THE ROLE OF THE NURSE IN CLINICAL TRIALS

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September 2019
I have no affiliations, associations or relationships with any pharmaceutical or other industry organizations/associates.
WHY DISCUSS NURSING IN CLINICAL TRIALS?

- Teaching in a Regulatory Science Program, I discovered that various non-Nurse Clinical Trial staff and Nurses in Clinical Trials had what they felt were “differing points of view”.

- These perceived differences caused some frustration between the groups.

- Goal: Create a collegial understanding between colleagues by defining the Nurse’s role in Clinical Trial Management.
1. Provide an Understanding of “Nursing”.

2. Define the various roles for nurses in clinical trials.

3. Describe the educational preparation of the RN in research and the connection to clinical research and clinical trial roles.

4. Analyze how the nurse can impact the clinical trial through patient health education.
Objective #1 - Understanding the “Nurse”

“The nursing profession was founded to protect, promote, and improve health for all ages.” -- American Nurses’ Association
## Roles Often Referred to as Nurses

<table>
<thead>
<tr>
<th>Nurse’s Aid</th>
<th>Medical Assistant</th>
<th>*LPN/LVN</th>
<th>*RN</th>
<th>*Advanced Practice Registered Nurses</th>
</tr>
</thead>
<tbody>
<tr>
<td>(most often in Acute Care)</td>
<td>(most often Out-Patient Settings)</td>
<td>Various Degree Levels</td>
<td>Nurse Practitioner</td>
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<tr>
<td>CNA</td>
<td>MA</td>
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<tr>
<td>NA</td>
<td>W/ or W/O Phlebotomy</td>
<td></td>
<td>Nurse Anesthetist</td>
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<td></td>
<td></td>
<td>Clinical Nurse Specialist</td>
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<td>Nurse Midwife</td>
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</tbody>
</table>

*Only roles that can legally call themselves/hold out as a “nurse”.*
WHAT ARE ALL THE INITIALS ABOUT?

- FAAN
- MPH
- RN
- DNP
- STEM
- ANP
- AACRN
Educational Pyramid and Credentialing

Doctorate
- Doctor of Nursing (ND)
- Doctor of Nursing Practice (DNP)
- Doctor of Nursing Science (DNSc)
- Doctor of Nursing Philosophy (PhD)
- Accelerated Option
  - BSN to PhD 5 years

MSN
- Master of Science in Nursing
  - 1.5 - 2 years if applicant has ADN or BSN
  - Universities
  - On campus or Online
- Specialties
  - Nurse Practitioner (NP)
  - Certified nurse midwife
  - Clinical Nurse Specialist (CNSS)
  - Certified Nurse Anesthetist (CNA)
  - Nurse Educator
  - School Nursing
  - Clinical Nurse Leader (CNL)
- Accelerated Option
  - Second-degree* MSN 1-3 years

BSN
- Bachelor of Science in Nursing
  - 4 years to complete
  - 1-2 years if applicant has ADN
  - Universities
  - On campus or Online
- Accelerated Option
  - Second-degree* BSN 1-1.5 years

ADN
- Associate Degree in Nursing
  - 2 years to complete**
  - Community Colleges
  - Trade Schools
  - Wait list to get in

Diploma
- Diploma in Nursing
  - 2-3 years to complete
  - Common prior to 1970s
  - Trained in hospital
  - Rare and being phased out

* The applicant already has a bachelor degree (BA or BS) in another field and no RN license
** Does not include completion time for prerequisite courses

2/21/11 Anna M. Wilson RN MSN

*hospital based programs no longer available
DEFINING A NURSE

• "NURSING ENCOMPASSES AUTONOMOUS AND COLLABORATIVE CARE OF INDIVIDUALS OF ALL AGES, FAMILIES, GROUPS AND COMMUNITIES, SICK OR WELL AND IN ALL SETTINGS." (WHO, 2019)

• NURSING SELF-BELIEF: IN ASSESSING A PATIENT...NURSES USE THEIR KNOWLEDGE AND JUDGMENT TO INTEGRATE OBJECTIVE DATA WITH SUBJECTIVE EXPERIENCE OF A PATIENT'S BIOLOGICAL, PHYSICAL AND BEHAVIORAL NEEDS.
  • THIS ENSURES THAT EVERY PATIENT, FROM CITY HOSPITAL TO COMMUNITY HEALTH CENTER; STATE PRISON TO SUMMER CAMP, RECEIVES THE BEST POSSIBLE CARE REGARDLESS OF WHO THEY ARE, OR WHERE THEY MAY BE. (ANA, N.D.).

• NO TWO NURSES HAVE THE SAME PATH...EDUCATION OR PRACTICE.
STRENGTHS OF NURSING

• **Life Longer Learners**
  - Asks questions
  - Seeks new learning/knowledge

• **Education**
  - Subject (Patient) Education
  - Staff Education

• **Policy Driven**
  - “Rule followers”
ULTIMATE FOCUS OF THE NURSE.....
OBJECTIVE #2 - DEFINE THE VARIOUS ROLES FOR NURSES IN CLINICAL TRIALS.
CLINICAL RESEARCH NURSING (CRN)

Recognized by the ANA as a specialty of Nursing Practice that focuses on the care of research participants and the management of clinical trials. (ANA, 2016)

✓ Subject advocacy

✓ Protocol advocacy
VARIOUS ROLES FOR NURSES FOUND IN THE LITERATURE:

• **Staff Nurse**—nurse who cares for subject outside of the study team, however, must connect with study management to maintain protocol.

• **Study Nurse**—nurse assigned to subject care needs while in the trial.
  - Medication administration (e.g. IV medications)
  - Assessment of IP tolerance during treatment(s)
  - Participant Observer
    - Enhanced understanding of context being studied

• **Nurse Pharmacist-IP Preparation/Management**
  - Prepares/mixes IP for administration
  - Turns IP over to Study Coordinator/Study nurse for dispensing/administration
  - Often trial mandated no subject contact
  - Responsible for IP inventory
  - Ensures IP safety (e.g. storage, expiration, sponsor updates)
VARIOUS ROLES FOR NURSES FOUND IN THE LITERATURE:

- **Clinical Research Coordinator**—Same role as other coordinators…just add the nursing education.
  - Brings with them their unique nursing background.
  - Brings in knowledge of disease and patient care.

- **Sub-Investigator**
  - Often an Advanced Practice RN or Advanced Practice Registered Nurse (NP, CNM, CNS, CRNA).
  - Is responsible for data collection through physical exam of the subject.
  - Is responsible for safety evaluation of the subject.

- **Clinical Trial Navigator**
  - Comparable to the Case Manager role in health care settings.
  - Ensures the overview of the subject’s journey in a clinical trial protocol.
  - Protects both the sanctity of the protocol and the subject’s rights during an individual subject’s journey.
VARIABLE ROLES FOR NURSES FOUND IN THE LITERATURE:

• **Quality Assurance Officer**
  - Ensures trial activities are preformed in adherence with GCPs.
  - Creates and Maintains the SOPs in conjunction with the Site Director and PI(s).
    - Ensures trial functions stay within the SOPs.
    - Education of new staff and Maintaining existing staff.
    - Reads protocols and ensures any updated SOPs are completed or new are created to ensure compliance.
  - Ensures IRB compliance is maintained
    - Reporting-from AE/SAEs to annual report or initial reporting interims.
    - Education to trial staff as needed.
  - Creates an environment of FDA Audit Preparedness

• **Site Director**
  - Same as Site Director role for non-nurse.
  - Requires advanced training in Clinical Trials/Research.
  - Usually has a Master’s Degree or higher with 2+ years in Clinical trial experience.
THE CRN IN PHARMACEUTICALS

• **Varies from Nurse Scientist to Protocol Monitors.**

• **Can be an expert in a particular field of medicine.**
  - E.g. Cardiology, Rheumatology, Oncology.

• **Most have a Master Degree or higher.**

• **Advanced or extensive experience in a given field.**
CHALLENGES OF THE CLINICAL RESEARCH NURSE

- **Research education** for a LPN/LVN & RN (at or below BSN) does not include a lot (if any) of research.
  - Introductory level at the bachelor’s level.
  - Depth of research increases at master’s level.
  - Doctoral education is heavy research focused.
  - **Most programs do not include any Clinical Trial Research.**

- **Role conflict**
  - Separating the trial from the subject.
  - Making the protocol just as important as the subject.
  - Pressure to provide care not included in the protocol.
  - Identifying areas of inadequacies in management of care, treatment, and delivery of care.

- **Average length of stay in clinical site is 2 years.**

(Ehrenberger & Lillington, 2004; Poston & Buesche, 2010; Spilsbury, Petherick, Cullum, Nelson, Mixon, & Mason, 2008; Trocky, 2001).
#3-Describe the educational preparation of the RN in research and the connection to clinical research and clinical trial roles.
VARIOUS FACTOR TO CONSIDER

- NIH states, “Clinical research should be seen as the social good that it is” (NIH, n.d.)

- Nursing Education lacks this content with some schools of higher education not seeing clinical trial research as “true research”.

- Many nurses do not have a connection to this field as a specialty and “stumble” into this field by chance.

- Training at clinical research sites is not always adequate for the staff including the nurse. (NIH, n.d.)
The Five Practice Domains:

1. Care coordination and continuity.
2. Contribution to science and nursing science practice.
3. Human subjects protection.
4. Management of clinical and research activities.
5. Clinical practice.
1) **GUIDING PRINCIPLES OF PRACTICE:**
   a. **SAFETY AND SELF-DETERMINATION OF PARTICIPANTS**
   b. **FIDELITY TO RESEARCH PROTOCOLS**
   c. **COMPLIANCE WITH REGULATIONS**
   d. **RESEARCH-SPECIFIC INFORMED CONSENT**

2) **HOW EACH OF THE PROVISIONS OF THE **Code of Ethics for Nurses** APPLY TO CRN PRACTICE**

3) **TRENDS AND ISSUES INCLUDING:**
   a. **BIG DATA**
   b. **ELECTRONIC HEALTH RECORDS**
   c. **THE EVIDENCE FOR PRACTICE**
   d. **MINORITY INVOLVEMENT IN CLINICAL RESEARCH**
MANY SITES OFFER MINIMAL EDUCATION

*Recommended:
Educational programs from Conferences, Seminars, & University Programs in Regulatory Science
WHAT INHIBITS ADVANCED TRAINING?
ONE OF NIH'S GOALS IS "TO DEVELOP, MAINTAIN, AND RENEW SCIENTIFIC, HUMAN, AND PHYSICAL RESOURCES THAT WILL ENSURE THE NATION'S CAPABILITY TO PREVENT DISEASE."

THE OFFICE OF CLINICAL RESEARCH HAS THE RESPONSIBILITY FOR COURSES WHICH PROVIDE CLINICAL RESEARCH TRAINING FOR THE SPECTRUM OF INVESTIGATORS AND OTHERS INVOLVED IN CLINICAL RESEARCH.

- INTRODUCTION TO THE PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH
- PRINCIPLES OF CLINICAL PHARMACOLOGY
- CLINICAL RESEARCH TRAINING ON-LINE COURSE FOR PRINCIPAL INVESTIGATORS
- ETHICAL AND REGULATORY ASPECTS OF CLINICAL RESEARCH
- NIH SUMMER COURSE IN CLINICAL AND TRANSLATIONAL RESEARCH
- NIH-Duke Master's Program
- SABBATICAL IN CLINICAL RESEARCH MANAGEMENT
UNIVERSITY BASES REGULATORY SCIENCE PROGRAMS

• For nurses with a Bachelor of Science, Graduate degrees in this area augments education for this specialty.

• Non-nurses-Bachelor level programs also exist.

• Online or Campus based.

• Few of these schools are listed*.
  • Utah Valley University
  • Northeastern University
  • University of California Irvine
  • Arizona State University—Accredited

*List is not inclusive. A full search of programs is recommended for anyone interested in pursuit of a degree in this field.
WHY DO NURSES LEAVE CLINICAL TRIAL SETTINGS?

1. Lack of Training
2. Lack of Advancement
3. Lack of Autonomy
4. Lack of Change
5. Lack of Hands-On Patient Care
6. Lack of Patient Focus

(Ehrenberger & Lillington, 2004; Poston & Buesche, 2010; Spilsbury, Petherick, Cullum, Nelson, Mixon, & Mason, 2008; Trocky, 2001).
#4. ANALYZE HOW THE NURSE CAN IMPACT THE CLINICAL TRIAL THROUGH PATIENT HEALTH EDUCATION.
IMPROVED QUALITY OF CLINICAL TRIALS

• Communication about the trial with staff and subjects.

• Strong education skills:
  • Increased recruitment.
  • Increased subject compliance.
  • Improved links between research and care.

(S PILSBURY ET AL., 2008)
DECISION MAKING SKILLS

- **Natural part of being a nurse is the ability to assist a subject on making educated decisions.**

- **Motivation on the patient’s behalf.**

- **Priorities & Organizational Skills.**
ESTABLISH RELATIONSHIPS

• **Collaboration:**
  • Team, Interprofessional, and Intraprofessional.

• **Subject relationship:**
  • Considers culture, personal obstacles, and psychosocial elements of the individual.
EDUCATE

- Likely Nursing’s strongest attribute!
  - Other team members
  - Patients
  - Community members
  - Extended healthcare team
FINAL THOUGHTS

- Nurses can make a significant impact in clinical trials work by using their expertise as:
  - Subject advocates
  - Safety advocates
  - Protocol / GCP advocates

- Nurses love to educate—give them this role!

- Training for the nurse is needed just as their non-nurse colleagues.

- Nurses make great collaborative team members!
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