 x Medical 4 x Musculo skeletal 2 x Neuroscience 1 x Core Clinical	4 x Clinical Research Nurse 0 x Senior Research 2 x Nurse 2 x Other	4 x 7 3 x 6 1 x 5	3 x Part Time 5 x Full Time

## Questionnaires

Table 2 shows the frequency of the performance of clinical skills. A test-retest administration of the on line questionnaire was conducted with seven complete data sets. The correlations for each skill were calculated for both confidence and essential nature of the skill.

The correlations for confidence in basic skills were satisfactory with only enteral feeding and female catheterisation scoring below 0.7. For intermediate skills the correlation was good except for male catheterisation which yielded a negative correlation (- 0.218). Spearman's rho for all other basic and intermediate skills was  $> 0.8$ . The advance skills correlated very well with scores greater than 0.9.

The correlation for the essential nature of the skill revealed similar results with only enteral feeding and female catheterisation scoring  $< 0.7$  for the basic skills. Administration of oral and intravenous medication scored in the 0.7-0.8 range. With regards to the intermediate skills male catheterisation revealed a negative correlation -0.218 again, with venepuncture correlating at 0.753. Spearman's rho for all other basic and intermediate skills was  $> 0.8$ . The advanced skills correlated well ( $>0.8$ ).

The internal consistency of each sub-scale and the full scale was assessed by means of Cronbach's alpha coefficient. Coefficients obtained for confidence were 0.979 for basic skills sub-scale and 0.904 for intermediate skills sub-scale ( $n = 13$ ). Coefficients for essential nature of skills were 0.976 for basic skills and 0.899 for intermediate skills. Full scale reached a Cronbach's alpha of 0.952.

**Table 2: Frequency of performing clinical skills (n=13)**

Skill	Weekly	Monthly	1-2 times a year	Never	Total N	Skills Spearman's rho
<b>Basic Skills</b>						
Monitoring Blood Pressure	4	3	3	2	12	0.976
Monitor Pulse	4	3	3	2	12	0.976
Monitor Temperature	4	3	1	4	12	0.813
Monitor respiration	4	3	2	2	11	0.813
Measure Oxygen Saturation levels	3	3	2	4	12	0.802
Administer Oxygen Therapy	1	2	2	6	11	0.885
Administer Oral Medication	1	2	3	5	11	0.733
Administer Subcutaneous Injections	1	2	2	6	11	0.932
Administer intravenous medication	0	2	2	7	11	0.741
Urinalysis	2	3	0	6	11	1.000
Administer Enteral Feeds	0	0	2	9	11	0.655
Female Catheterisation	0	0	1	10	11	0.488
Wound Care	0	1	3	7	11	1.000
Specimen Collection	3	2	0	6	11	0.842
<b>Intermediate Skills</b>						
Male Catheterisation	0	0	3	8	11	-0.218
ECG Monitoring	2	4	0	5	11	1.000
Venepuncture	4	2	1	4	11	0.753
Cannulation	1	1	1	8	11	1.000
Bandaging	0	2	2	7	11	0.843
Care of a Central Line	0	0	0	10	10	1.000
Patient Education on how to self-medicate	2	2	3	4	11	0.891
<b>Advanced Skills</b>						
Taking Full medical History	3	1	1	6	11	0.958
Non-medical prescriber	1	0	0	10	11	0.843

Nine respondents were positive about performing basic skills; however four lacked confidence. Similarly six respondents were confident about performing intermediate skills; three remained neutral while four were negative (Table 3). The same four respondents reported negative attitudes to both basic and intermediate skills.

**Table 3 Confidence in performing basic skills**

Answer Options	Not at all	Moderately	Very	No Response	Total N
<b>Basic Skills</b>					
Monitor Blood Pressure	1	0	12	0	13
Monitor Pulse	1	0	12	0	13
Monitor Temperature	1	0	12	0	13
Monitor Respiration	1	0	12	0	13
Measure Oxygen Saturation Levels	1	0	12	0	13
Administer Oxygen Therapy	1	4	8	0	13
Administer Oral Medication	1	1	10	1	13
Administer Sub Cutaneous medication	1	5	7	0	13
Administer Intravenous Medication	2	3	8	0	13
Urinalysis	1	1	11	0	13
Administer Enteral Feeds	6	3	4	0	13
Female Catheterisation	6	5	2	0	13
Wound Care	2	6	5	0	13
Specimen Collection	1	4	8	0	13

<b>Intermediate Skills</b>					
Male Catheterisation	7	3	2	1	13
ECG Monitoring	3	4	6	0	13
Venepuncture	1	2	10	0	13
Cannulation	6	5	2	0	13
Bandaging	3	5	5	0	13
Care of a Central Line	7	1	5	0	13
Patient Education on how to Self-Medicate	2	4	7	0	13
<b>Advanced Skills</b>					
Taking Full Medical History	4	6	3	0	13
Non-Medical Prescriber	12	0	1	0	13

Nine respondents considered that basic skills were essential to their role whilst four did not. For the intermediate skills, five respondents reported that these skills were essential to their role, four did not think that that the intermediate skills were essential to their role whilst for remained neutral (Table 4). Again the same four respondents reported negatively for essential nature of basic and intermediate skills to their role.

**Table 4 Essential nature of skills**

Skills	Not at all	Moderately	Very	No Response	Total N
<b>Basic Skills</b>					

Monitoring Blood Pressure	3	1	7	2	13
Monitor Pulse	3	1	7	2	13
Monitor Temperature	3	1	7	2	13
Monitor Respiration	3	1	7	2	13
Measure Oxygen Saturation Levels	4	0	7	2	13
Administer Oxygen Therapy	5	4	2	2	13
Administer Oral Medication	4	2	5	2	13
Administer Sub Cutaneous medication	4	5	2	2	13
Administer Intravenous Medication	5	5	1	2	13
Urinalysis	4	4	3	2	13
Administer Enteral Feeds	9	2	0	2	13
Female Catheterisation	10	1	0	2	13
Wound Care	7	3	1	2	13
Specimen Collection	4	1	6	2	13
<b>Intermediate Skills</b>					
Male Catheterisation	9	1	0	3	13
ECG Monitoring	4	2	5	2	13
Venepuncture	2	1	7	3	13

Cannulation	4	4	3	2	13
Bandaging	7	3	1	2	13
Care of a Central Line	9	0	2	2	13
Patient Education on how to Self-Medicate	3	2	6	2	13
<b>Advanced Skills</b>					
Taking Full Medical History	3	3	5	2	13
Non-Medical Prescriber	6	4	1	2	13

### *Qualitative Interview*

All interviewees reported that the questionnaire questions and content were appropriate to their role as CRN's and that using an electronic format to deliver the questionnaire was positive. However, communication skills were identified as an important skill that should have been included in the questionnaire.

Interviewee 1 did not think that some of the basic skills were essential to her role. She confirmed that she was not confident in performing them. However, she did not feel she required any further relevant training because she did not use these skills often enough.

Interviewee 2 reported being moderately to very confident in all basic skills in the questionnaire. She thought that these skills were moderately to very essential to her role and she did not require any further training on basic and intermediate skills.



Interviewee 3 demonstrated in his responses that some basic skills are not essential to his role; he reported not being competent in these skills but did not feel that he required further training.

An advanced skill such as obtaining medical history was identified by Interviewees 1 and 2 as essential to the role of the CRN. They reported having received training in this skill, used this skill regularly and felt confident about performing this skill. Interviewee 2 added that she was also a non-medical prescriber but did not think that this skill was essential to her role.

Interviewee 1 said, "It is important to be clinically updated as research nurses may be called upon at any time to support their colleagues in the wards". She expressed her personal concern that she has been off the wards for a long period and would not feel confident at the moment if asked to work in the clinical environment. Interviewee 3 however thought that, whilst he did not feel confident in practising some skills, further training for skills that are not frequently used would not be beneficial.

## Discussion

Clinical Research Nurse managers are challenged with training and developing CRNs and to improve the effectiveness of the future CRN workforce. The Royal College of Nursing (2011) has developed competency frameworks to facilitate this, however the clinical skills of CRN roles are hard to define due to the variety of the research projects they are employed to work on (RCN, 2011). A validated tool could be used as part of personal skills reflection or as part of an annual appraisal. This could identify what clinical skills are essential to the role of the individual CRN. The tool would support research managers in monitoring competence and provide appropriate training. This project developed a short pragmatic tool to assess which clinical skills are used by CRN's and their frequency of use. This tool in combination with an individual CRNs project role could ensure the enhanced maintenance of both clinical and research skills.

The results from piloting indicate that the questionnaire has strong face validity and despite the small number of participants, it showed good levels of reliability and is therefore worth further development. The combination of the results of the repeat administration and the alpha coefficients indicates that the questionnaire satisfies conditions for adequate reliability (Spector 1992; Oppenheim 1992).

This presented work in part builds upon Gordon (2008) who suggested that there is a need to look closer at the specific roles, competencies and daily activities of those nurses whose specialist skills involve conducting research in a general sense, according to clinical trials protocols. A comprehensive document detailing these responsibilities and the competence required to perform these duties at individual levels would be extremely useful in management and support of the CRN and could be supported by the measure developed in

the current research. This pair of documents could be used to clearly define what clinical skills are central to the role of the CRN, and how competence is achieved. However, at present it is difficult for the CRN to justify the development of new skills, or for employers to structure their services to facilitate competence maintenance and development.

Although the main aim of this project was to develop a questionnaire, the results show differences in opinion about the relevance to practise for some skills, even with the small sample size. Although there is a debate about sample size in relation to establishing reliability, it is generally accepted that a relatively large sample size is not needed for this purpose (Bonett 2002). In this context it can also be noted that, despite the small sample size, Cronbach's alpha for each of the two sub-scales that addressed the essential nature and confidence in performing basic skills was good, and the test- retest coefficients were only slightly less than optimum (Oppenheim 1992). It can be argued that the piloting and validation of the scale has gone some way to establishing its robustness, although it is recognised that further validation work is required across medical fields and organisations. It should also be noted that this is the first research of its kind, and the findings have implications for the management and training of CRNs; however, further research in this area is required.

## **Conclusion**

It has been possible to design a questionnaire that can identify clinical competencies that are central to the role of the CRN, as well as individual development needs. This can assist research managers to support CRNs to achieve an appropriate optimum level of competence and to function safely and confidently in their role.

The questionnaire can provide a tool that CRNs could use to monitor and reflect on their confidence regarding the included skills, and to facilitate discussion with line managers regarding their on-going training and development needs. In the long term this may help CRNs progress to advanced practitioners, as is essential in today's NHS (Department of Health 2006).

## References

- Bonett DG. 2002. Sample Size Requirements for Testing and Estimating Coefficient Alpha. *J Edu Behav Stat.* 27(4): 335-340. doi: [10.3102/10769986027004335](https://doi.org/10.3102/10769986027004335)
- Bryman A. 2008. *Social research Methods*. 3<sup>rd</sup> edition. New York (USA): Oxford University press Inc.
- Cassell CK. 2004. Quality of care and quality of training: a shared vision for internal medicine? *Ann Internal Med.* 140(11): 927-928.
- Calvin-Naylor NA, Jones CT, Wartak MM, Balckwell K, Davis JM, Divecha R, Ellerbeck EF, Kieburtz K, Koziel MJ, Luzuriaga K, Maddox J, Needler NA, Murphy S, Pemberton K, Radovich C, Rubinstein EP, Selker HP, Tenaerts P, Unsworth K, Wilson K, Wright JE, Barohn R, Shanley TP. 2017. Education and training of clinical and translational study investigators and research coordinators: A competency-based approach. *Journal of Clinical and Translational Science*. <https://doi.org/10.1017/cts.2016.2>
- Connelly L M. 2008. Pilot studies. *Medsurg Nursing.* 17(6): 411-2.
- Department of Health. 2006. *Modernising nursing Careers- setting the direction*. Edinburgh, UK: Crown Copyright Available from [www.gov.scot/resource/doc/146433/0038313.pdf](http://www.gov.scot/resource/doc/146433/0038313.pdf) [Accessed 12th March 2018]
- Evans D, Pearson A. 2001. Systematic reviews: gatekeepers of nursing knowledge. *J Clin Nurs.* 10(5): 593-599.
- Gordon C. 2008. Exploring the new speciality of clinical research nursing. *Nursing Times* (online) 17<sup>th</sup> July. Available from <http://www.nursingtimes.net/exploring-the-new-speciality-of-clinical-research-nursing>
- Jones H. 2015. Clinical research nurse or nurse researcher? *Nursing Times.* 111(19):12-14
- Kaid LL. 1989. *Content analysis*. In P. Emmert & L. L. Barker (Eds.), *Measurement of communication behavior* (pp. 197-217). New York: Longman.
- Maehle V, Cooper K, Kirkpatrick P. 2017. Absolute clinical skills decay in the medical, nursing and allied health professions: a scoping review protocol. *JBIC Database System Rev Implement Rep.* 15(6):1522–1527.
- Mori C, Mullen N, Hill EE. 2007. Describing the role of the clinical research nurse. *Research practitioner.* 8(6): 220-228.
- Oppenheim AN. 1992. *Questionnaire design, Interviewing and attitude measurement*. 2<sup>nd</sup> edition. London, UK: Continuum

Royal College of Nursing. 2009. Research ethics RCN guidance for nurses, 3<sup>rd</sup> edition  
Available from <https://www.rcn.org.uk/professional-development/publications/pub-003138>  
[Last Accessed 12th March 2018]

Royal College of Nursing. 2011. Competency Framework for clinical research nurses, version 2. Available from  
[https://cambridge.crf.nihr.ac.uk/.../Research\\_Nurse\\_Competency\\_Framework\\_-\\_Versi...](https://cambridge.crf.nihr.ac.uk/.../Research_Nurse_Competency_Framework_-_Versi...)  
[Last Accessed 12th March 2018]

Spector PE. 1992. *Summated Rating Scale Construction. An introduction*. Newbury Park, CA: Sage Publications Inc.,

Stat Trek. 2018. Random number generator [Internet]. Available from  
<http://stattrek.com/statistics/random-number-generator.aspx> [Last accessed 12th March 2018]

Stephens- Lloyd A. 2004. The extended role of the clinical research nurse: Building an evidence base for practice. *NT research*. 9(1): 18-27. doi: 10.1177/136140960400900104

United Kingdom Clinical Research Collaboration (UKCRC) Sub-committee for Nurses in Clinical Research. 2007. Developing the best research professionals. Qualified graduate nurses: recommendations for preparing and supporting clinical academic nurses of the future. Report of the UKCRC subcommittee for nurses in clinical research (workforce). Available from [www.ukcrc.org/wp-content/uploads/2014/07/Nurses-report-August-07-Web.pdf](http://www.ukcrc.org/wp-content/uploads/2014/07/Nurses-report-August-07-Web.pdf) [last accessed 12th March 2018]