Negotiating tensions: Ethical issues in clinical research nursing

Abstract

The role of the clinical research nurse is pivotal to the day to day management of clinical trials. The complex and diverse roles of the registered nurse, as clinical research nurse, are noted in the literature. The role of the clinical research nurse, for registered nurses, poses contradictory commitments to the ethics of care inherent in nursing and creates potential conflicts within the professional identity of nurses. Previous nursing research in this area has been analyzed and will be elaborated on to further explore the professional tension that nurses, as clinical researchers, experience. Ethical frameworks guide the work of the registered nurse and the clinical research coordinator. This paper will include ethical challenges unique to the role of the clinical research nurse. Implications for nursing practice will be discussed. A key recommendation suggests that continuing education on the guiding principles of good clinical practice may assist in negotiating ethical tensions inherent in clinical research.

Keywords: Clinical research nurse, ethics, nurse identity
Introduction

The role of the clinical research nurse

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. Contract research organizations (CROs) often provide support to industry in clinical trial management. The research team conducting clinical trials consist of investigators, clinical research nurses (CRNs), laboratory and pharmacy personnel as well as administrative staff. Principal 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 including protocol review and feasibility, submission and approval of regulatory bodies, patient recruitment and retention, compliance of study protocol, subject visits and management, education and data collection. The scope of the CRN is complex and the responsibilities are intensive and multi-faceted. While the role of the CRN may be staffed with non nurses, a registered nurse or a registered nurse with an advanced degree is often preferred. It has been suggested that the intricacies of the foundational knowledge of pharmacology and pathophysiology necessary to execute clinical trials demand the expertise of a registered nurse and that the involvement of nurses in clinical research has been associated with positive
Clinical research involves complex and comprehensive scientific studies. Randomized controlled trials are considered the gold standard of research designs and are believed to provide the highest level of evidence in clinical research. The role of the clinical research nurse (CRN) is pivotal to the day to day management of the clinical trial. CRNs, also known as study coordinators, must have detailed knowledge of study protocols and an understanding of regulatory requirements to assist them in the protection of human subjects in research.

The diverse roles of the registered nurse as clinical research nurse have been noted above. As a registered nurse, the role of the CRN may pose contradictory commitments to the ethics of care inherent in nursing and create potential conflicts within the professional identity of nurses. The purpose of this paper is to discuss the ethical frameworks that guide the work of the registered nurse and the clinical research coordinator. The aim of the inquiry is to expose the inherent ethical challenges unique to the role of CRN. Implications for nursing practice will be discussed.

**Ethical considerations for the clinical research nurse**

*Professional Identity*

*Culture and gender.* Occupations are chosen to suit the perception we hold of ourselves.
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.\textsuperscript{5} 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.\textsuperscript{4}

Caring has been identified as central to nurses’ professional identity. In a Canadian survey of nurses, across cohort and nursing groups, caring has remained one of the most important reasons for becoming a nurse and staying in nursing.\textsuperscript{6} In other studies, altruism, also considered the moral orientation of care, has been an overall philosophy underlying professional identity among nurses.\textsuperscript{7} It has been argued that nurses who see intrinsic value in their work experience self affirmation when they believe they have made a difference in the lives of others and that this desire is a transcending aspect of a nurse’s professional self.\textsuperscript{8} This is a necessary part of nursing identity.

Nurses are involved in the provision of health care and in every area of the health care system. As a profession, nurses are expected to espouse professional values of caring and safeguarding public safety.\textsuperscript{9} Public opinion polls confirm that Canadians greatly admire the nursing profession, “they are synonymous with health care, compassion and good work”.\textsuperscript{10} Nurses are embedded in the system’s core and are fully integrated into it
structures. They are respected as legitimate, knowledgeable professionals who are concerned with patient safety. As a clinical research coordinator, the registered nurse offers a public persona and professional identity that may place them in a position of trust.

It is suggested that gender acts as a persistent social structure shaping the perceptions of the CRN in the workplace. Because the clinical team is composed of predominantly male investigators and predominantly female coordinators, research is seen to be structured by the traditional dynamics of the nurse doctor relationship serves to gender the role of the clinical research nurse. Although coordinators have less authority in clinical trials than principal investigators, they have greater daily responsibilities. Often overseeing multiple studies, the coordinator must balance many elements of the clinical trial delegated to them by the principal investigator. CRNs spent more time with study participants than any other research staff associated with clinical research. Much of the work of nurses, and in turn, clinical research coordinators, depends on the nurse-patient relationship. These interpersonal relationships are often associated with ‘soft skills’ that are highly gender specific and feminized. Interpersonal skills are instrumental in the recruitment and retention of subjects in clinical trials and are valued by the industry in establishing a trust among participants that they will be taken care of during the study. Because of its association with nursing, the professional identity of the clinical research
nurse is also related in altruistic terms.\textsuperscript{12} Nurses foster a caring holistic approach in the execution of a clinical trial that humanizes the research process for participants.\textsuperscript{13,14} This is often helpful in meeting the demands of clinical research.

\textit{Ethical Obligations of the Registered Nurse}

\textit{Care and practice}. A care orientation would seem fundamental to the nurse patient relationship and to the nursing profession. Registered nurses have a responsibility to provide care that is safe and ethical and are guided in this manner according to their code of ethics.\textsuperscript{9} The Code of Ethics is intended for nurses in all contexts and domains of nursing practice and serves as an ethical basis from which nurses can advocate for environments that support the delivery of safe, compassionate ethical care.\textsuperscript{9}

Caring and nursing are historically intertwined.\textsuperscript{15,16,17} Nursing practice is based upon a commitment to deliver expert care. This commitment to care, the investment in a caring relationship, is considered the ‘ethic of care’.\textsuperscript{17,18} Nurses care about their patients in ways that are complex and intimate. An ethic of care has been argued as not only desirable in nursing practice but needed to guide moral relationships between people.\textsuperscript{19} Therefore, an ethic of care in nursing practice must not only be understood in terms of rights and responsibilities but in relationships. Related to the ethic of care is the concept of advocacy.
Advocacy, described as the act of informing and supporting a person so that he or she can make the best decision possible, has been considered a form of caring and compassion. Advocacy has become a central part of ethics in professional nursing practice and is universally considered a moral obligation for nurses. Nurses act as patient advocates because to do so reflects of kind of practice nurses value. In the statement, ‘all nurses must advocate for a safe and healthy environment,’ the International Council of Nurse (ICN) Code of Ethics includes a central role for advocacy. The ethical dimensions of providing patient centered care in systems that are constrained for resources are challenging and increasingly, moral ethical advocacy has become a central part of ethics in professional nursing practice.

The special dynamics and interpersonal characteristics of relationships in nursing practice has been referred to as relational ethics. Advocacy in nursing may be considered in a relational context. The nature and quality of nurses’ relationships with their patients cause them moral consideration. Advocacy is not merely the defense of infringement of patients’ rights but must stem from a philosophy of nursing in which practice supports and promotes health as it is understood by the individual; it becomes an ‘ethic of practice.’ 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. 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.  

*Good clinical practice and the clinical research nurse*  

*The research subject and compliance.* The goal of clinical research is to develop generalized knowledge that improves human health or increases understanding of human biology.  

Clinical trials test potential treatment, specifically drugs, biologics or medical devices to determine if they should be approved for wider use in a general population. Clinical trials in Canada are performed under strict conditions and follow Good Clinical Practices (GCP), international ethical and scientific quality standards for designing, conducting, recording and reporting trials that involve the participation of human subjects. This regulatory framework is meant to protect the rights, health and safety of participants in the trial, to ensure that trials are well designed and conducted by trained professionals and to ensure that trial data is credible. The CRN adheres to these ethical guidelines in order to protect subjects and to preserve the integrity of data collected. Compliance with GCP assures the public that the rights, safety and well being of trial subjects are protected. The CRN has obligations to the principal investigator, to regulatory authorities and to the study sponsor to adhere to these guidelines and to comply strictly with the protocol as a way of producing reliable data and information about new
therapies. The study coordinator also has responsibility to the patient as advocate and caretaker. In the realm of clinical research, the CRN embodies the ‘catch all’ role for the management of the administration of the clinical trial, as well as the management and protection of the human research subject.¹

The CRN is often responsible for the recruitment and retention of study subjects. There is a strong emphasis placed on the interpersonal skills of coordinators to get subjects to enrol in the study and to motivate them to follow the protocol.¹² Notwithstanding the ethical guidelines, it is necessary for the CRN to understand that for the sponsor or pharmaceutical company, drug development is a goal of the clinical trial and that it is the coordinator’s responsibility to actively recruit subjects for the study and to gather data that will be used to support the development of the investigational product.

Discussion

Conflicting roles and resulting tensions

Research and care. Generally, nurses feel responsible for the welfare of those who need care and current nursing practice appears to reflect the changing needs of patients. The goals of clinical research however, 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. Maintaining balance in the commitments to all stakeholders involved in clinical research is often fraught with tension and conflict for the CRN as ethical practice at the research site is often less related to the treatment of human subjects and more focused on the data that are produced in the study.

The major contributor to this tension is the fact that clinical research is not a therapeutic activity devoted to the personal care of patients. Clinical trials are designed for answering a scientific question. Even the language of the clinical trial process denotes the objectifying, positivistic orientation of the scientific method. For example, the term, patient, ubiquitous in nursing care, is replaced with the term, subject. However, the prevailing ethical framework views clinical trials through a therapeutic lens. The mainstream ethical approach to clinical trials attempts to view clinical trials as a scientific experiment aimed at producing knowledge that can help improve the care of future patients. This makes it possible to perform clinical trials without sacrificing the therapeutic obligation of providing individualized care and constitutes ‘therapeutic misconception’.

One of the hardest lessons for nurses, in the role of the CRN, is that research is not care. There is a need for coordinators to distinguish between research and care however prioritizing the goals of research over the best therapeutic outcome for individual participants is difficult. Clinical research coordinators experience role conflict in which
their obligations to the patient must be balanced with their obligations to the study sponsor. For example, coordinators understand that randomization means that subjects may receive a placebo instead of the active treatment in a clinical trial. As CRNs, nurses are challenged to reconcile the fundamental understanding that experimental treatments may have adverse or unanticipated effects, or may have no discernible effect. Patients may express a sense that the experimental treatments will be beneficial or provide a “last hope” for improved health outcomes. Coordinators 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. Nurses must juggle what is ethically paramount in nursing, the best interest of their patients, with the larger interests of science and conduct of the trial.

An important part of the CRN’s work in recruiting study subjects is the process of obtaining informed consent. A consent form has both a legal and ethical function which sometimes conflict with the practicalities of recruiting individuals to participate in research. Consent forms have been criticized as lengthy, bureaucratic and difficult to read. Even when individuals are given sufficient time and encouragement to read a consent form, many consistently fail to read the entire document. Much attention is paid to the
process of informed consent of subjects in clinical trials however, the interaction between the person soliciting consent and the prospective participant can shape the recruitment encounter. Huntington & Robinson suggest that ‘a research coordinator’s skill in generating trust is a factor affecting participation of study subjects that may be unrelated to the specific risks and benefits of the study at hand.’ In obtaining an individual’s agreement to participate in a trial, the coordinator must establish a rapport and sense of trust. The study coordinator must explain the information and interpret the subject’s responses. The attempt to clarify a subject’s interest in the study may be misinterpreted as badgering or coercing the patient. Being perceived as part of the authority system of the hospital may allow the CRN to gain additional level of trust and influence and therefore exert power over the decisional process. The nuances of recruitment are subtle, but require the close attention of the CRN in research trials.

Clinical trials are designed so that subjects are randomized to different arms of the study, whether it is an active treatment or a placebo. In a care setting, treatments for patients are not decided in a random fashion. Each case is judged individually; this is what it means to provide therapeutic care for patients. 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 to serve them. Patient centered health care is often understood by what it is not - ‘technology centered, doctor centered, hospital centered, disease centered. However, in the design and implementation of a scientific clinical trial attention to individual needs would wreak havoc on experimental design and the validity and generalizability of studies. In many ways, strict compliance with all aspects of the research suggests a standardization of nursing practice. Individual nursing judgments about patient care are replaced with more objective measurements and standardization tools.

*Interprofessional relationships in the clinical research setting*

CRNs may oversee multiple studies simultaneously and must verify that details of each study are done according to the protocol. This involves managing significant paperwork as well as people. It is important that the CRN maintain relationships with principal investigators and hospital staff involved in different aspects of the trial.

It is acknowledged that physicians have lower levels of involvement in clinical trials. Principal investigators delegate many aspects of the trial to clinical research staff. Fisher argues that the investigator- coordinator relationship re-inscribes a gendered hierarchy. Investigators in clinical trials are predominantly male with medical degrees, in contrast to coordinators who are predominantly female nurses. Because of the nature of
this type of relationship, investigators and coordinators are not equal and the skills and expertise of the coordinator are subordinated. Often the nurse coordinator will seek to re-dress the power imbalance by fostering a professional relationship with the principal investigator.

Primary care nurses, lab and pharmacy staff are often delegated to perform specific tasks in a clinical trial. Treating patients enrolled in a clinical trial may be perceived as adding to the workload of these departments. Primary care nurses have reported dissatisfaction with their role in clinical trials, often feeling segregated from research staff and considered as bystanders in the overall picture. In coordinating the care of subjects, as well as the overall execution of trial protocols, the CRN must establish collegial relationships with all stakeholders.

In some institutions, clinical research positions are dependent upon the funding that is associated with robust clinical trial recruitment and enrolment. Clinical trials are often funded on a cost recovery basis. The funds generated through the clinical trial contracts offset the wages of the study coordinator, research assistant and other associated costs. Typically, nurses are not compensated in this way. This situation introduces another potential ethical concern as coordinators are very aware that the level of recruitment and in
some cases, the number of subjects screened, generate income and are tied to the institution’s ability to fund the department.

Figure 1. Balancing commitments in clinical research nursing

*Negotiating tensions in the role of clinical research nurse*

Patient advocacy is at the center of nursing practice ethos and nurses are committed
through their code of ethics to serve patient interests.\textsuperscript{9,20} The CRN may struggle to maintain a balance in the commitment to the patient, and in clinical research, the subject. In addressing the tensions and ethical dilemmas that may arise out of perceived incongruence, the CRN must reflect on unique ways to manage the conflict (Figure 1). Fisher & Kalbourgh suggest that altruism is adopted by CRNs as a strategy to handle various conflicts they experience in a difficult job.\textsuperscript{12} Understanding their work in altruistic terms, that they are helping to advance scientific knowledge and developing new treatments that will benefit patients and societies, may help the coordinator to minimize the conflict between research and care. CRNs view participation in clinical trials as beneficial because medical and nursing interactions are much richer due to time spent with patients/subjects, one on one.\textsuperscript{12} Reframing their work in this manner may act as a strategy to manage the tensions they experience. The linking of altruism and care, however, could alternately be perceived as further gendering the work, whereby the coordinator’s identity is associated with a female profession that is undervalued.\textsuperscript{11}

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.
Implications for practice

Nurses must be acknowledged for their work associated with clinical research. Increasingly, there is a move to formalize the research coordinator role and to establish an internationally recognized body of research professionals for human subject research. Delineating the various coordinator roles and responsibilities and standardizing qualifications for the position would ensure high ethical and scientific rigour is met in conducting each trial. Learning on the job and feeling professionally isolated have been issues raised by nurses in the clinical research role. Many nurses are not prepared for the role of CRN. Sessions designed to orient new staff have been dubiously named, “Sink or Swim: Diving into Clinical Trials,” and may capture the sense of chaos a new coordinator feels. This underscores the 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 administration has a professional responsibility to recognize the needs for CRNs and provide tools for professional development. Attending research conferences and other related workshops may serve to create a network for coordinators to
feel supported and foster a learning environment. Providing resources in this manner may allow coordinators to more fully understand the nuances and complexities associated with clinical research.

**Conclusion**

Clinical research coordinators are critical to the success of clinical trials. Caring and advocacy has long been associated with the nursing profession. 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. The complex and diverse roles of the registered nurse, as clinical research nurse, pose contradictory commitments to the ethics of care inherent in nursing and create potential conflicts within the professional identity of nurses. There is a need for coordinators to distinguish between research and care, however, prioritizing the goals of research over the best therapeutic outcome for individual participants is difficult. Nurses must juggle what is ethically paramount in nursing, the best interest of their patients, with the larger interests of science and conduct of the trial. Familiarity with the role and responsibilities, as well as continuing education on 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.
Acknowledgements

The author would like to acknowledge Dr. Kim Bergeron for her support.

Conflict of Interest

The author declares no conflicts of interest.

Funding

The author received no funding from any agency.

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