Clinical Research Career Development for Nurses

Ralueke Ekezie (my brief)

• SANOFI: Connecting-Nurses Care-Challenge Innovation Award Winner 2012
• HIFA Country Representative of Year 2013
• Maternal Health Ambassador (MAMA)
• INSEAD: Strategic Innovation for Community Health(STICH) Nairobi 2017
• Fellow Circle of Health International (COHI) - Austin Texas

Chief Executive Officer: Blue Torch Home Care Limited
Flow of Presentation

- Skills required: Clinical Research Nurse (CRN)
- Career Growth: CRN
- Responsibilities / job description: CRN
- Scopes and standard of practice: CRN
- Education and Training: CRN
- Employers: CRN
- Salary: CRN
- Summary
Basic Definitions

- **Clinical research nurse**: nurse researcher(s) conducting research that informs evidence-based practices to improve patient care and work independently and with other research team members in conducting clinical based research.

- **Clinical nursing research**: Research carried out by nurses in the clinical setting and designed to provide information that will help improve patient care.

- **Specialized practice of nursing profession**: which focuses on equilibrium between care of research participants and fidelity to research protocol-IACRN 2012.
Preparing for a career in Clinical Research Nursing

Need:

• Knowledge-Education
• Current / relevant: Courses, Trainings, workshops
• Professional association/organization membership
• Clinical research environment
• Start!
Skill Required by a Clinical Research Nurse

- A solid foundation in General Nursing practice
- Understanding of the research process and terminology
- An in-depth knowledge of a variety of specialties working in investigation
- Further development of management, leadership, organizational, communication, teaching and mentoring skills
- IT and data recording skills
Clinical Research Nursing: a bespoke career succession

Typical CRN career titles: LMIC
- Research nurse
- Clinical research nurse
- Research nurse coordinator
- Clinical research worker
- Research assistant
- Study coordinator or Project coordinator
- Data Manager
- Field worker

- Clinical Research Associate (CRA)
- Clinical Research Coordinator (CRC)
- Clinical Research Scientist (CRS)
- Clinical Quality Assurance Auditor (CQA)
- Principal Investigator (PI)

NIH Clinical Center

Nursing Science

Clinical Research Nursing

Clinical Nurse Specialist
Post-Doctoral Training
Pre-Doctoral / Doctoral student
Advanced Practice Nurse
Research Nurse Coordinator
Clinical Research Nurse
New graduate
Undergraduate student
Roles of Clinical Research Nurse

- Clinician (Direct care provider, study coordinator, Advanced clinician)
- Manager
- Clinical research associate (CRA) Jr. research associate, clinical trial administrator
- Clinical Research Coordinator (CRC)
- Educator
- Advocate

LMIC: development required for CRNs to fulfill

- Regulatory specialist
- Nurse scientist
Roles include

- Doing the job on pre-trial procedures
- Participating investigator meetings (IM)
- Coordinating with ethics committee (EC)
- Coordinating with regulatory authority
- Monitoring and training Jr. staff
- Project management
Practice domains:
Clinical Research Nursing practice

TGHN/ GRN e-Learning courses / workshops

Study management
Clinical practice
Care coordination + continuity
Human subject protection
Contributing to science

ANA+ IACRN, October 2016
Study Management: Domain of Practice

CLINICAL RESEARCH NURSE

- Research Participant needs
- Standard of care needs
- Protocol needs

GRN support / e-learning courses for Non-CRN nurses

ANA+ IACRN, October 2016
Principles guiding Clinical Research Nursing practice

• Synthesis of *nursing practice* integrated with **Good Clinical Practice** (GCP)

• **Direct** nurses practicing in CRN specialty

• **Combined** with patient care: *safe* research environments, produce **reliable, valid** data

  • Safety and determination
  • Research informed consent
  • Fidelity to the research protocol
  • Regulatory compliance (LAWS)
Respect for the individual
Commitment to the patient
Advocacy for protection of the patient
Authority, accountability and responsible practice
Duties to self and others
Ethical work settings and care environments
Nursing profession advancement
Collaboration with the public and health professionals
Nursing profession integrity, values and social justice
Standards of Practice

Clinical Research Nursing practice

**Nursing process:**
1. Assessment, 2. Diagnosis 3. Outcomes identification

**Professional performance**
7. Ethics
8. Cultural congruent practice
9. Communication
10. Leadership
11. Education
12. Evidence based practice and research
13. Quality of practice
14. Professional practice evaluation
15. Environmental health
Core Competency Framework

Map the different roles within the clinical research teams.

Create a set of **global competencies** needed for the conduct of **clinical research**.

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**Area of competency**

**Data management**

**Type**: Task-based

The individual manages the data process in the trial; they oversee the task and specifications for its safe storage. They operate the data management system (DMS), and execute quality management strategies for the data. They check the timely resolution of database queries, and review reports generated from the databases as required. Data management requires excellent of the data flow plan, processes and guidelines, and good project management skills.

**Expert**

Experts may work with other sites to implement data management solutions during multicentre trials, and support the improvement of the management process when necessary.

**Related competencies**

**Knowledge base**: Research regulations; Ethics & human subject protection (confidentiality); Good Clinical (or other) Practice

**Required skills**: Computer and IT skills; Record-keeping

**Similar tasks**: Developing CRF & data management system; Analysing data; Collecting accurate data; Creating and maintaining database; Project management; Safety & AE management

**Keywords**

Data management; Data flow; Data transfer

**Abilities**

- Manage the flow of data in the trial: how it is acquired, cleaned and processed
- Ensure quality of data management and data systems
- Operate data management system
- Assist in defining data specifications and summaries, and data listing
- Reconcile data transfers
Framework parts

How does it work?

**Competency Wheel**

The Competency Wheel shows on a single page all the 50 competencies that make the Framework, applying to the entire research team.

The Competency Wheel and Dictionary are very flexible, and can be used to determine how a team will break down responsibilities involved in a new study, or to perform analyses of gaps in resources at a site.

**Competency Dictionary**

The Competency Dictionary gives a full description of each competency, and its associated tasks and keywords. This should clarify what is meant by the competencies listed on the Wheel.

**Grading System**

The grading system includes a template for grading an individual’s level of expertise for each area of competency; as well as a scale (0-5) to help grading consistently. Grades can be represented pictorially through the use of a radar diagram.

**Role-Specific Frameworks**

The role-specific frameworks are adapted from the generic framework for specific roles (research nurse, investigator, etc.). They contain examples of what a competency means for that particular role, and suggest a desired grade for junior/senior staff.
# Team roles

<table>
<thead>
<tr>
<th>Role</th>
<th>Junior</th>
<th>Senior</th>
<th>Expert or Specialist setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data staff</td>
<td>Data clerk; Data assistant; Data entry and administration personnel</td>
<td>Data manager; Senior or Lead data manager</td>
<td>Biostatistic</td>
</tr>
<tr>
<td>Laboratory scientist</td>
<td>Laboratory (lab) technician; Scientific lab technician; Lab technician; Lab research assistant</td>
<td>Assistant lab manager; Lab manager; Lab scientist; Head of laboratory (at site)</td>
<td>Head of laboratory(ies); Chief specialist scientist; Research scientist (medical); Senior lab analyst; Science lead; Clinical pharmacist</td>
</tr>
<tr>
<td>Trial pharmacist</td>
<td>Pharmacy administrator/coordinator; Trial pharmacist; Pharmaceutical technologist; Pharmacy technician</td>
<td>Lead pharmacist</td>
<td></td>
</tr>
<tr>
<td>Community engagement staff</td>
<td>Fieldworker; Research assistant</td>
<td>Senior fieldworker; Field research officer; Community engagement officer; Community engagement and ethics coordinator</td>
<td>Counsellor</td>
</tr>
<tr>
<td>Research nurse</td>
<td>Nurse; Nurse assistant; (Clinical) research nurse; Study nurse; Vaccination nurse</td>
<td>Clinical research coordinator; Study coordinator</td>
<td></td>
</tr>
<tr>
<td>Study physician</td>
<td>(Clinical) research physician; Clinical development physician; Study physician; Medical officer; Research clinician; Clinical investigator</td>
<td>Sub-investigator; Lead clinical research physician; (Clinical) safety physician; Pharmacovigilance physician; Public health officer</td>
<td></td>
</tr>
<tr>
<td>(Principal) investigator</td>
<td>Investigator (at site); Co-investigator; Medical science physician</td>
<td>Principal Investigator; Head of clinical trials; Global clinical Leader; Senior director of clinical R&amp;D; Senior global clinical pharmacologist</td>
<td></td>
</tr>
<tr>
<td>Trial manager or Project coordinator</td>
<td>(Clinical) research/trial coordinator; Project/study coordinator; Clinical research/trial manager; Clinical research operations manager; Clinical research administrator; Trial clinical officer; Support officer; Clinical trials facility manager</td>
<td>Senior research coordinator; Chief trial manager</td>
<td></td>
</tr>
<tr>
<td>Quality Control monitor</td>
<td>Clinical trial monitor; Quality assurance manager; Quality control specialist; (Clinical) Research associate (industry)</td>
<td>Lead monitor; Monitoring senior associate; Monitoring team leader; Quality assurance officer</td>
<td>Data quality controller; Safety specialist; Regulatory affairs specialist; Regulatory coordinator; Senior ethic clinical trials specialist</td>
</tr>
<tr>
<td>ECs and IRBs</td>
<td>Ethics Committee (EC) or Institutional Review Board (IRB) member (permanent or lay)</td>
<td>EC/IRB coordinator; EC/IRB vice-chair or chair</td>
<td></td>
</tr>
<tr>
<td>Sponsor</td>
<td>Not applicable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

# Competency grading

<table>
<thead>
<tr>
<th>Grade</th>
<th>Task</th>
<th>Knowledge</th>
<th>Skill</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Highly experienced; able to train and guide others.</td>
<td>Expert knowledge; able to teach and assess others.</td>
<td>Use skill appropriately, consistently and confidently.</td>
</tr>
<tr>
<td>4</td>
<td>Experienced; regularly perform the task in their job.</td>
<td>Highly knowledgeable; use, reflect, critically evaluate information related to the topic.</td>
<td>Use skill appropriately, in all relevant situations.</td>
</tr>
<tr>
<td>3</td>
<td>Capable to perform the task.</td>
<td>Knowledgeable; frequently apply knowledge of topic.</td>
<td>Use skill appropriately, but only occasionally.</td>
</tr>
<tr>
<td>2</td>
<td>Some experience; already performed the task at least once.</td>
<td>Some exposure; already applied knowledge of topic in their job at least once.</td>
<td>Use skill inconsistently and occasionally.</td>
</tr>
<tr>
<td>1</td>
<td>Little experience, but received training.</td>
<td>Little exposure, but followed courses or read about the topic.</td>
<td>Use skill with difficulty and/or very rarely.</td>
</tr>
<tr>
<td>0</td>
<td>No experience; never performed the task before.</td>
<td>No exposure; never heard of the topic before.</td>
<td>Unable to use skill.</td>
</tr>
<tr>
<td>NA</td>
<td>Not applicable (e.g. if the competency is not useful for the role of the individual assessed)</td>
<td></td>
<td></td>
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Clinical Research Nursing: education towards bespoke career?

- Employer specific only
- Employer specific + informal career focused (short courses / modules / certificates)
- Employer specific + formal career focused (degree / post graduate diploma / CRN certification)
- Formal career focused
- Informal career focused

PhD  Masters degree  Clinical specialisation  Short courses  ?
Required minimum education and training
Diploma in General Nursing (3 years)

Required minimum work experience
Minimum 1 year research experience

Desirable additional education, work experience
Diploma in Primary Health Care or similar will be an advantage
Certification in good clinical practice
Experience in a research environment
Good administrative skills together with working knowledge of Microsoft Office
Self-motivated, able to work independently and as part of a multidisciplinary team
Working knowledge of Microsoft Office packages
Examples: Clinical Research programmes offered

• Sollers College, New Jersey
  – Clinical Research Nursing Program (also online)
  – MSC. In Clinical trials management, short term courses and graduate certificate programmes

• James Lind Institute, Singapore
  – PG Diploma in Clinical research
  – Clinical programmes (also online programmes)

• University of San Diego, USA
  – Masters of Science in Clinical research
Examples: Organizations involved Clinical Research Nursing in Africa

• The Global Health Network (TGHN) – Global Research Nurses (GRN)

• International Association of Clinical Research Nurses (IACRN) - African chapter pending

• American Society of Clinical Oncology (ASCO): International Society of Clinical Trials Workshops (ICTW)
Typical employers: CRNs

- Universities
- Private research organisations
- Contract Research Organization (CRO)
- Biotech companies
- Pharmaceutical companies
- Self-employment (Freelance basis)

Country Annual Average clinical research nurses

- USA and Canada: $60,000-74,000
- Singapore: S$ 37,000
- United Kingdom: £ 35,000
- South Africa: R 297,599
- Australia: AU $ 79,200
SUMMARY

• No limitation to roles nurses can play in clinical research
• Education, trainings and resources available to explore as career pathways for CRN
• Need for formalized career pathway for CRN
• Existing clinical research nursing organization supporting clinical research nurses / nursing in Africa
• Clinical research is vital for discovering innovative ways to improve our patients care
Acknowledgements

TGHN: Prof Trudie Lang and team in Oxford

GRN: Organisers of this workshop

Dr. Elize Pietersen

Blue Torch Home Care Limited
Regulatory specialist role of the Clinical Research Nurse

1. Monitor, oversee progress of clinical trial (conducted, recorded + reported) in accordance with protocol standards SOP, GCP + applicable regulatory requirements

2. Must conduct work in settings of research practice, center, or hospital or within industry or governmental agencies

3. Have advanced knowledge of regulatory science (train through research-specific continuing education or Master’s education) with focus on regulatory science

Examples of job title:
Clinical research associate, Monitor, Industry Review Board (IRB) Director, Quality Assurance manager
Nurse scientist role of the Clinical Research Nurse

- Prepared at the **doctoral level**
  [Doctor of philosophy (PhD) or Doctorate of nursing science (DNSc)]

- Work in **inter-professional teams** with myriad of collaborators

- Engage in **scientific pursuit** of new knowledge to ultimately improve patient outcomes + health care delivery

- Activities include conducting + disseminating **original** research, participating on advisory **boards**/appointed committees + **educating/mentoring** others

Examples of jobs: senior leadership positions in clinical research enterprises as Directors, Senior scientists, Consultants
Master’s degree in clinical research – UC San Diego

**Program overview**

- principles of epidemiology
- bio-statistics
- patient-oriented research
- health services/outcomes research
- applied quantitative analysis
- professional development for clinical researchers
- integrative, high-level clinical research project in the student's final term

https://clre.ucsd.edu/program-overview/
Master’s degree in clinical research – UC San Diego

Objectives and Competencies

• Analyse a clinical problem including its relevant epidemiology, pathophysiology, and current therapy
• Design potential observational and interventional studies or health services research including:
  • Grants to support the study
  • Protocol with hypothesis, background, methods, and analytic plans
  • Human subjects application
  • Budgeting

https://clre.ucsd.edu/program-overview/
Master’s degree in clinical research – UC San Diego

Competencies gained

- Epidemiological concepts
- Bio statistical concepts, skills including use of SPSS and R software
- Scientific writing for grant requests and research papers
- Ability to design and implement a clinical (patient-oriented) research study including:
  - Selection of study methods
  - measures of the intervention and outcomes
  - data collection, management
  - Data analysis
  - Ethical and regulatory knowledge and practical skills (write IRB applications and utilise Data Safety Monitoring Boards)
Research Process

- Selection of Research Problem
- Extensive Literature Survey/review
- Making Hypothesis
- Preparing the Research Design
- Sampling
- Data collection
- Data Analysis
- Hypothesis Testing
- Generalization and Interpretation
- Preparation of Report