DEVELOPMENT OF A NURSE EDUCATION MODULE
TO NAVIGATE CLINICAL TRIAL PROTOCOLS
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TOPIC
A knowledge gap exists among staff nurses for the administration of clinical trials in a general outpatient oncology infusion unit.

PURPOSE/BACKGROUND/RATIONALE
- Clinical trial protocols require strict adherence to specific instructions in the administration of investigative agents.
- A lapse in protocol compliance may result in a major violation that affects the integrity of the clinical research with potential outcomes for patient safety.

LITERATURE REVIEW
- Clinical nurses following general nursing orientation are often unable to define roles within clinical research (Smith & Buscemi, 2005)
- Staff nurses provide "research care" in the form of:  
  - administration of study drug
  - identify, monitor, document and treat side effects
  - assess patient responses (Offenhartz, McClary, & Hastings, 2008)
- Staff nurses are key players in the successful conduct of clinical trials (Barrick, 2008)
- Staff nurses have skill sets for successful implementation of clinical trials (Barrick, 2009)

LEARNING THEORY
- Knowles defined self-directed adult learning as a process where learner:  
  - takes the initiative with or without assistance by others
  - diagnose their learning needs
  - formulate learning goals
  - identify human and material resources for learning
  - implement appropriate learning strategies
  - evaluate learning outcomes (Smith, 2002)

THEORY OF ANDRAGOGY
- Knowles defined 6 core principles for adult self-directed learning:  
  - need to know why for learning
  - self-concept relating to self-direction
  - prior learning and experiences
  - readiness to learn
  - orientation to learning
  - motivation to learning (Knowles, 1970)

EDUCATION LEARNING OBJECTIVE
At the conclusion of the education module the nurse will demonstrate increased knowledge and proficiency in:
- patient-specific computer access of the on-line protocol
- identification of protocol sections pertinent to nursing
- use of “bookmark” tabs for:  
  - alert page
  - eligibility
  - treatment programs
  - required data
  - toxicities/dose modifications
  - adverse events
  - nursing protocol education sheets (PES)

MODULE COMPLETION
- Written post-test
- Computer-based return demonstration test
  - for a summative assessment of the actual quality of knowledge, skills, and attitudes related to clinical trial administration.

REFERENCES

SUMMARY
- This education module is the basis for future development and/or refinement of a protocol education template for staff nurses involved in clinical trials.
- Annual web-based competencies for staff nurses caring for patients in clinical trials will be developed.
- The education module and competencies have been evaluated by a small focus group.
- Refinements to the tool and test are ongoing.