Clinical Research Nurses

A bespoke career

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Flow of discussion

• Clinical Research Nurses (CRN)
• Clinical Research Nursing: Scope and standards of practice
• Role of CRN in clinical trials
• FUTURE FULFILLED
My Clinical Research Nurse career

• Hons. B.Soc.Sc (general nursing, psychiatry, midwifery, community health)

• M.Soc.Sc (Psychiatric nursing, Nursing education)

• Hons. B.Soc.Sc (Psychology)

• Postgraduate Diploma: Nursing Education, Administration

• PhD (Medicine)
  ‘Molecular epidemiology, susceptibility profiles, outcomes and transmission dynamics in patients with extensively drug-resistant tuberculosis (XDR-TB) in two provinces of South Africa’
My Clinical Research Nurse career

- **Lecturer**
  (graduate students, post-basic students, staff nurses, auxiliary nurses, home-based carers)
  - general + psychiatric nursing, social science, community health

- **Clinical practice**
  - Psychiatric nursing
  - **General nursing**: medical ward, cardio-thoracic ICU, oncology
  - **Rural hospitals**: midwifery, trauma, general nursing
  - **Private hospitals**: cardio-thoracic ICU, oncology
My Clinical Research Nurse career

• **Clinical Research**

**Human Genetics** *(UCT)*
- Bipolar disorder
- Colorectal cancer genetics *(hnpcc)*
  - Identification / recruitment eligible families
  - Predictive genetic testing counselling
  - Randomised control trial (double blind: aspirin + starch)

**Lung Infection and Immunity Unit** *(UCT)*
- Extreme drug-resistant tuberculosis
  - *Acquired fluoroquinolone drug-resistance tuberculosis*
  - *Social determinants of health (tuberculosis)*
QUESTION: what are your challenges re research?

As NURSE EDUCATORS: what are (your) challenges re research?

As CLINICAL PRACTICE NURSES: what are (your) challenges re research?

As CLINICAL RESEARCH NURSES: what are (your) challenges re research?

What would you want to have different?
Relevance of clinical research nurses

- Evidence based medicine has become the norm

- CRNs fundamental to clinical research
  - by caring for research participants
  - performing research protocol tasks
  - management of clinical research studies

- Acknowledgment role of clinical research nurses

- Require properly-defined CRN career pathway / specialty
Practice domains

Clinical Research Nurses

- Study management
- Clinical practice
- Care coordination + continuity
- Human subject protection
- Contributing to science
Study management (practice domain)

CLINICAL RESEARCH NURSE

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

Non-CRN nurses

ANA+ IACRN, October 2016
Roles: clinical research nurse

- Clinician
- Manager
- Educator
- Advocate

- Regulatory specialist
- Nurse scientist
Regulatory specialist (role of CRN)

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 CRN)

- 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
Principles guiding CRN

- 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
CRN practice: nursing ethics

• Respect for the individual
• Commitment to the patient
• Advocacy for + protection of the patient
• Authority, accountability + responsible practice
• Duties to self + others
• Ethical work settings + care environments
• Nursing profession advancement
• Collaboration with the public + health professionals
• Nursing profession integrity, values + 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
What is a **Clinical Trial**?

- **Effectiveness** of intervention to **treat** a disease
- **Safety** of a new drug
- Defining **dose** administration
- Testing **drug formulation**
- Exploring **combination therapies**
- Evaluating **effect** of therapies on **quality of life**
Types of Clinical Trials

- **Treatment**
  - Test new approaches to treat a disease
- **Prevention**
  - What approaches can prevent disease
- **Early-detection/screening**
  - What are new ways to find hidden disease
- **Diagnostic**
  - How can new tests or procedures identify disease
Clinical (randomised) **drug** trials = **TEAM** sport
Clinical (randomised) drug trials = TEAM sport

CLINICAL RESEARCH NURSE

Research Participant needs

Standard of care needs

Protocol needs

- Treatment Group
  - Patients
  - Random assignment
  - Follow-up
- Control Group
  - Patients
  - Random assignment
  - Follow-up
- Compare results
CRN role in (randomised) drug trials
complex, varied, interesting

• Principal investigator (PI) has ultimate responsibility for any study

• CRN coordinate day-to-day management = leadership + organisational skills + flexible, adaptable approach

• CRN have a central + essential role
  – comprehensive understanding of the specialty studied
  – extensive knowledge of the research process
  – extensive knowledge of research-related legislation
  – variety of computer-based skills (word processing, spreadsheets, database, internet searches)
  – able to give clear explanations + excellent communication + interpersonal skills
CRN role in (randomised) drug trials
complex, varied, interesting

• Screening for potential participants

• Informed consent before being enrolled to trial
  – understand the purpose, risk + benefit of the study
  – no obligation to participate
  – free to withdraw at any time without it affecting treatment or care

• Quality and reproducibility of data collected: accurate + complete date, attention to detail

• Prompt reporting of (serious) adverse events + appropriate actions

• Act as teacher, mentor and advisor: other health professionals, patients

• Participant protection / advocacy
Informed Consent

Information: key facts about a trial before deciding whether to participate

- Research study purpose
- Risks/Benefits
- Alternative treatments
- Confidentiality of records
- Medical treatment available if injury occurs
- Whom to contact for answers to questions
- Statement that participation is voluntary
Challenge: patient recruitment

- Poor patient recruitment is the number one reason that trials fail
- Reasons for this relatively low number are many
- CRN standard of practice determines continued enrolment on study
Documentation: research

Source Documents:

- original records
- certified copies of original clinical findings and observations
- other activities in a clinical trial necessary for the reconstruction and evaluation of the trial (GCP guidelines apply)

Case Report Forms: (CRF’s)

- printed
- electronic document designed to capture subject related data
Aim documentation: research

Record

- **all** of the **protocol required** information
- to be **reported** to the sponsor (GCP guidelines apply)
- to **capture essential** source data for **analysis**
- to **answer** the hypothesis / research question of a study.
Data Management: responsibility of the research staff (including CRN) and IT professionals related to data

- Collection
- Entering
- Security
- Preservation

Data Integrity: based on policies and ethical practices for consistent procedures that properly manage the full data lifecycle needs
Source Data Lifecycle to achieve Data Integrity

Key Members involved

• Clinicians, **Nurses** and Clinical Research Coordinators (Site)
• Clinical Research Associates or CRA Monitors (Industry)
• Data Safety Committee (DSC) monitors
• Data Offices (Industry)
• Database Managers
• Biostatisticians (Site or Industry)
• **Nurses**, Doctors who manage safety offices for drug manufacturers

The Principle Investigator is the custodian of the data chain
CRN role in (randomised) drug trials

complex, varied, interesting

Attention to detail
Follow GCP guidelines
Carry out protocol precisely as written

Accuracy
Completeness
Timeliness
Data entry & Corrections
Clinical Research Nursing
a bespoke career in Africa
Strengthening the connection between clinical research and clinical health care.
FUTURE FULFILLED

• **Accredited** CRN education and training in/for Africa

• CRN declared **specialty** by [country] Nursing Council

• Dedicated CRN **career pathway**

• Nursing **Research Association** (Council/Institute) for Africa

• **Self-generated** clinical research by CRNs in/for Africa

• **Funding** opportunities for CRN **research projects**

• Clinical health science **research conferences** in/for Africa
Nursing process:
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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
Thank you