Research Nurse Competency Framework

RCN Research Society Fringe Event
Congress
14 May 2009
Where did we start?

- Many clinical research nurses, often working alone.
- Professional and clinical isolation.
- Expertise not being used to its full potential.
- Little, if any, career structure.
- No formal training.
- No competencies.
- Often working outside normal ‘boundaries’ (informed consent).
Spring 2007

- Ongoing debate.
- Caroline Humphreys
- Ann McMahon
Working Group i

- Sue Boase, General Practice and Primary Care Unit, Uni of Camb
- Ruth Boyd, Northern Ireland Cancer Clinical Trials Unit
- Kathrine Craig, Cardiff Wellcome Trust CRF
- Carol Dealey, University Hospital Birmingham NHS Trust
- Eileen Dillon, Northern Ireland Cancer Clinical Trials Unit
- Leslie Gelling, Faculty of Health & Social Care, Anglia Ruskin Uni
- Anne Gordon, Edinburgh Wellcome Trust CRF
Working Group ii

- Angela Grainger, King’s College Hospital, London
- Caroline Gunnell, East of England Primary Care Research Network
- Nikki Hale, Skills for Health
- Caroline Humphreys, formerly Cambridge Wellcome Trust CRF
- Sara Jones, Cambridge Wellcome Trust CRF
- Sandra Mulrean, East of England Diabetes Research Network
- Helen Pidd, Manchester Wellcome Trust CRF
Working Group Meetings

- 5 June 2007 – Wellcome Trust CRF, Cambridge
- 29 October 2007 – University Hospital Birmingham NHS Trust
- 17 March 2008 – Skills for Health, Solihull
- 17 July 2008 – Clinical School, Cambridge
- Consultation
- 9 October 2008 – Wellcome Trust CRF, Manchester
Consultation

• July to September 2008
• Total responses = 119
• Very positive with a large number of useful suggestions
• Thank you.
## Consultation

### General Evaluation

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>I/we agree with the development of this document</td>
<td>58</td>
</tr>
<tr>
<td>I/we do not agree with the development of this document</td>
<td>0</td>
</tr>
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<td>No response</td>
<td>12</td>
</tr>
</tbody>
</table>
Consultation

It is hard to disagree with something which tries to bring some order to the chaos that is the lot of the research nurse.

The importance of this document rests in the fact that it will provide a structure and focus to the work and training of clinical research nurses in the future, alongside career enhancement. This is particularly important to nurses within local trusts who will become recognised as something more than data collectors. In addition it protects and clarifies the research nurses role within the clinical research team.

The development of such competencies within a recognised and accessible framework is essential to supporting the evolution of a nursing research workforce that is fit for the future. This is required if research standards are to be built upon and improved, ultimately improving the quality of nursing practice as it creates a sound evidence base.
COMPETENCY FRAMEWORK FOR CLINICAL RESEARCH NURSES

Version 1

December 2008

Date for revision: December 2009
4.1 A ‘Clinical Research Nurse’ (CRN) refers to any nurse who is ‘employed principally to undertake research within the clinical environment’ [7]. This can include a variety of nursing roles but they all share the common feature that research is a central part of their employment. For the purposes of this document, it is important to differentiate between the CRN and the ‘Nurse Researcher’. A Nurse Researcher will also have primary engagement in research but they may not be directly involved in clinical research. The primary focus of this Competency Framework is on CRNs but there may be some overlap between this role and the roles undertaken by other nurses involved in health and social care research.
Competency Framework

2.1 For the purposes of this document, a competence is defined as:

“The ability to demonstrate the application of knowledge, understanding, practical and thinking skills to achieve effective performance in a professional or occupational role. This involves problem solving and being sufficiently flexible to meet changing demands.”

2.2 The purpose of a competence is to enable an individual to:

- Understand more clearly what is expected of them,
- Identify personal development needs,
- Provide evidence of achievements to support career development and progression.
3. **How to use these competencies**

3.1 In preparing this Competency Framework, the Working Group was keen to provide a framework that was sufficiently flexible to be of use for the many nurses involved in clinical research. It is important to remember that these competencies may need to be adapted for local use. In particular, it might be possible to tailor the ‘performance criteria’ and ‘contextual factors’ to meet local needs.
7. Competency 1: To demonstrate knowledge and understanding of the evolution of clinical research

## Evidence of achievement

<table>
<thead>
<tr>
<th>Band</th>
<th>Competence</th>
<th>Performance criteria</th>
<th>Knowledge and understanding</th>
<th>Contextual factors</th>
<th>KSF</th>
<th>SFH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Articulates the significance of the major events and documents influencing the evolution of clinical research, including the political imperatives and government strategies.</td>
<td>Political and strategic developments in clinical research.</td>
<td>'Human medical trials.' [15] 'In the name of science.' [16] 'Research governance: where did it come from, what does it mean?' [17]</td>
<td>C3</td>
<td>C5</td>
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<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td>International Conference on Harmonisation Good Clinical Practice (GCP) [18]</td>
<td>G5</td>
<td></td>
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<tr>
<td>7</td>
<td>Has a comprehensive understanding of the historical background, political influence and strategic developments relating to the evolution of clinical research.</td>
<td>Demonstrates comprehensive knowledge and understanding of the historical background, political influence and strategic developments relating to the evolution of clinical research.</td>
<td></td>
<td>GCP [19], including section 2. 'Research Governance Framework for Health and Social Care.' [20]</td>
<td>C1</td>
<td>C2</td>
</tr>
</tbody>
</table>

|      |                                                                            |                                                                                      |                                                                                           |                                                                                                               | C3  | C5  |
|      |                                                                            |                                                                                      |                                                                                           |                                                                                                               | G5  |     |
Competency Framework

4.2 ‘Band’ refers to the pay band on which nurses are contracted to work. The majority of CRNs will be employed on Bands 5 to 7 and a smaller number will be employed on Band 8. It is accepted that some centres might not employ CRNs at Band 5. This again emphasises the need to amend these competencies for local use.
4.4 A ‘performance criteria’ describes how the required competence can be demonstrated as being performed in each of the three Bands. It should be noted that a nurse performing at Band 6 is expected to demonstrate the ‘performance criteria’ for Bands 5 and 6. Likewise, a nurse performing at Band 7 would be expected to demonstrate ‘performance criteria’ relevant to all preceding Band levels.
Competency Framework

4.5 ‘Knowledge and understanding’ describes the essential knowledge and understanding required to perform a competence. It has only been possible to include some examples of the knowledge and understanding that might be required to achieve a competence. This should not be considered to be an exhaustive list and should be amended to meet local needs. For example, CRNs undertaking research with children and young people will need to add key elements of knowledge and understanding relevant to their area of practice.
4.7 ‘Contextual factors’ will include specific reference to information pertinent to the area of practice within which the competence will be used, including:

- Books, reports and other documents
- Journals and other papers
- Legislative and regulatory requirements
- Codes of practice
- Websites
## Consultation

### Contextual information

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<thead>
<tr>
<th>Description</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
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<td>18.6%</td>
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<tr>
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Core Competency 1

To demonstrate knowledge and understanding of the evolution of clinical research.

<table>
<thead>
<tr>
<th>Band</th>
<th>Competence</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Broad understanding of the historical background, political influence and strategic developments relating to the evolution of clinical research.</td>
</tr>
<tr>
<td>6</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Has a comprehensive understanding of the historical background, political influence and strategic developments relating</td>
</tr>
</tbody>
</table>
Core Competency 2

To apply knowledge and skills in the clinical research environment:

- Research studies – design and types of research
- Key personnel
- Financial management
- Practical skills
- Collection of data and completion of study documentation
- Data storage
Core Competency 3

To work within, and adhere to, the requirements of research ethics, research governance and legislation:

• Research ethics committees
• Seeking an ethical opinion and governance approval: preparation of documentation and submission
• Participant confidentiality
Core Competency 4

To understand the principles and practice of obtaining valid informed consent.
Academy of Nursing, Midwifery and Health Visiting Research (UK)

Who we are

The Academy of Nursing, Midwifery and Health Visiting Research has been established as a collaborative enterprise by the Royal College of Nursing, CPHVA – UNITE and the Royal College of Midwives in partnership with The Council of Deans for Health, the Nurse Directors group of the Association of UK University Hospitals, the Association for Leaders in Nursing, the Queens Nursing Institute, Mental Health Nurse Academics UK, the UK Clinical Research Facility Network and Nurses in Primary Care Research.

The need for an Academy.

The need for a collective voice on matters relating to research that involves nurses, midwives and health visitors is immediate. The necessary policy infrastructure to shape clinical academic careers is now in place (UKCRC 2007) and a requirement to develop mentorship schemes and expert support for those developing their clinical academic careers is important. The combined expertise of the collaborating organisations that form the Academy is powerful, as is our collective capacity to lobby for investment and change, particularly the strength given by our participating membership organisations. Clinical leadership as a force for innovation and improvement, has re-emerged within Government policy across the UK, including for example, proposals in England which specifically support the development of clinical academic careers for nurses, midwives and Health Visitors. A renewed purpose is beginning to emerge from that landscape as well as the new structures that will deliver research and development for health and social care. The Academy has a unique part to play in shaping that landscape and can offer a strong platform of professional expertise. We believe we can offer a unique contribution and add value.
RCN Research Society

Competency Framework for Clinical Research Nurses

Dr Leslie Gelling, RCN Research Society Steering Committee member, and Chair, Competency Framework for Clinical Research Nurses Working Group writes:

Clinical Research Nurses (CRNs) make a significant contribution to high quality clinical research in the United Kingdom (UK). For many years the work of CRNs has varied considerably between research sites and between clinical specialties. It has not been uncommon for CRNs to undertake very different roles and to receive very different levels of support for professional and career development. CRNs face many complex challenges in developing their own careers and in developing the role of the CRN. Recent advances, including formation of the UK Clinical Research Collaboration (UKCRC) and specialist research networks, have contributed to making significant improvements in the support offered to CRNs. It is hoped that this Competency Framework will offer further practical support for CRNs at various stages in their careers. Most importantly, this Framework will offer considerable guidance to nurses new to the CRN role.

In any research environment it is essential that staff demonstrate the necessary levels of competence to undertake their roles. This Competency Framework offers a process through which CRNs can demonstrate the acquisition and application of the knowledge and skills required by CRNs. The Framework has been designed to be as flexible and practical as possible and the Working Group is keen to learn about the experiences of those who implement the Framework. This feedback will be used in the preparation of future versions of this Framework.

This document contains a large amount of information and it is essential that it is kept up to date. The Working Group is well aware that the publication of this document marks only the start of this work. The first revision will be undertaken in twelve months. Please let us know if and/or how the Framework works for you or how it might be improved.

Document: Competency Framework for Clinical Research Nurses (PDF, 266K)
Where next?

- Publication
- University of Lincoln
- Cambridge University Hospitals NHS Foundation Trust
- Other
1\textsuperscript{st} Revision ... December 2009
... Discuss
“Mr. Osborne, may I be excused? My brain is full.”