Career Pathways in Research: Clinical Research Nurse

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This article is the second in the series on research career pathways. The clinical research nurse career pathway will inform you of the knowledge, skills and expertise required to conduct clinical therapeutic trials to International standards, as well as the options for pursuing a career in this area. Many nurses start their career in research as a clinical research nurse, and the skills and knowledge required to conduct numerous multi-centre studies provides an excellent grounding in the discipline, organisation and management of research conducted to recognised standards.

In the last 20 years, numerous papers have been published on the role of the nurse involved in clinical therapeutic trials (Arrigo, 1994., Audley, 1995., Cassidy, 1991., Di Giulio 1996., Scott, 1993). The Institute for Clinical Research (formerly the Association of Clinical Research in the Pharmaceutical Industry) has a sub-committee dedicated to addressing career acknowledgement, educational and ethical issues pertaining to their employment and career progression (ACRPI 1996). The Royal College of Nursing employment brief (1998) for Clinical Research Nurses (CRNs) details the wide range of titles for nurses involved in clinical therapeutic trials for which the RCN uses the generic title CRN. Skills often cited as important include reliability, organisation, communication, motivation, self-discipline and critical thought.

Clinical research nurses (CRNs) are nurses who are involved in the conduct of any phase of a clinical therapeutic trial (CTT). A clinical therapeutic trial is a prospective study of medicinal products in human subjects. There are usually four phases in the research process:
- Phase I – The first human studies are usually conducted on healthy volunteers, except in certain cases such as the administration of cytotoxic drugs that can only be given to patients.
- Phase II – The first randomised controlled trials for new drugs, which are frequently placebo controlled to be able to determine if they have a therapeutic effect.
- Phase III – These studies are to confirm therapeutic effect and dose range compared to established treatments.
- Phase IV - These are formal post-marketing surveillance studies, conducted to monitor if a high incidence of toxicity occurs with a new compound to enable the withdrawal of the drug at an early stage.

To ensure scientific, ethical and safe practice in the conduct of CTTs nurses need to have a comprehensive knowledge of research methodology and the principles of practice that are laid down by various governing bodies both nationally and internationally. The fundamental principle, that the majority of researchers adhere to, is expressed by the World Medical Association ‘Declaration of Helsinki,’ (2000) in that the patient’s interest should come first. However, the most effective agreement has come from the tripartite International Conference of Harmonisation guideline for good clinical practice (GCP, 1996) which was developed with consideration of the current good clinical practices of the European Union (EU), Japan and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organisation (WHO). GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve human subjects. These are now being developed into European Directives, which have time limits set on each one of them to become law in countries within the EU. At present, research on human subjects is covered by the Laws of the Land, by which the research team includes the CRN, as an integral part of the research team, must abide. The CRN has also to consider the standards set by the their regulating body the United Kingdom Central Council for nurses, midwives and Health Visitors (UKCC, 1996) which has identified standards for their professional conduct.
Career Development

Often in the past, many CRNs worked in isolation from their professional colleagues in an extended and specialised role conducting clinical therapeutic trials. Many nurses unfortunately had no comprehension of the discipline and knowledge that these nurses required to undertake their job competently and they were frequently derided as mere data collectors. Many of these nurses took up this role originally by chance as it was considered convenient whilst raising their family due to not having to work evening shifts or weekends. However, this has changed as many nurses are now applying for these posts as they have an acknowledged career structure.

It has been recognised by the Royal College of Nursing that a nurse undertaking this role should not be paid less than an E grade as the application of their knowledge of research methods is integral to their role. It has also to be taken into account that a nurse may be undertaking the same research role but due to the required clinical expertise the research post may be graded at a higher level. The role, knowledge, skills and expertise are demonstrated in figure 1. The career progression demonstrates the responsibility, autonomy, accountability and managerial skills required at each level.

Training/ Qualifications

In the last 5 years there has been an increase of short courses for CRNs the UK. These range from tailored training for specific studies organised by pharmaceutical companies to more generalised courses about the conduct of CCTs organised by Health Trusts, the Institute of Clinical Research and university departments. At present there is only one recognised university course for study site co-ordinators (SSCs)/CRNs developed in conjunction with the Institute of Clinical Research and John Moores University, Liverpool. Although this route goes from certificate to masters level, unfortunately this is only to certificate level for SSCs/CRNs. The course attendees are study site co-ordinators/CRNs and clinical research associates from the pharmaceutical companies. However, curriculum development is currently ongoing at other universities for the development of courses/modules to Masters level for CRNs. Such developments will at last enable CRNs to achieve academic recognition for the job that they have undertaken to international standards for decades.

Benefits of the Job

- The conduct of research to international standards
- Travelling to investigator meetings and conferences nationally and internationally
- Eating at good restaurants to discuss the research project/s and to network
- No shift work

Drawbacks of the Job

- Drowning in a sea of research jargon
- Frequently working in isolation
- Other nurses view the CRN as a data collector
- Short term contracts
- Sometimes have to arrange holidays around studies in progress
Linkage to other pathways/careers

CRNs in the conduct of clinical therapeutic trials have to adhere to regulations such as the European Code of Practice and the International Conference of Harmonisation (ICH) which trains them in the discipline of research. This training can enable them to cross over into other research careers:

Career within the Pharmaceutical Industry starting as a Clinical Research Associate (CRA)

In the conduct of CTTs the CRN frequently meets personnel from the different pharmaceutical companies. Therefore a shift in employment from CRN to CRA frequently occurs as the representative from the company on a site visit is monitoring the work undertaken at the research centre.

Phase I Trials Units within pharmaceutical companies

Although nurses employed by pharmaceutical companies within their Phase 1 unit are in many respects are working as CRNs, units, they are sometimes called pharmaceutical nurses. These nurses monitor volunteer patients on the first dosing of a new compound into human subjects. Volunteers as subjects are often staff employed by the company, in another capacity, and get paid for their participation.

Health Services Research

After conducting numerous CTTs many CRNs decide that they wish to undertake health services research which can be conducted within Trusts or in academic settings.

This helps to highlight the fact that nurses have the ability to develop their career in research within one discipline and then widen their knowledge and capacity within other arenas.

Pay scales

Distinguishing features of grading is the individual’s clinical expertise, responsibilities, accountability, autonomy, management/supervisory position and educational qualifications. However, there is room for negotiation between the clinical research nurse and their employer. Due to the nature of their job, CRNs frequently travel to visit patients in their homes so a car plus expenses are considered as an ‘extra’. However, the normal pay parameters in Table 1 are meant as guidance. Although not included pharmaceutical companies frequently cover the cost of research personnel at investigator sites to attend conferences within their own speciality.
Table 1. Guidance for pay scales of clinical research nurses

<table>
<thead>
<tr>
<th>Grade/position</th>
<th>Pay Ranges</th>
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<tbody>
<tr>
<td>Grade E</td>
<td>£16,510 to £19,935</td>
</tr>
<tr>
<td>Grade F</td>
<td>£18,310 to £22,865</td>
</tr>
<tr>
<td>Grade G</td>
<td>£21,605 to £25,420</td>
</tr>
<tr>
<td>Grade H</td>
<td>£24,135 to £28,945</td>
</tr>
<tr>
<td>Grade I</td>
<td>£26,725 to £31,620</td>
</tr>
</tbody>
</table>

*These are pay scales as of 1st April 2001

Sources of Funding

CRNs are financed by ‘soft’ money, which means that nurses are paid from the income generated by conducting clinical therapeutic trials. In the past, pharmaceutical companies frequently covered the cost of a member of staff for a set time period but now companies pay pro rata for work done. This can cause nurses great anxiety due the worry of having to continually generate income. However, many successful research units have excellent organisation and planning and therefore have an abundance of research contracts.

Job Applications

All job advertisements request the submission of a detailed curriculum vitae (CV). However, it is important to remember that future employers prior to advertising the post have had to set down specifications for the position. In that they have had to state what are essential and desirable requirements. These set requirements are then used when the short-listing candidates takes place. Consequently, if an essential requirement is stated in the job specification and this is not addressed within your application for the post do not be surprised if you are not invited for interview. Equally any information stated within your application is open for questioning during the interview. Hence, it is important to make detailed preparation of your application form and also for the interview. For those involved in the selection process it is evident who has prepared but may be nervous to those that are unprepared and unsure.

Places jobs advertised

- RCN R&D Co-ordinating Centre
- RCN bulletin
- Nursing Standard
- CRF Clinical Research Focus
Sample of job adverts

**Research Nurse RGN Grade E/F**

Full or Part-time  
An excellent opportunity to gain new research skills to assist in the organisation and management of clinical trials, adhering to specific trial protocols. As part of a small research team, it is essential to possess good communication and interpersonal skills to effectively communicate with patients and their families. Accuracy in data collection and documentation is essential.  
For information pack, including application details please telephone………….  
For informal discussion please contact……………..

**Head of Trial Co-ordination**  
Applications are invited for this full-time post co-ordinating national and international trails for cancer therapy. The successful applicant will be a graduate, with a proven experience of management of major clinical trials, preferably in the cancer field. Computer literacy, good presentational and interpersonal skills, experience at team management, and a good working knowledge of good clinical practice (GCP) and it application are essential. Informal enquires, please contact………….  
More details are available on our website…………..
References to further information and reading


Audley T Harrison M (1995) Study Site Co-ordinators – a ‘job definition’ challenge!  *Clinical Research Focus* 6 (6); 12-17.


We would like to thank everybody who attending meetings and gave us feedback on the career pathways especially Abi Masterson Consulting Ltd, Roswyn Hakesley-Brown, President of the RCN Ann McMahon, R&D Co-ordinating Centre Director.

Feedback

Any comments or feedback that could assist other nurses to develop their career to the RCN R&D Co-ordinating Centre c/o Dave O’Carroll

www.man.ac.uk/rcn/
## Nursing Research Careers: Clinical Research Nurse Pathway

<table>
<thead>
<tr>
<th>Grade E</th>
<th>Grade F &amp; G</th>
<th>Grade H</th>
<th>Grade I</th>
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<tbody>
<tr>
<td><strong>Typical Role</strong></td>
<td>Identify and screen suitable patients for trials; carry out procedures and treatment interventions according to pre-determined protocol. Practical organisation of the trial, collection of data, coding, entering data onto computer and patient support.</td>
<td>The CRN at an ‘F’ grade will not be in an ‘assistant’ capacity but act with a degree of autonomy frequently conducting concurrent research studies. Liaising with the sponsor companies and multi-disciplinary research teams. The CRN has an active role in ethical requirements including ethic committee submissions, informed consent process and patient support. The CRN at level ‘G’ would also have an educational and developmental role.</td>
<td>Leading the development of research projects and negotiating research funding; accountable for nursing and financial elements of research projects; responsible for submissions to research ethics committees; responsible for developing relations with sponsoring companies; advising specialists in the field on the application of research; dissemination and publication of research findings.</td>
</tr>
<tr>
<td><strong>Experience</strong></td>
<td>First experience in research capacity but clinical experience at post-registration level within specialty. Works under close supervision.</td>
<td>Experience of running concurrent research studies with minimal supervision to the standards required by good clinical research practice. Ability to give advice on the organisation and management of the research in progress.</td>
<td>Development of research protocols and study documentation; negotiating contracts with sponsoring companies; supervision of research teams; Co-investigator on trials.</td>
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<td><strong>Knowledge</strong></td>
<td>Knowledge of Good Clinical Research Practice; the health service; and health service R &amp; D and pharmaceutical industry partnership.</td>
<td>Knowledge of research design and methods; understanding of the analytical process</td>
<td>Comprehensive knowledge to enable costing of clinical trials appropriately; understanding of the complexity of ethical issues for research staff involved clinical research.</td>
</tr>
<tr>
<td><strong>Training</strong></td>
<td>Post-registration training within clinical specialty. Good clinical research practice. IT skills</td>
<td>Certificate in clinical research and specialist procedures required for each research project.</td>
<td>Masters level training including issues on ethics, law, drug development and management in clinical research.</td>
</tr>
<tr>
<td><strong>Skills</strong></td>
<td>Numerate; IT skills; ability to adhere to pre-determined protocols; ability to liaise with research staff and representatives of sponsor companies; good time and project management.</td>
<td>Good project management skills; protocol development, data analysis and writing for publication skills.</td>
<td>Ability to develop, assess and direct research protocols; manage resources including finances, equipment and staff members; maintain the overall standard of care for patients at all times.</td>
</tr>
<tr>
<td><strong>Desirable Qualifications</strong></td>
<td>UKCC Registration</td>
<td>First Degree; Certificate in Clinical Research</td>
<td>Masters degree (Research)</td>
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