Clinical Trials Informed Consent

An educational intervention to improve nurses' knowledge and communications skills

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BACKGROUND: Teach-back is an evidence-based tool recommended for use during informed consent (IC) discussions. The nurses' role in the IC process is important, particularly for patient education and advocacy.

OBJECTIVES: The aim was to initiate and evaluate an educational program for nurses to improve knowledge and communication skills used in IC for cancer clinical trials.

METHODS: An educational program was presented to nurses. Anonymous pre-, post-, and one-month postprogram surveys measured nurses' knowledge of research and the importance of and confidence using teach-back during IC discussions.

FINDINGS: Nurses had high research knowledge scores and statistically significant improvement in pre- and post-test scores of conviction and confidence using teach-back. Nurses employed essential elements of teach-back before the program but had greater recognition of elements after the program.

KEYWORDS
informed consent; cancer; nursing; patient understanding; teach-back

DIGITAL OBJECT IDENTIFIER
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CLINICAL TRIALS ARE DESIGNED TO INVESTIGATE NEW TREATMENTS and discover the safety and efficacy of novel agents or modification of an existing regimen. The National Institutes of Health (2018) reports 288,177 research studies worldwide; 64,467 are cancer-related. Informed consent (IC) is required for participation in clinical trials and is based on historically significant events and grounded in the ethical principles of respect for people, beneficence, and justice (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Federal regulations intended to protect participants in research define the basic requirements for IC. Included in these are the following (U.S. Department of Health and Human Services Office for Human Research Protections, 1998; U.S. Food and Drug Administration, 2018):

- Disclosure that the study involves research, that participation is voluntary, and of costs associated with participation
- An explanation of the risks and benefits, how confidentiality is maintained, and who to contact for questions

A change was made to the federal Common Rule governing consent for clinical research (U.S. Department of Health and Human Services, 2017). The new rule is aimed at strengthening protection for people who volunteer to participate in research and highlights efforts to promote understanding of clinical research participation. The importance of nurse involvement in the IC process for patient education, for adherence to ethical standards, for study adherence, and to advocate for patients is recognized by the Oncology Nursing Society ([ONS], 2016) and the American Nurses Association ([ANA], 2016). One recommended core competency for oncology clinical trials nurses is to "demonstrate leadership in ensuring patient comprehension and safety during initial and ongoing IC discussions" (ONS, 2016, p. 12). However, the complexity of cancer-related clinical trials presents additional challenges to the IC process; this has resulted in abundant research addressing issues related to patient understanding of IC.

Literature Review

The electronic databases PubMed, CINAHL®, Cochrane Database, and OVID were searched for articles published from 2000–2017. Search terms were as