

ROLES OF NURSES IN CLINICAL TRIALS

A PAPER PRESENTED
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OBJECTIVES

- Understand why research is important in Nursing.
- Discuss the need for evidence based practice, and types of Evidence and Evidence Hierarchies.
- Identify alternative sources of evidence for nursing practice.
- State the roles of nurses in clinical trials.


What is Nursing Research?

- Research is an indispensable part of a modern, effective health service and essential to the provision of effective and safe health and social care (Royal College of Nursing, 2009; Department of Health, 2005).
Therefore, nursing research is a systematic inquiry designed to develop trustworthy evidence about issues of importance to nurses and their clients (Polit & Beck, 2018).


What is Nursing Research?


CONT'D

Clinical nursing research is research designed to guide nursing practice, and it typically begins with questions stemming from practice problem – problems one may have already encountered (Polit & Beck, 2018). An example of nursing research is: Assessment of daily experiences of patients receiving hemodialysis treatment for end-stage renal diseases.

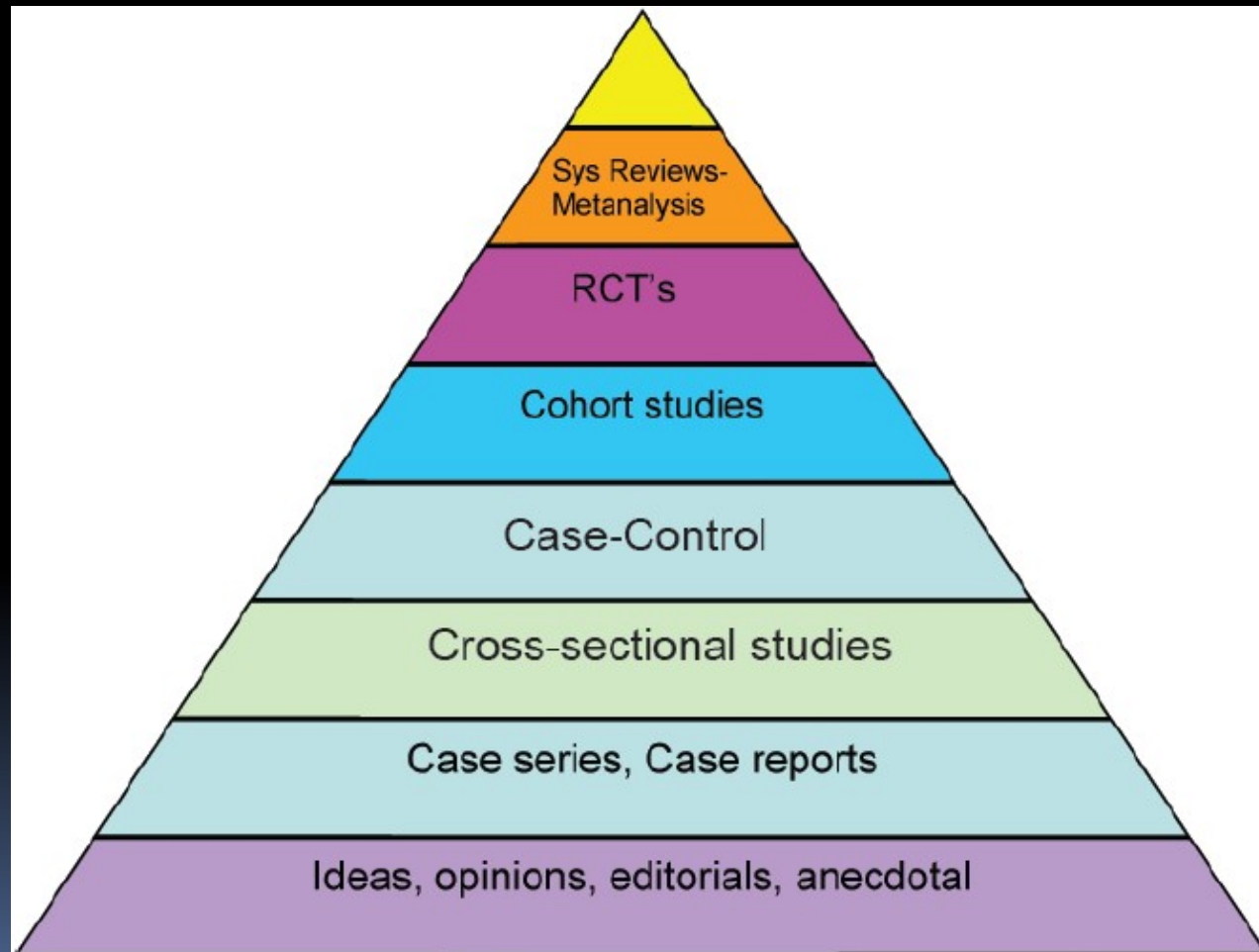


The Importance of Research to Evidence-Based Nursing

1. Nursing profession has experienced profound changes in the past few decades. Nurses are increasingly expected to understand and undertake research and base their practice on evidence from research – that is, to adopt an evidence-based practice (EBP) (Polit & Beck, 2018).
 2. Evidence-based practice, broadly defined, is the use of the best evidence in making patient care decisions. Such evidence typically comes from research conducted by nurses and other health care professionals (Polit & Beck, 2018).
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3. Nursing leaders recognize the need to base specific nursing decisions on evidence indicating that decisions are clinically appropriate and cost-effective and result in positive client outcomes (Polit & Beck, 2018).
 4. In some countries, research plays an important role in Nursing credentialing and status.
 5. Changes to nursing practice are happening everyday because of EBP efforts. (Polit & Beck, 2018). Example of evidence-based practice is, “Kangaroo care”, the holding of diaper-clad.


TYPES OF EVIDENCE







The Randomized Control Trial (RCT)

The Randomized Control Trial, the true experimental design involves assigning individuals by special randomization techniques into two or more groups, where one group receives the intervention under investigation and the other(s) receives no treatment, a placebo, or a standard intervention.



Pick et al (2010) stated five (5) key points about clinical research

- Clinical research is vital for finding new treatments and improving patient care. Research nurses are at the forefront of this process.
- Research nurses need a thorough understanding of the research process and terminology, and in-depth knowledge of the specialty under investigation.
- The nurses play a key role as patient advocate, ensuring patients' safety and protection, and that patients are well supported throughout the research study.

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- Research nurses need a wide range of skills including management and organizational skills, teaching and mentoring, communication and IT.
 - Collaboration and cooperation with other researchers and members of the multidisciplinary team is crucial for successful research.
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The multidisciplinary care team on a clinical trial


- Nurse Practitioner (NP)
- Physician Assistant (PA)
- Clinical Research Nurse (RN)
- Clinical Research Coordinator (CRC)
- Pharmacist/Pharmacy Technician
- Bio-specimen Coordinator
- Regulatory Coordinator
- Research Assistant (RA)



Clinical Research Nursing


As it includes all advanced practice competencies, clinical research nursing involves decision making and concrete thinking.

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1. A Clinical Research Nurse
 2. A Nurse Researcher



Areas of Research Interests and Research Priorities for Nurse Researchers

These may include the following five (5) areas of focus viz:

- 1. Promoting health and preventing disease.
 - 2. Symptom management and self-management
 - 3. End-of-life and palliative care.
 - 4. Innovation
 - 5. The development of nurse scientists (<http://www.ninr.nih.gov>). (NINR's strategic plan 2013).
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SOURCE OF EVIDENCE FOR NURSING PRACTICE

- **Tradition and Authority**
 - **Clinical Experience and Trial and Error**
 - **Assembled information**
 - **Disciplined Research**
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THE PURPOSES OF NURSING RESEARCH

- 1. Identification
 - 2. Description
 - 3. Exploration
 - 4. Prediction and control
 - 5. Explanation
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ROLES OF NURSES IN CLINICAL TRIALS/CLINICAL RESEARCH

1. The research nurse's job is complex, varied and interesting
2. Preparing trial protocols and other trial-related documentation.
3. Submitting study proposals for regulatory approval
4. Coordinating the initiation, management and completion of the research.
5. Ensuring patients give fully informed consent before being enrolled to trials.
6. Give clear explanations, along with excellent communication and interpersonal skills.
7. be responsible for randomization, and for collecting and recording data.


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8. Prompt reporting of adverse events for patient's protection (European Medicines Agency, 2002).
 9. Act as teachers, mentors and advisors to other health professionals
 10. Live presentations at conferences and other meetings.
 11. Patient's advocacy role

Indeed, Nurses can serve in a variety of roles when it comes to clinical trials — from being a research nurse or a vital piece of the multidisciplinary team (Department of Health, 2005).

In the current EBP environment, every nurse is likely to engage in one or more activities along a continuum of research participation.



At the end of the continuum are users or consumers of nursing research (nurses who read research reports) to keep up-to-date on findings that may affect their practice (Polit & Beck, 2018).



At the other end of the continuum are the producers of nursing research (nurses who actively design and undertake studies).

Between these two end points on the continuum lie a variety of research activities in which nurses engage. Even if a nurse never conducts a study, he/she may do one of the following:

1. Contribute an idea for a clinical inquiry.
2. Assist in collecting research information.
3. Offer advice to clients about participating in a study.
4. Search for research evidence.
5. Discuss the implications of a study in a journal club in your practice setting, which involves meetings to discuss research articles (Polit & Beck, 2018).

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THANKS

FOR

LISTENING