Negotiating Tensions in Clinical Research Nursing

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Background

The role of the clinical research nurse (CRN) is pivotal to the day to day management of clinical trials. Clinical trials are investigations initiated by a sponsor or industry to determine the efficacy and safety of new drugs or medical devices in human subjects. The research team conducting clinical trials consist of investigators, clinical research nurses, laboratory and pharmacy personnel as well as administrative staff. Investigators, physicians who are responsible for the study, delegate most of the day to day responsibilities to study staff. In collaboration with the principal investigator and study staff, the CRN will coordinate all aspects of the clinical trial.1

The position of the CRN is usually held by a registered nurse. Professional nurses are inculcated with an identity that is predicated on patient advocacy and caring. Being a member of the profession brings with it respect and trust of the public. The role of the clinical research nurse, for registered nurses, may pose contradictory commitments to the public. The role of the clinical research nurse, for the public. The role of the clinical research nurse, for registered nurses, may pose contradictory commitments to the public.

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Professional Identity. Nurses are health care professionals who construct their self concept and professional identity from their public image, their work environment, education and traditional social and cultural values.2 Internalizing these values provides a framework for nurses’ decision making and helps in developing a range of beliefs and attitudes about the profession of which they are a part. Being a member of the profession brings with it respect and trust of the public.

Code of Ethics. As professionals, nurses have a duty to uphold the standard of the profession and provide ethical care in keeping with the best interests of the patient. As a clinical research coordinator, the registered nurse offers a public persona and professional identity that places them in a position of trust.

Good Clinical Practices (GCP). Clinical trials in Canada are performed under strict conditions and follow Good Clinical Practices, international ethical and scientific quality standards for designing, conducting, recording and reporting trials that involve the participation of human subjects.3 The CRN adheres to these ethical guidelines in order to protect subjects and to preserve the integrity of data collected.

Figure 1. Ethical Guidelines

Conflicting Roles – Resulting Tensions

Research and care. Nurses feel responsible for the welfare of those who need care. One of the hardest lessons for nurses, in the role of the CRN, is that research is not care. Clinical research is not a therapeutic activity devoted to the personal care of patients. Clinical trials are designed for answering a scientific question. The goals of clinical research are not necessarily synonymous with nursing goals. Nurses feel conflicted in their role as CRN and moral distress may be the result of negotiating tensions that arise in the research setting.

Compliance and advocacy. CRNs have characterized their positions as generating three overlapping and sometimes competing ethical responsibilities: patient advocacy, as it pertains to individual well being, subject advocacy as a participant of the study and study advocacy relating to compliance with the protocol.4 Nurses must judge what is ethically paramount in nursing, the best interest of their patients, with the larger interests of science, compliance to the study protocol and conduct of the trial.

Experimental Design and Patient-Centered. Recent changes in nursing philosophy see the patient at the center of decision making, maximizing patient participation in a collaborative environment. The essence of patient centered health care is that patients occupy the central, organizing role of the entire health care system and the system is accessible and is designed and implemented of a scientific clinical trial, attention to individual needs would wreak havoc on experimental design and the validity and generalizability of studies.

Figure 2. Balancing commitments in clinical research nursing

Balancing Commitments

CRNs are challenged to reconcile the inherent tension between care for the patient, subject and the potential for benefitting science and society.

• Being critically conscious of the tacit nature of these inherent tensions, may help coordinators understand their roles as complementary with an overall goal of providing safe, ethical patient care.

• Altruism is adopted by CRNs as a strategy to handle various conflicts they experience in a difficult job.5 Understanding their work in altruistic terms, that they are helping to advance scientific knowledge and developing treatments that will benefit patients and societies, may help the coordinator to minimize the conflict between research and care.

Implications for practice

Many nurses are not prepared for the role of CRN. There is a need for advanced education in this domain. Familiarity with the role and responsibilities, as well as the guiding principles of good clinical practice, will help the new coordinator negotiate the ethical tensions and balance the conflicting commitments inherent in clinical research. Nursing education programs could be adapted to include more specific training related to clinical research.

• Nursing administrators have a professional responsibility to recognize the needs of CRNs and to provide tools for professional development. Providing resources in this manner will allow coordinators to more fully understand the nuances and complexities associated with clinical research.

References