Advanced Oncology Certified Nurse Practitioner

REVIEW COURSE 2024

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THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

Clinical Trials and Research

- Based on the Advanced Oncology Nursing Certification Review and Resource Manual (Third Edition), published by the Oncology Nursing Society
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Objectives

- Identify the potential benefits and risks associated with participation in clinical trials for patients
- Describe the essential elements of the informed consent process
- Explain the function of the Institutional Review Board (IRB)
- Discuss the various roles and responsibilities of advanced practice nurses (APNs) in clinical trial settings

What is Clinical Research?

- Studies that follow a systematic scientific approach to conduct observational research or clinical trials in people, aimed at improving medical knowledge and care by collecting data to test new treatments, devices, or ways to prevent, detect, or manage diseases.
- For example, clinical trials for immunotherapy in cancer treatment.
- Many opportunities for APNs to be involved in clinical research.

Types of Clinical Research

- Observational
  - Participants receive interventions without assignment
  - For example, the Framingham Heart Study
- Interventional
  - Clinical trials
  - Participants receive a specific intervention per the protocol
  - For example, CheckMate057

Accessing Investigational Therapies

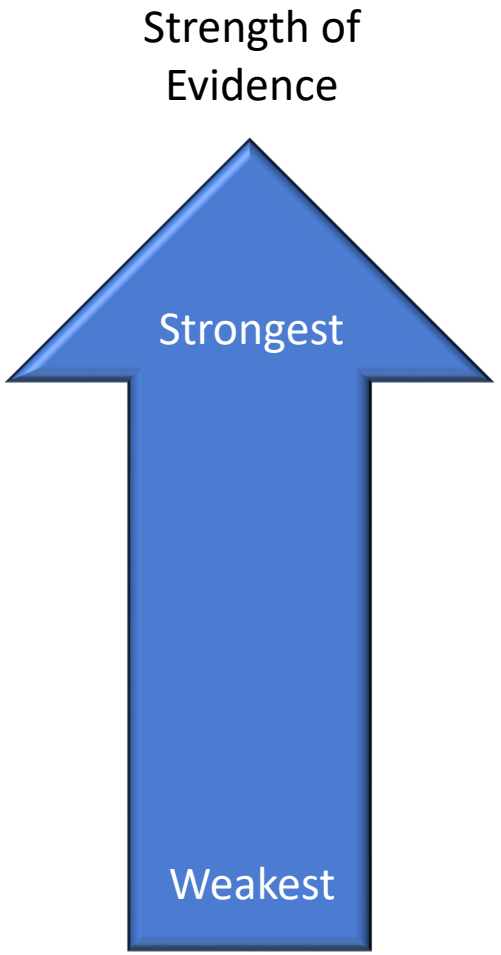
- ClinicalTrials.gov
  - Established following the 1997 Food and Drug Administration Modernization Act
  - Provides public access to information on study designs, eligibility criteria, and results.
  - Managed by the National Library of Medicine and National Institutes of Health (NIH)
- Recruitment for clinical trials remains a significant challenge

Accessing Investigational Therapies

- Compassionate Use
  - Provides access to unapproved drugs or devices for patients with serious or life-threatening conditions.
  - Patients must have exhausted all available treatment options.
- FDA Expanded-Access Program:
  - Offers investigational treatments for patients unable to join clinical trials.
  - Requires healthcare providers to demonstrate that potential benefits outweigh the risks.

Hierarchy of Evidence

- Meta analysis or systematic review of multiple randomized controlled trials
- Evidence-based clinical practice guideline
  - Systematic literature search of existing studies, clear documentation of how the recommendations were developed, and a rating of how strong the evidence is to support clinical decisions.
- Randomized controlled trial
- Cohort study
- Uncontrolled study (correlational or descriptive)
- Case reports
- Clinical practice guideline developed by consensus
- Expert opinion



Phases of Clinical Trials

Phase 0	Phase 1	Phase 2	Phase 3	Phase 4
First-in-human testing, involving a small sample size and low dose to see how the drug behaves in the human body	Focuses on finding a safe dosage and delivery method while assessing the drug's impact on the body and its interaction with the disease	Involves more participants and continues to evaluate the drug’s effects on the body and disease, while looking for signs of efficacy	Compares the new treatment or intervention to the standard of care in a larger group of participants, assessing both safety and effectiveness	After FDA approval, these trials monitor the drug’s safety in the general population, collecting more data for long-term effects

Risks and Benefits of Clinical Trials

- Potential Benefits
  - Access to new therapies
  - Close monitoring of side effects
  - Ability to help future patients
- Potential Risks
  - Increased number of invasive procedures (research biopsies)
  - Frequent visits to academic medical centers with long days of monitoring
  - Uncertainty regarding efficacy, potential toxicities

Institutional Review Board (IRB)

- Role: Protects the rights and welfare of research participants.
- IRB Approval: Required for all clinical research before enrolling participants.
- Review Process: Systematic review of study design and protocols to ensure safety and compliance.
- Regulating Bodies: Overseen by the Office for Human Research Protections (OHRP) and FDA.
- Feasibility Review: Includes assessment of cost, staffing, training, regulations, and funding sources.

Ethical Issues in Clinical Trials

- Medical privilege has historically led to mistreatment and unethical clinical research in the past
  - Nazi Medical Experiments: Atrocities committed during the Holocaust.
  - Tuskegee Syphilis Study: 400 African American men were denied treatment for syphilis to study disease progression.
  - Henrietta Lacks: Cancer cells taken without consent, leading to widely used cell lines.

Protection of Human Subjects

- Ethical guidelines are essential to prevent mistreatment in research, emphasizing valid study design, fair participant selection, risk-benefit assessment, independent review, and informed consent.
- Nuremberg Code (1947): Established in response to Nazi war crimes, it emphasizes the necessity of voluntary participation in research.
- National Research Act (1974): Outlined basic principles and methods to ensure ethical conduct in research.
- Belmont Report (1974): Identified three core principles—respect, beneficence, and justice—that guide biomedical research.
- APNs should understand and adhere to these ethical guidelines in clinical trials.

Informed Consent

- Protects participants by ensuring they make informed decisions about joining clinical trials.
- Involves a clear explanation of the intervention, including what it is, how it is performed and when it takes place
  - Emphasizes that participation is voluntary and can be withdrawn at any time.
- Notifies participants of their rights and informs them that they may not benefit from the trial
- Studies show suboptimal recall of consent details by patients
  - Care must be taken at subsequent visits to ensure participants understand the trial and wish to continue.
  - Investigators must update consent forms when new findings or toxicities arise, and all participants must sign the revised forms.
- Informed consent documents require approval from the IRB to ensure they include all necessary elements before use.
- It may be the responsibility of the clinical trial nurse to prepare updated documents, submit them to the IRB for approval, and obtain updated consent from current participants.

Confidentiality

- All study participants deserve respect, even if they choose not to enroll.
- The research team must uphold privacy and confidentiality, including respecting participants' rights to decline further involvement.
- Use of locked offices or file cabinets for secure data storage is important.
- Individual identification numbers are used instead of personal health information.

Vulnerable Populations

- Vulnerable populations include
  - Minority groups
  - Low socioeconomic status and resource-limited individuals
  - Pregnant women and children
  - Individuals with preexisting health conditions
  - Incarcerated individuals
  - Those with language barriers
  - Refugees and military personnel
  - Terminally ill or comatose patients
  - Older adults
  - Individuals with sensory impairments or diminished mental capacity
- When conducting research involving these groups, additional safeguards are necessary to ensure ethical treatment.

Use of Placebo

- Not typically used in early phase (phases 0-2) clinical trials
- May be used in later phases when no current effective treatment exists

Role of the Advanced Practice Nurse

- Provide direct patient care, including monitoring treatment response and side effects.
- Educate patients, nurses, and healthcare providers.
- Recruit participants and obtain informed consent.
- Serve as regulatory specialists and monitor studies.
- Conduct insurance coverage reviews.
- Coordinate research efforts and manage data.
- Act as institutional review board administrators.
- Manage research teams.
- Interpret research findings and facilitate their translation into practice.

Role of the Advanced Practice Nurse

- Determining clinical trial eligibility
  - Must think about your individual patient and future patients
    - Early clinical data affects the ultimate fate of the drug
    - Careful patient selection is important

Clinical Trial Recruitment

- All recruitment materials must be approved by the institutional review board as part of the informed consent process.
- Materials should be clear, concise, and free of misleading information to avoid misinterpretation, coercion, bias, or discrimination.

Role of the Clinical Trial Nurse

- Care for research participants
- Maintain protocol integrity and accurate data recording
- Administer drugs/procedures and communicate with investigators

Role of the Clinical Trial Nurse

- Specialty Certifications
  - National organizations offer certifications
  - Society of Clinical Research Associates' Certification Program for Research Professionals establishes internationally accepted standards
- Oncology Nursing Society (ONS) Support
  - ONS offers educational resources and established competencies for clinical trial nurses

Thank you!

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