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VALIDATING A TAXONOMY OF NURSING PRACTICE FOR ONCOLOGY CLINICAL TRIAL NURSES

by

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy Department of Nursing

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July 28, 2016
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Abstract

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The University of Texas at Tyler
July 2016

Confusion exists on the roles and contribution of oncology nurses in the care of cancer clinical trial patients. Quantitative evidence of their roles and contributions is lacking in the literature and job descriptions vary. A study to fill this gap examined the dimensions of nursing practice and evaluated tasks performed by three groups of United States oncology nurses who practice in research settings: direct care providers, study coordinators, and those with a dual role of both coordinator and direct care provider. The study tested a theoretical, five-dimensional model of nursing practice by using the Clinical Research Nurse Role Delineation survey. Nurses were asked to rate the frequency they perform tasks and the importance of those tasks to their role. The frequency and importance scales were analyzed and the results did not support the five-dimensional model of practice. Results revealed two different more multi-dimensional models of oncology research nursing practice: one pertaining to task frequency and one pertaining to task importance. The resulting models provide a high-level overview of two things; 1. What these nurses do (Frequency Domain of Practice- Figure 1) and 2. The relevance of those activities to their role (Importance Domain of Practice- Figure 2).

ANOVA revealed a difference in the groups and post-hoc analysis showed the differences lie between the direct care providers and the coordinators and those with a dual role. Overall, direct patient care providers had similar patterns of frequency and importance scores but
the coordinators and dual role nurses had discordance in frequency and importance scores
bringing up the issue of role conflict and decreased autonomy. This new knowledge regarding
the role of the oncology nurse and dimensions of practice enhances understanding of the nurse’s
contribution and also highlights the need for more work to be done in increasing autonomy and
control over nursing practice. This study can inform practice by providing theoretical
dimensions of practice and also practical information for use in important activities like writing
job descriptions or development of competencies.

      Keywords: clinical trials, oncology, clinical research nurse, clinical trial
coordinator, autonomy, factor analysis
Chapter One

Overview and Purpose of the Research Study

The nursing care of patients participating in oncology clinical trials is unique and highly specialized. Patients enrolled in oncology clinical trials are have complex needs and care is often driven by the requirements of the trial and collection of research data (Hastings, Fisher, & McCabe, 2012). Given the experimental and medically complex nature of oncology clinical trials, coupled with the devastating effects of a cancer diagnosis, patients and their families expect an expert clinical trial team prepared to ensure the safety of human subjects.

The need to foster an environment where nurses perceive they have autonomy over practice remains a challenge for nurses who work in protocol-heavy or rule-driven environments such as clinical trial units. The ability of nurses to influence the workplace is a cornerstone of job satisfaction. It is clear that ability to control practice is the basis of autonomy. In order to define the role of the oncology nurse in the care of patients enrolled in clinical trials, it was recommended that the oncology trial nurse community develop an agreed upon taxonomy or classification system (Castro et al., 2011). Such a taxonomy of nursing specialty practice should involve a clear understanding of the dimensions of practice (Castro et al., 2011; Chang, Gardner, Duffield, & Ramis, 2012) and the specific job activities within each dimension (Castro et al., 2011). A model and measurement tool currently exist that nurses and hospital administrators can use to better understand practice. Prior to this study, it was unknown if the Clinical Research Nurse Domain of Practice model (Bevans et al., 2011; Castro et al., 2011) and the Clinical Research Nursing Role Delineation Measure (Appendix A) represented the activities performed by oncology nurses caring for patients enrolled in trials. This study provides evidence that fosters understanding of oncology nursing. Based on the results of this study, two domains of
oncology clinical trials nursing are proposed (Figure 1 and Figure 2) and issues around autonomy and control over nursing practice are discussed.

Introduction to Articles

This program of research began with the intent to learn more about the workforce of nurse’s response for care of patients enrolled to cancer clinical trials and the conformity of those trials. A concept analysis presented in Chapter 2, An Evidence Base for the Relationship Between Autonomy and Job Satisfaction in Clinical Trial Nurses, discusses professional autonomy, control over nursing practice, and the issue of role confusion. Autonomy can be compromised by role confusion. Role confusion is a result of unclear job descriptions or being asked to perform tasks that aren’t perceived as important to one’s role. Very little quantitative, objective evidence exists to quantify frequency of tasks performed related to conduct of clinical trials nor the perceived importance of those tasks to the role. If nurses are frequently performing tasks they do not perceive as important to their role, then role confusion can result. Therefore, an evaluation of both the frequency of tasks and importance to the role were studied. The Clinical Research Nurse (CRN) Role Delineation Measure (Appendix A) was used in a quantitative study, and results are presented in Chapter 3, Validating a Taxonomy of Nursing Practice for Oncology Clinical Trial Nurses. The CRN Role Delineation Measure was created based on a theoretical five-dimensional model of care. This study tested that five-dimensional model in the oncology nursing setting and the results rejected previous results that a five-dimensional model represents the taxonomy of oncology clinical trials nursing practice. Based on the results of this study, two distinct role delineation surveys are presented in Appendices B and C. Reporting both the frequency and importance of nursing tasks is a big step towards decreasing role confusion and increasing empowerment to develop the profession.
Chapter Two

An Evidence Base for the Relationship Between Autonomy and Job Satisfaction in Clinical Trial Nurses

Abstract

The purpose of this article is to explore autonomy, job satisfaction, and the relationship of these two concepts to staff retention for nurses who coordinate clinical trials. A review of the literature was conducted and synthesized for this article. Data Sources: An extensive literature search was done using CINAHL® as well as the internet. Data Synthesis: Sources included peer-reviewed journal articles and professional nursing association websites. National and international quantitative and qualitative studies were synthesized. Conclusions: The ability for nurse managers to understand staff nurse’s autonomy and job satisfaction can foster insight into staff retention. Knowledge Translation: Professional autonomy and a feeling of control of nursing practice have been associated with increased job satisfaction. Valid and reliable questionnaires exist for use in understanding staff autonomy and job satisfaction. In order to understand how autonomy and job satisfaction relate to staff retention of clinical trial nurses, further research should be done in this specialty practice area. Implications for Nursing: Little work has been done to characterize the workforce of nurses who care for patients enrolled to clinical trials including understanding sources of autonomy, job satisfaction, and staff retention.

Keywords: professional autonomy, job satisfaction, clinical trial nurse, practice environment, nurse retention
The purpose of this article is to explore autonomy as it relates to job satisfaction as a context for studying the retention of clinical trial nurses in the U.S. Since the 1930s, nurses have been involved in the conduct of clinical trials, but it was only recently that the role of the clinical trial nurse (CTN) has been established in the literature. The boundaries of clinical trial coordination are often established through interactional processes with the physician investigator and on-the-job training (Mueller, 2001). The tenuousness of these relationships which are integral to the CTN’s control over practice impact the perception of autonomy in the workplace. This article will discuss the relationship of autonomy and job satisfaction as a basis for establishing strategies to recruit and retain CTNs to meet the needs of a nation with a new national mandate to provide better health options aimed at better health outcomes.

Brief Overview of Autonomy in Nursing

Autonomy is self-direction that leads to engagement in one’s work (Pink, 2009). Castaneda and Scanlan (2014) concluded that job satisfaction in nursing is the affective, emotional reaction to a job. The strength of one’s perceived level of autonomy or feelings of self-direction have been shown to predict job satisfaction in nursing (Aiken et al., 2011; Lambrou, Merkouris, Middleton, & Papastavrou, 2014). For many years, nursing leaders have worked from the premise that autonomy in nursing practice is desired and even essential for optimal patient outcomes and improved nurse retention. The links between autonomy and job satisfaction are particularly important in clinical specialties where the rules of practice are somewhat blurred. Successful clinical trials depend on having explicit and effective guidelines and knowledgeable professionals to ensure the guidelines are followed. However, stringent rule-following seems like the antithesis of nurse autonomy. In reality, CTNs are tasked to coordinate research activities to minimize subject risk but are often left to ‘figure it out on their own’
Stress experienced by staff nurses and its effect on burnout, job satisfaction, turnover, and patient outcomes is documented in the literature (Gray-Toft & Anderson, 1981). A potential source of stress for CTNs is this same role ambiguity which can lead to decreased perceived autonomy and job satisfaction (Irvine-Doran, Sidani, Keatings & Doige, 2002; Spilsbury, 2008). Retention efforts often must focus on the role tension between clinical and research roles as the CTN strives to adhere to protocols while providing excellent nursing care as the patient advocate through practice that is governed by licensure and ethical considerations. Stress related to role ambiguity is an important consideration in trying to improve the job satisfaction of clinical trial nurses.

Autonomy refers to the ability to act according to one’s knowledge and judgment, providing nursing care within the full scope of defined practice (M.J. Weston, 2008). Autonomy, competence, and relatedness are three basic intrinsic psychological needs necessary for optimal psychological functioning (Baard, Deci, & Ryan, 2004). Relatedness is a sense of mutual respect and reliance with others, and competence is the ability to overcome challenging tasks (Baard et al., 2004). The concept of autonomy is accepted as a desired trait in American culture and is widely discussed in sociology, government, and nursing. The definition of autonomy in nursing practice will continue to evolve in tandem with shifts in healthcare culture (individual vs interprofessional teams) and should be re-examined periodically. The key role of nursing is patient care, whether directly or indirectly impacting patients’ lives; therefore, autonomy and control over nursing practice are critical to positive outcomes. Weston (2010) wrote about the important association between clinical nurse autonomy and control over nursing practice to both job satisfaction and improved patient outcomes. She points to increasing nurse competence and
engaging nurses in the decision making aspects of practice as important to promoting and ensuring autonomy.

**Competence in decision making as a facet of autonomy**

Levels of autonomy exist on a continuum depending on role preparation, knowledge base, work preparation, and nurse’s own self-direction (Baard et al., 2004; Mrayyan, 2002; Varjus, Suominen, & Leino-Kilpi, 2003). Professional autonomy is the ability to utilize knowledge, competence, and abilities without oversight of another (Bularzik, Tullai-McGuinness, & Sieloff, 2013). Autonomy in nursing is defined as freedom to make decision based on knowledge, clinical expertise, and evidence-based findings (Papathanassoglou et al., 2012). Specialty nurses who obtain certification are an example of groups of nurses demonstrating commitment to competence based on their knowledge and expertise. This certificate of competency in specialty practice not only demonstrates commitment to best practice, it also validates nursing knowledge and skills leaving nurses well positioned for autonomous practice (AACN, 2014a).

**Participation in decision making as a facet of autonomy**

Enhancing control over nursing practice in clinical and administrative decision making involves nurse participation in decisions at every level. From a workforce point of view, autonomy is viewed as a work characteristic involving intrinsically motivated work behavior (Heidemeier & Wiese, 2014). Autonomy is used to refer to the degree of discretion the one has in defining and executing work. Self-determination theory discusses the degree to which an external regulation has been internalized (Gagne & Deci, 2005). Autonomy in the workplace is defined as the degree to which the job provides freedom, independence, and discretion (Hackman & Oldham, 1975). An organizational structure for nurse participation in
administrative decisions such as workload, benefits, scope of practice, and hospital policy allows nurses to exercise their autonomy. In order to embrace this responsibility, nurses must be educated in the decision-making process. Nurses should be coached and supported through early decision making processes; and leadership skills, such as focus group facilitation, should be part of professional development for all levels of nurses (Weston, 2010).

Autonomy in nursing is the opportunity for nurses to participate in decisions about scope of practice. Advanced Practice Nurses (APNs) have assumed a leadership role in defining and actualizing autonomy. Based on advanced training, this group of nurses takes on higher levels of patient care responsibilities. These nurses have a high level of perceived autonomy, yet feelings of empowerment are often low (Bahadori & Fitzpatrick, 2008) which illuminates the issue of control over nursing practice. These nurses feel autonomous in the role they are given but do not feel empowered to develop this role within their workplace. It is possible that this same type of stymied empowerment happens to clinical trial nurses who know the right thing to do but are restrained by study protocols or micromanagement by clinical trial directors. In fact, control over organizational issues, such as scope of nursing practice, may more strongly predict job satisfaction than control over clinical practice (Itzhaki, Ehrenfeld, & Fitzpatrick, 2012; Weston, 2010). Participation in organizational decisions may help minimize the lack of autonomy in some aspects of practice which may be superseded by prescribed clinical trial protocols demanding adherence to ensure the rigor of the trial. Although levels of perceived autonomy are commonly associated with job satisfaction in the hospital setting, it is not always the most important predictor of job satisfaction, but more work should be done to validate initial findings (Itzhaki et al., 2012).
Brief Overview of Job Satisfaction in Nursing

The Magnet® Recognition Program is a perfect example of the hospital industry embracing the importance of contributions made by nurses. An essential component of the Magnet® program is a focus on nurse satisfaction (ANCC, 2014). In fact, the national Magnet® research agenda includes RN satisfaction with their current job as a research priority (Lundmark & Hickey, 2007). When an employee’s sense of fulfillment, commitment, and engagement (Redmond, 2014) are optimized, job satisfaction will be increased (Field, 2008).

Fulfillment as a Facet of Job Satisfaction

Nurses are no different than any other employee group who seeks to feel some intrinsic sense of fulfillment and satisfaction in the work that is done. Baard, Deci and Ryan (2004) explained that satisfying intrinsic needs of workers has a positive relation to the motivation basis of work. A sense of fulfillment naturally comes from the daily work of many nurses who touch the lives of others during difficult times. The nurses’ perception of their role as caregivers, and more importantly their effectiveness in that role, predicts job satisfaction (Nagel, Gender, & Bonner, 2010; Shaver & Lacey, 2003). External factors, such as adequate resources to fulfill the role or optimal time to provide patient care, may affect the sense of fulfillment (Castaneda & Scanlan, 2014; Shaver & Lacey, 2003).

Intrinsic needs of nurses are often met in their actions as a group. Nurses have used their sense of belonging to a group who makes a significant contribution to a worthy cause as one facet of their job satisfaction (Bularzik et al., 2013). Not only do nurses work as a team on the individual unit, they often band together as members of professional organizations. These organizations vary from specialty practice organizations, such as the Oncology Nurse Society, to general nursing associations, such as the American Nurses Association. Membership in these
organizations provides a presence within the profession to form groups known as specialties and create a sense of pride and fulfillment shared by members (Matthews, 2012). The ability to fulfill one’s job duties in nursing is critical to optimal patient outcomes, and this sense of fulfillment has an impact not only on the nurses’ feelings of satisfaction with their jobs but also has a direct impact on patient outcomes. Fulfillment can be supported by nurse leadership and administrators by facilitating staff development programs and encouraging participation in policy and decision making (Cummings et al., 2008). Fulfillment in nursing comes from being part of a group, touching the lives of others through patient care, advancing their professional development, and gaining confidence in the nursing role.

**Commitment as a Facet of Job Satisfaction**

Commitment to quality patient care, commitment to the organization or hospital, and commitment to nursing as a profession are all related to job satisfaction. Not surprisingly, short staffing and the nurse’s perception of inability to meet patients’ needs has a negative association with job satisfaction (Lambrou et al., 2014; Shaver & Lacey, 2003). The employer’s commitment to providing a healthy work setting and perception by nurses that there are enough RNs to provide quality care impact work satisfaction (Aiken et al., 2011; Cummings et al., 2008). Nursing autonomy to make important patient care decisions also has an impact on job satisfaction which encompass the defining attributes of autonomy and patient care (Cummings et al., 2008).

Commitment is often visualized by a desire to stay the course, to continue to contribute to the outcomes of a group or organization. Staff retention and turnover are related to job satisfaction (Van den Broeck, Vansteenkiste, De Witte, Soenens, & Lens, 2010). The commitment to stay in nursing may vary based on workplace setting and characteristics of the
nursing workforce (Wieck, Dols, & Landrum, 2010). Nurse intention to stay in the job can be enhanced by hospital administrators and managers, but these nursing leaders need training and development to ensure they are prepared to lead today’s nursing workforce (Wieck et al., 2010). Exogenous variables, such as visibility of leadership and physician/nurse relationships, as well as factors such as age and gender, may be associated with commitment and ultimately job satisfaction (Cummings et al., 2008). The commitment to quality patient care is important to a nurse. If nurses perceive their ability to provide quality patient care is limited due to perceptions in short staffing, disengaged leadership, or inadequate training to perform a task, their intention to stay in current role is likely to be affected.

**Engagement as a Facet of Job Satisfaction**

Opportunities for engagement in nursing begin in nursing school with leadership councils and liaison positions (AACN, 2014b). Opportunities for involvement can occur at any level in nursing including staff nurse, administrative nursing leadership, and nurse faculty positions. Institutional committees also offer a platform for nursing input and professional growth and are a source of job satisfaction (Cummings et al., 2008; Lambrou et al., 2014). Interpersonal relationships were found to have an effect on job satisfaction, specifically managerial relationships and relationship with physicians (Aiken et al., 2011; Cummings et al., 2008). Management can assist with conflict resolution and help nurses to clarify their philosophy of nursing. Engagement and quality of work satisfaction are affected by management’s ability to assist with conflict resolution. Staff nurses look to leadership for support and guidance in their quest to feel needed and engaged (Cummings et al., 2008).

Feeling that one can competently contribute to the overall goal of the unit or organization is important feelings of engagement. Competence is a basic psychological need (Van den Broeck
et al., 2010). Relationships with leadership influence opportunities for staff development which in turn increases job satisfaction (Cummings et al., 2008). The basic psychological need for satisfaction with relatedness gets to the root of why satisfying the need for engagement increases one’s work satisfaction (Baard et al., 2004; Doran, Sidani, Keating, & Doidge, 2002; Van den Broeck et al., 2010).

An Alternative View

The alternative to satisfaction exhibited through fulfillment, commitment, and engagement can be burnout. Commitment can also be over-done with negative consequences. It may be possible to over-commit by working too much overtime or too many hours resulting in fatigue and its negative outcomes. Engagement also calls for moderation to avoid pitfalls. Over-engagement with an emotional patient care situation or ethical conflicts may sap the nurse’s energy. The result can be moral distress which Corley (1995) has defined as a disequilibrium that results from knowing the right thing to do but being unable to do it. Another sign of over-engagement is a phenomenon called “compassion fatigue” which involves physical, emotional, and spiritual depletion associated with intense caregiving situations, such as intensive care and trauma nursing (Hinderer et al., 2014). The inability to have fulfillment in nursing can lead to burnout and stress (Nagel et al., 2010). Lack of fulfillment of the need to nurture can also put nurses at risk for burnout (Gwede, Johnson, Roberts, & Cantor, 2005). Fulfillment of caregiving tasks is another important aspect of job satisfaction and professional. Simply stated, if the nurse has the perception of inability to fulfill patient care duties, job dissatisfaction is a high risk.

Measurement Challenges in Nurse Job Satisfaction

Measuring job satisfaction for nurses may be conducted as a one-time measurement, in a longitudinal survey method, or as a qualitative study. Job satisfaction in nurses can be measured
using quantitative methods, such as survey techniques, or qualitative methods, such as interviews or focus groups. Unit based surveys, individual nurse surveys, or hospital wide satisfaction surveys provide different perspectives on RN satisfaction. Aggregated information from unit surveys or hospital wide surveys may provide results that are broad where nurses do not feel the questions or results apply to their daily work-life. Yet given that nursing professionals typically comprise one of the largest professional practice groups within a hospital, it is important for the unified voice to be heard. Novice nurses may seek out support and competent leadership as important to their security and job satisfaction. On the other hand, seasoned nurses may be more comfortable in an autonomous role with a need for professional development in order to feel satisfaction in the nursing role. Measures that can discriminate between different subsets within the nurse staff mix provide more insights into interventions which have the best chance of improving job satisfaction and retention. Individual reports regarding job satisfaction may not be reliable, and aggregate information depends on whether nurses agree about ideal practice environment characteristics and outcomes (Lake, 2002).

A well-respected job satisfaction instrument is the Nursing Work Index-Revised (NWI-R) which captures organizational attributes as opposed to individual nurse perception of the practice environment. The NWI-R reports both a job satisfaction score and a quality of care score (Aiken & Patrician, 2000). The NWI-R is a 65-item valid and reliable tool to measure characteristics of professional nursing practice environments. There are five subscales, and each subscale includes approximately 3-10 items. Created from the Nursing Work Index, the Practice Environment Scale (PES) allows researchers to understand the contribution of the practice environment to nurse and patient outcomes. The McCloskey/Mueller Satisfaction Scale (MMSS) measures nurses’ attitudes towards their job situations and has been used both
nationally and internationally to identify aspects of the job that can be strengthened to promote retention and recruitment (Tourangeau, McGillis-Hall, Doran, & Petch, 2006). The MMSS is a 31-item questionnaire that uses Likert scales ranging from 1 (very dissatisfied) to 5 (very satisfied) (Tourangeau et al., 2006). The PES-NWI-R is appropriate for aggregating hospital wide survey data to understand the practice environment, while the MMSS is helpful in understanding the nurse’s attitude towards the job.

Given the emotional attachment one has to the perception of work, qualitative research can illuminate aspects of satisfaction in the workplace (Cooney, 2011; Skar, 2009). Qualitative inquiry is a valid method to better understand factors that influence job satisfaction, especially in specialty areas of nursing where workforce issues become more complex. These studies contribute an in-depth view of the nurse’s perspective and enrich the findings of quantitative studies. Qualitative methods of inquiry in this area are based on small numbers of participants with homogenous professional demographics (Skar, 2009). These studies can help to reveal coherent meanings and thematic trends in nursing but are not able to provide statistical results often required by executive leadership to enact evidence-based changes. In nursing, the attributes most frequently associated with job satisfaction are autonomy, interpersonal relationships, and patient care (Castaneda & Scanlan, 2014). Probing questions that include these attributes will enable researchers to understand the nurse’s lived view of job satisfaction; in addition, follow-up measurement can then quantify if these attributes are present and to what extent the contribute to the general feelings of nurse satisfaction. The results can guide actions of nurse leadership in exploring how to improve job satisfaction and how to relate the concept to nurses’ perceived feelings of control over practice or autonomy.
Measurements of Autonomy

Nurse autonomy in the workplace has also been measured. In fact, it is possible to measure both perceived autonomy as well as nurse satisfaction with autonomy. The Dempster Practice Behavior Scale (DPBS) is a reliable and validated scale measuring perceptions of autonomous behaviors using a 30-item instrument with five-point Likert scales (Dempster, 1990; Maylone, Ranieri, Quinn Griffin, McNulty, & Fitzpatrick, 2011). This survey operationalizes the definition of autonomy using the total score with a higher score indicating greater extent of autonomy (Dempster, 1990b). Another surveys allowing quantitative analyses of the nurses’ perceptions of their own autonomy is the Nursing Activity Scale (NAS) (Bularzik et al., 2013). This scale operationalizes levels of autonomy using the total score with a higher score indicating higher levels of professional autonomy (Bularzik et al., 2013). The NAS is a 30-item instrument that uses a four-point Likert scale (1- very unlikely for me to act in this manner; 4- very likely of me to act in this manner) (Bularzik et al., 2013). Both questionnaires are a practical way for nurse managers to understand their staff while providing for anonymity of responses.

Qualitative measures of autonomy are also helpful to illuminate intrinsic factors, yet are often conducted by nurse researchers who are in a position of power over the participants. Qualitative studies of perceptions of autonomy in nursing are specific to very small populations of nurses and in homogenous populations. This limits generalizability of findings to enact changes. The strength of this type of study is increased understanding of the phenomena which identify the basic themes consistent among nurses. Focus groups provide an excellent medium for the discussion of how nurses perceive facilitators and barriers to their ability to control their practice. Interviews can also add to the richness of context regarding the impact that perceived autonomy in the clinical setting may have on job satisfaction of nurses.
Relationship between Autonomy and Job Satisfaction to the Supply of Clinical Trial Nurses

Enhancing autonomy is of interest to maintain nursing standards, promote the profession, and improve staff retention through job satisfaction (Blegen & Mueller, 1987; Mrayyan, 2002). The diversity of the nursing workforce creates challenges for nurse researchers in the area of autonomy and job satisfaction. Nursing populations may include such diverse groups as immigrant nurses, advanced practice nurses, specialty nurses, novice nurses, seasoned nurses, and nurse managers. Furthermore, generational differences may affect the importance of autonomy on job satisfaction (Wieck, Dols, & Northam, 2009). Weston (2010) describes a healthy work environment as one that is “…invigorating, robust, flourishing, and able to flexibly adapt to a constantly changing set of circumstances” (n.p.). The ability of nurses to influence the workplace is a cornerstone of job satisfaction. It is also clear that ability to control practice is the basis of nurse autonomy. The need to foster an environment where nurses perceive they have autonomy over practice remains a challenge for nurses who work in protocol-heavy or rule-driven environments such as clinical trial units in a role that is not clearly defined.

Implications for Nursing

Typically funding sources for CTNs are from granting agencies and not the hospital budget. This means nurses may be directly reporting to the primary investigator with only casual interactions with nursing leadership adding more difficulty to the problem of understanding sources of job satisfaction and staff retention. CTN managers may be tasked with administrative duties and trial coordination, therefore doing the job of both the manager and the staff nurse. An understanding of levels of job satisfaction and perceptions of autonomy in the CTN population of nurses is a strong start to solving the problem of staff turnover, yet little empirical evidence exists in the literature as to the role of the trial nurse. Increased autonomy should promote higher
job satisfaction which is an important first step to recruiting and retaining enough expert clinical trial nurses. An adequate workforce supply is necessary to continue the important work of pharmaceutical and durable equipment research to improve the health environment and produce better healthcare for patients with cancer. In order to ensure an adequate number of clinical trial nurses in the future, strategies to increase their perceptions of control in their environments must be found.
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Chapter Three

Results of an Oncology Clinical Trial Nurse Role Delineation Study

Abstract

**Purpose/Objectives:** To evaluate the relevance of a five-dimensional model of clinical research nursing in the oncology clinical trial nurse population; to compare the roles of three groups of oncology nurses, including clinical nurses providing direct patient care to research participants, clinical nurses who primarily coordinate clinical trials, and clinical nurses who do both direct patient care and clinical trial coordination; and to evaluate the reliability of the Clinical Research Nurse Role Delineation Survey. **Design and Sample:** A cross-sectional survey via Qualtrics involved 167 US oncology nurses: 91 have a dual role of direct patient care and trial coordination, 41 are coordinators, and 35 do direct care. **Methods:** Principal Components Analysis (PCA) tested the five-dimensional model, Analysis of Variance (ANOVA) compared practices among the three groups, and Cronbach’s alpha evaluated reliability. Descriptive statistics of Likert-type scale scores regarding ‘frequency’ and ‘importance’ of activities performed by the oncology nurse was also assessed. **Main Research Variables:** Self-reported importance and frequency scores of 59 activities were examined. **Findings:** The results did not support the original 5-dimensional model of care but revealed 2 separate more multi-dimensional models. There were significant role differences in the three groups of oncology nurses. **Conclusions:** Analysis of frequency data revealed an 8 dimensional model of oncology research nursing: *care, manage study, expert, lead, prepare, data, advance science, and ethics.* Analysis of importance data revealed a 6 dimensional model: *manage study, advance science, care, lead, ethics, and data.* **Implications for Nursing:** The two evidence based models improve understanding of the multi-dimensional roles of oncology nurses caring for cancer
patients enrolled to clinical trials. Discordance in frequency and importance scores shows evidence of decreased autonomy and role confusion that should be further explored. **Knowledge Translation:** Updated surveys and domains of practice are available for future research.

Differences in the roles of direct patient care providers, study coordinators, and those with a dual role of direct patient care and coordinator exist and this knowledge can be used in workforce development.

*Keywords:* clinical trial nurse, oncology, factor analysis, research nurse, research coordinator
Results of an Oncology Clinical Trial Nurse Role Delineation Study

Background

The recent formation of the Cancer Moonshot task force by President Obama and Chaired by Vice President Biden is a national initiative to make the US the country that cures cancer once and for all. The search for a cure can only be achieved through clinical trials. The Oncology Nurse Society (ONS) encourages both the President and Vice President to pull from resources within the nursing community and remember that nurses stand at the forefront of this Moonshot initiative. “Clinical Research Nurses are involved at the very deepest level of patient care in clinical trials.” (Barton-Burke, 2016, p.1). This recent development and call to action by Dr. Barton-Burke underscores the importance of the nursing profession to empirically define their role in the care of oncology patients enrolled to clinical trials.

The roles and contributions of nurses in the care of cancer patients participating in clinical trials are not clearly delineated in the literature. The job descriptions, scope of practice, and titles of oncology clinical trial nurses also vary. In some clinical trial settings, the role is narrowly focused to either coordination aspects of clinical trials or only direct patient care, while in other clinics or hospitals the role may be broader with a dual role of direct patient care and clinical trial coordination. Clinical trial patients are cared for in a variety of settings including inpatient units, outpatient infusion centers, ambulatory care clinics, private oncologists’ offices, and radiation therapy facilities (Rieger & Yarbro, 2003). Their nursing care must meet varied patient emotional, medical, and educational needs while adhering to strict trial and research data guidelines (Hastings, Fisher, & McCabe, 2012). Given the experimental and medically intricate nature of oncology clinical trials, patients and their families need a high level of care and expect competent clinicians well-versed in the care of research subjects. But the activities performed by
oncology clinical trial nurses are not well documented in the literature. That is the gap filled by this study.

Clinical trial nurses administer experimental therapies, collect research data, and ensure the healthcare team and patient are informed and compliant with the study procedures (Hastings et al., 2012) but the depth and scope of tasks performed are unclear. It is not uncommon for a physician investigator (PI) or a staff member to have the question, “Can the nurse do this?” or state, “I didn’t know I could ask the nurse to do that”. This role confusion leaves nurses uncertain about their scope of practice and preparation (Thomas-Jones & Wilson, 2013). Unlicensed personnel also perform activities that should be performed by nurses (Thomas-Jones, 2013) but the Code of Federal regulations is vague on delegation of authority by the principal investigator (PI) (US, 2014, CFR Title 21). The PI, who is ultimately responsible for the clinical trial, may not know what and to whom they can delegate. Clinical trial oncology nurse role clarity is needed to advance practice (Bevans et al., 2011; Ehrenberger & Lillingston, 2004; Nagel, Gender, & Bonner, 2010; Spilsbury et al., 2006).

The dimensions of clinical research nursing practice were theorized using a five-dimensional model categorizing clinical trial nursing activities (Bevans et al., 2011; Castro et al. 2011). The domains conceptualized by nursing experts at the National Institutes of Health (NIH) included: (a) care coordination and continuity, (b) clinical practice, (c) contributing to the science, (d) human subject protection, and (e) study management. Within each dimension, specific nursing activities were proposed. The Clinical Research Nurse Role Delineation Survey was initially tested in a single-research institution (NIH) in a sample of nurses (n = 412) with clinical research roles. The survey performed well with Cronbach’s alpha reliability for the frequency items of $\alpha = 0.95$ and importance items of $\alpha = 0.96$ (Bevans et al., 2011). Nurses
cared for varied patient populations; oncology, behavioral/mental health, medical/surgical, critical care, and OR/PACU (Bevans et al., 2011). This study did not report the explained variance of each dimension. Two distinct roles of the clinical research nurse and research trial coordinator were described but this leaves out the third dual role, that of a combination coordinator and clinical nurse. Further study was recommended using a large, national sample of nurses (Castro et al., 2011; Chang, Gardner, Duffield, & Ramis, 2012).

Methods

Research Design

A survey design was used to obtain data from a sample of nurses across the United States. Data were collected online via Qualtrics. The survey was voluntary and anonymous. Informed consent was presumed based on commencement of the survey.

Sample

This study was reviewed and approved by the University of Texas at Tyler Institutional Review Board (IRB). A convenience sample of 167 nurses employed in the United States, working in a clinical research setting (direct patient care, coordination of a clinical trial, or a combination thereof) was recruited. A list of potential nurse participants was drawn from several databases, including the Oncology Nurse Society (ONS) Clinical Trial Nurse Special Interest group, the International Association of Clinical Research Nurses (IACRN), and the researcher’s professional network.

Email invitations and direct solicitations through social media provided an overview and study purpose. Two initial screening questions determined subject eligibility: 1) nurses currently practicing in the US; and 2) currently working in oncology clinical trials via direct patient care,
trial coordination, or a combination. Qualified participants who consented to participate in research completed the survey online.

Instrument

The Clinical Research Nurse Role Delineation Survey was used with permission (Bevans et al., 2011) in this study. Twelve demographic questions were asked to characterize the participant’s demographics. No personal identifiable information was collected. Participants were given a list of 59 activities to provide two ratings: to rate both the frequency and importance of each activity in their current role. Frequency items had 6 choices: ‘not part of my practice’, ‘infrequently (1-2 times/year)’, ‘multiple times/year; monthly’, ‘more than once/month; weekly’, ‘once/day’, ‘multiple times/day’. Importance items had 6 choices: ‘not part of my role’, ‘not important to my role’, ‘somewhat important to my role’, ‘important to my role’, ‘very important to my role’, ‘essential to my role’. Survey completion time averaged 15 minutes. The survey was open from December 2015 through February 2016.

Hypotheses

The hypotheses of this study were: Among oncology clinical trial nurses:

Ha1: The five-dimensional Clinical Research Nursing Domain of Practice model represents the role of the oncology nurse who cares for patients enrolled to clinical trials.

Ha2: There are differences among the three groups: nurses providing direct patient care, nurses coordinating clinical trials, and nurses involved in both direct patient care and clinical trial coordination.

Ha3: The Clinical Research Nurse Role Delineation survey will have internal consistency reliability.
Analysis

Data were downloaded and imported into Statistical Package of the Social Sciences (SPSS) (IBM) version 21. Principal Components Analysis (PCA) using varimax rotation evaluated the first hypothesis examining the dimensions of importance and frequency of nursing activities in the care of patients enrolled to oncology clinical trials. Analysis of variance (ANOVA) evaluated the second hypothesis examining the three roles of oncology trial nurses. Cronbach’s alpha assessment was performed to evaluate the third hypothesis assessing the reliability of the scales.

Results

Demographics

The majority of nurses practiced for 20 or more years \((n = 106; 60.6\%)\), were aged 50-59 \((n = 68; 33.8\%)\), worked full-time \((n = 158; 90.8\%)\), and have been in their research role for 5 years or more \((57.1\%)\). Most study participants were Bachelor’s prepared \((n = 85; 48.6\%)\), and cared for adults \((n = 171; 98.2\%)\) (see Table 1: Demographic Data). Participants were geographically evenly spread throughout the US in line with population statistics. For example more participants were from the northeast than the midwest region likely due to denser populations. Most respondents reported their role is a dual role of direct patient care and study coordination \((n = 93; 54\%)\), 21% \((n = 36)\) were direct care providers exclusively, and 25% \((n = 43)\) primarily coordinated clinical trials.

Factor Analysis

Both the importance and frequency scales met the criteria set by Field (2009) for the Kaiser-Meyer-Olkin (KMO) values of 0.92 and a significant Bartlett’s test of sphericity indicating the data were amenable to PCA. Eigenvalues >1 and the rotated matrix were used to
determine the dimensions of each of the two models: oncology clinical trial nurse’s frequency of activities and oncology clinical trial nurse’s perception of importance of activities to their role. Evaluation of the frequency scale revealed 8 factors and 51 items that explained 64.12% of the variance (see Table 2 and Table 4). The eight factors of the frequency practice domain were classified and labeled as: care (.957), manage study (.914), expert (.855), lead (.810), prepare (.771), data (.755), advance science (.765), and ethics (.784). Cronbach’s alpha for each factor was acceptable. The frequency dimension of care explains the majority of the role (37.60%) compared the other factors. Evaluation of the importance scale revealed 6 factors and 57 items that explained 64.20% of variance (see Table 3 and Table 4). The six factors of importance were classified and labeled as: manage study (.961), advance science (908), care (.897), lead (.817), ethics (.720), and data (.746). Cronbach’s alpha for each scale was acceptable. The importance dimension of manage study explained the majority of activities (37.50%) that nurses felt were most important to their role. The results of the PCA of the frequency domain revealed a more multi-dimensional nursing practice than the results of the PCA using the importance domain (8 dimensions versus 6 dimensions) (Figure 1 and Figure 2). The frequency domain of practice had two additional dimensions, expert and prepare.

Difference in Three Groups

The three groups of nurses self-identified as primarily involved in direct patient care or trial coordinator, or both care and clinical trial coordination. The largest group (n = 91) has a dual role of direct patient care and trial coordination, followed by coordinators (n = 41), and direct care clinicians (n = 35). Exploratory data analysis was done to evaluate parametric assumptions using methods recommended by Field (2009). The data showed that the three groups differed in how often they performed tasks (frequency), F(2, 163) = 29.75, p < .001, $\eta^2 =$
.517 and how they evaluated the importance of tasks (importance) F(2, 163) = 32.20, p < .001, \( \eta^2 = .532 \), both with a large effect size (Field, 2009). Post-hoc analysis was done and tasks were ranked and grouped (see Tables 4 – 8). The top three most frequent activities for all groups were in the care dimension; direct care providers most frequently monitored patients, provided direct care for patients, and recorded data while the coordinators protected data, complied with guidelines and facilitated teams; the dual role clinicians protected data, complied with guidelines, and monitored patients. Direct care providers top three activities had patterns that were similar for frequency and importance. Coordinators and those with a dual role had discrepancies between top three importance and frequency scores. The direct care providers and the dual role group had similar patterns for least frequency and important activities. The coordinators only activity which were congruent for both importance and frequency was ‘serve as a specialty area expert’.

Strengths/Limitations

Limitations of this study include potential ineligible participants enrolled due to the self-selection and anonymous nature of the survey. To control for this threat, communications on social media, via email, and personal communication was utilized in an attempt to educate nurses on the eligibility and decrease the chances of enrollment of ineligible participants. It is difficult to determine if this group is representative of US oncology trial nurses because no previous studies or reports of a national sample are available. The demographics of this population were similar to previous studies in age distribution, gender, years as a nurse, years practicing in their current role and educational preparation though this sample included more slightly more DNP and/or PhD nurses than previous studies. Social desirability in response to questions regarding
caring or ethics may have affected scores, this threat was controlled by use of an online anonymous survey.

Use of self-report of frequency and importance measures for hypothesis testing is not ideal because of the chance of recall bias. Nurses were expected to be currently working in a clinical research setting to decrease this threat. Strengths of this study include the robust statistical technique to determine theoretical frameworks and parametric testing to examine group differences. An additional strength is the national sample of oncology nurses from various research settings.

Discussion

Domains of Practice

The results of the PCA rotated matrix led to the rejection of the hypothesis of a single five-dimensional model and provide evidence for two models; frequency domain of oncology clinical trials nursing practice and importance domain of oncology clinical trial nursing practice. Nurses spend the majority of their time caring for patients. This is an important finding to highlight since many trial coordinators may not be perceived as providing patient care. Evidence from this study shows that their scope of practice clearly extends beyond patient care since managing studies explained what nurses perceive as most critical to their role.

The frequency domain of nursing practice has two additional dimensions of expert and prepare, showing that they are often called on to be ‘prepared experts’. The absence of these dimensions in the importance domain of practice is concerning as nurses may not have fully realized this as an essential facet of their role. So even though nurses are frequently doing these activities, they may not be fully trained on these tasks or understand the importance of these tasks to their role. Nurses are called on to be prepared experts and should be empowered to
develop these dimensions of the role within their workplace. This can foster their autonomy and lead the job satisfaction.

The more multi-dimensional frequency domain versus the importance domain (8 dimensions versus 6 dimensions) means there is a gap between perceived role and the reality of day-to-day practice. The multi-dimensional domains of practice show evidence of the complex nature of an oncology trial nurses role. In fact, the evidence shows the oncology nurses role is more complex than previously reported (Bevans et al., 2011). Among the three groups, direct care providers are a more empowered group of nurses with similar patterns in perceived importance and frequency of activities. The study coordinator group and the dual role group have a gap between the perceived role and the reality of practice. Nurses performing activities not perceived as essential to the role may negatively impact intrinsic needs of workers such as feeling of autonomy, fulfillment and ultimately job satisfaction. The oncology nursing domains of practice are complex, leaving coordinators and dual role nurses at risk for role confusion. All oncology nurses involved in the care of patients receiving experimental therapies are expected to be autonomous in a role that is rule laden with care driven by the guidelines in the clinical trial. Evidence of role conflict in those with study coordinator responsibilities threatens autonomy.

In this study, nurses with a dual role were the largest group out of the three groups therefore this role should be well understood. Past role delineation study of research nurses dichotomized the population to either direct patient care provider or study coordinator leaving out this important third group of nurses (Bevans et al., 2011). The inclusion of community oncology research practice settings, large comprehensive cancer centers and academic institutions is likely the reason for a more diverse sample population.
This is a smaller sample than in previous studies (Bevans et al., 2011) but the sample is demographically more diverse drawing from oncology clinics across the US while previous study participants were all employed at a single institution and were not focused only in cancer trials. This sample was similar to previous studies (Bevans et al., 2011) in that most participants were at least Bachelor’s prepared. Also similar to previous studies a minority of participants reported their highest degree at the graduate level or a Nurse Practitioner. In this study slightly more participants had DNP or PhD level education. This trend towards post-graduate preparation in the clinical research setting is encouraging as more schools of nursing recognize the importance of supporting the educational needs of these nurses. The fact that both this study and the study conducted at the NIH showed the majority of nurses with advanced age and greater than 20 years practicing as a registered nurse provide evidence that this role is not considered an entry level nursing position and requires maturity, educational preparation, and prior nursing experience. Consistent with previous findings, the nurse practitioner (NP) has a role on the clinical research team but due to low numbers of NPs enrolled to this trial and differences in scope of practice due to licensure makes it difficult to draw conclusions about the domain of practice for these nurses.

Future Directions

Additional studies to test the updated importance domain of clinical trial nurse practice and the frequency domain of clinical trial nurse practice are needed. Given the complex nature of the role and the rapidly evolving landscape, the oncology clinical trial nurse role should be periodically re-examined. Cancer clinical trials are becoming more complex and with awareness and support for patient enrollment to clinical trials through the Cancer Moonshot Initiative, nurses must be well prepared. The fact that nurses are frequently being called upon to
be ‘prepared experts’ in support of clinical research, but do not perceive this as important to their role should be further explored.

In the interest of evidence based practice, parsimony and convenience for volunteer participants, administering the shortened surveys is recommended. The refined surveys can be utilized in future studies to ask the question regarding both frequencies of activities or perceived importance of activities in one survey or a researcher can elect to evaluate these variables separately.

Incongruence between perceived importance of tasks to one’s role and the reality of practice is an issue that deserves further clarification. Studies to understand perceptions of autonomy in clinical trials nursing may help improve understanding in where nurses need more support to have control over practice.

Future studies should continue to include large numbers of nurses from various practice settings and geographies to ensure the full scope of clinical trials nursing practice is documented. An understanding of the role under different forms of government and systems of healthcare are needed in the form of international studies.

Implications for Nursing

This study is significant because it provides robust evidence for two domains of practice that explain what oncology trial nurses do and perceived importance of these tasks to their role. This understanding sets the foundation for professional advancement of nurses, workforce development, competency development, and scopes and standards of practice. This study also assists those responsible for employing these nurses to better understand the service profile which can assist in job descriptions, performance evaluations, and justify salaries. This study
informs practice by providing objective and reliable data for use to answer the question ‘What is the oncology nurse’s role in the care of patients enrolled into a clinical trial?’

Autonomy in nursing practice is desired and essential for optimal patient outcomes and improved nurse retention. The differences between perceived importance of tasks to one’s role and the reality of practice is an issue for study coordinators and those with a dual role of study coordinator and direct care provider. Given the majority of participants in this study reported having a dual role, this disconnect of frequency and importance of tasks is a relevant issue to the majority of oncology nurses in the clinical research setting. Discordance between what nurses perceive as important to their role versus what they actually do each day causes role confusion and decreased autonomy. Awareness of this difference in importance scores and frequency scores may be a first step in solving the problem.

Conclusion

Due to prior findings and those of the current study, nurses are well positioned for the call to action to empirically define their role in the care of oncology patients enrolled to clinical trials. All oncology nurses who care for trial patients have a multi-dimensional role and findings from this study highlight differences in groups of nurses within the specialty. Nurses should have control over nursing practice and gaps between roles and reality of practice for coordinators and dual role nurses is concerning. Clinical trial nurses care and manage studies but there is more work to be done to understand the prepare and expert dimensions. Although there is discordance in frequency and importance scores, conclusions about autonomy, job satisfaction and role conflict are difficult to make based on quantitative study results.
## Tables

**Table 1: Demographic Data**

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<th>Demographic</th>
<th>N</th>
<th>%</th>
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<tr>
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<td>4.6/95.4</td>
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<td>20-29</td>
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<td>30-39</td>
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<td>40-49</td>
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<td>50-59</td>
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<td>&lt;= 5 years</td>
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<td><strong>Direct Patient Care (yes/no)</strong></td>
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### Table 2: Factor Analysis Results - Frequency

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<th>Manage Study</th>
<th>Expert</th>
<th>Lead</th>
<th>Prepare</th>
<th>Data</th>
<th>Advance Science</th>
<th>Ethics</th>
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<td>Variance</td>
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<td>4.35%</td>
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<td>Monitor for adverse events</td>
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<td>Teach participants/family about study</td>
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<td>Report potential adverse events to team</td>
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<td>Record research data</td>
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<td>Explain study procedures to participants</td>
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<td>Care for RPs</td>
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<td>Help with research participant inquiries and concerns</td>
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<td>Coordinate research specimens</td>
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<td>Coordinate research to minimize risk</td>
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<td>Support participant in reasons and goals in study</td>
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<td>Comply with ICH &amp; GCP guidelines</td>
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<td>Mentor team members</td>
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<td>Help analyze research data</td>
<td>Record research data</td>
<td>Oversee people involved in the research process</td>
<td>Address ethical conflicts with team</td>
<td>Help handle research specimens</td>
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<tr>
<td>Coordinate study visits</td>
<td>Support study grant development</td>
<td>Care for RPs</td>
<td>Lead interdisciplinary team</td>
<td>Manage potential ethical and financial conflicts of interest for self</td>
<td>Facilitate research specimens</td>
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<tr>
<td>Help identify research participant’s eligibility</td>
<td>Identify practice questions from a new study procedure or intervention</td>
<td>Monitor for adverse events</td>
<td>Develop study budget</td>
<td>Identify care implications in study development</td>
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<td>Recruit participants</td>
<td>Help set up study database</td>
<td>Coordinate research specimens</td>
<td>Develop care innovations with team</td>
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<td>Help ongoing informed consent</td>
<td>Help develop study</td>
<td>Report potential adverse events to team</td>
<td>Mentor junior research team members</td>
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<td>Schedule study procedures</td>
<td>Identify research trends</td>
<td>Explain study procedures on participants</td>
<td>Resource to new investigators</td>
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<tr>
<td>Coordinate research to minimize risk</td>
<td>Expert to team in study development</td>
<td>Collaborate interdisciplinary team</td>
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<td>Facilitate team education about the study</td>
<td>Serve as specialty area expert</td>
<td>Record data on study documents</td>
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<th>Table 7: Rank order of most important activities by group</th>
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<tr>
<td>2</td>
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<tr>
<td>3</td>
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<td>Rank</td>
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<td>------</td>
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<tr>
<td>59</td>
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<tr>
<td>58</td>
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<tr>
<td>57</td>
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</tbody>
</table>
Figure 1: Frequency Domain of Oncology Clinical Trials Nursing Practice
Figure 2: Importance Domain of Oncology Clinical Trials Nursing Practice
References


https://www.ons.org/newsroom/news/oncology-nurses-are-essential-component-cancer-moonshot-initiative


Chapter Four
Summary and Conclusion

Until the early 2000’s reports regarding the contribution of nurses in development of new cancer therapies were anecdotal and descriptive. Evidence regarding tasks performed by clinical trial nurses and insight into the role was limited. Care of oncology patients is complex with varied emotional and clinical components. The conduct of clinical trials is complex and highly regulated. An understanding of nurse preparedness for the role and control over practice is lacking. If nurses experience role conflict, inadequate training to perform a task, or think leadership doesn’t understand their contributions, their intention to stay in their current role is likely to be affected. Novice nurses seek out support and competent leadership for security and job satisfaction. Seasoned nurses may be more comfortable in the role but need professional development in order to feel job satisfaction.

The first article, *An Evidence Base for the Relationship Between Autonomy and Job Satisfaction in Clinical Trial Nurses* establishes the need for strategies to retain specialized nurses who care for patients enrolled to clinical trials. It highlights the importance of autonomy and a sense of empowerment to control one’s own nursing practice to have job satisfaction. Perceptions of autonomy and job satisfaction have not been studied in the clinical trial nurse workforce nor are sources of role conflict well understood. Work done to prepare that manuscript made it clear that studies to understand these concepts were not possible unless the role of nurses was well characterized leading to conceptualization of the current study.

The report, *Results of an Oncology Clinical Trial Nurse Role Delineation Study*, reports findings from original research that evaluated the relevance of a five-dimensional model of clinical research nursing practice using the Clinical Research Nurse Role Delineation survey and
explored differences in the roles of the clinical trial nurse. Findings rejected earlier reports that this construct can be represented by a single five-dimensional model because the role is more multi-dimensional and complex. The two domains of practice are the frequency domain of practice which includes the dimensions of care, manage study, expert, lead, prepare, data, advance science and ethics and the importance domain of practice includes manage study, advance science, care, lead, ethics and data. The frequency domain of practice had two more dimensions than the importance domain; expert and prepare. This incongruence between frequency and importance scores bring into question issues of autonomy and role conflict. The incongruence in scores lies primarily between patient care activities and activities related to adherence to regulations and guidelines. Differences in ranked scores between frequency of tasks and importance of tasks means more work needs to be done to understand this incongruence between perceived important nursing activities and the reality of day to day practice.

The results of this study provide updated theoretical models and practical knowledge about the role of oncology clinical trials nurses. The refined theoretical frameworks give a broad understanding of the role and is now available for use in future research. The Clinical Research Nurse Role Delineation survey is a relatively new instrument but is becoming the standard for use in evaluating the clinical trial nursing workforce. The survey had acceptable reliability in this US oncology nurse population and the refined surveys are available for use (Appendix B and Appendix C). From a practical point of view, this survey and these domains of practice can be utilized to help hospital administrators better understand what these nurses do and provide a foundation for job descriptions, education, and evaluation. Further research involving the two models is recommended.
Evidence regarding differences in the roles of direct care providers, study coordinators and clinicians with a dual role contributes to the previous gap in knowledge and warrants further exploration. Results regarding differences between direct care providers and study coordinators supports previous findings. New knowledge regarding a third role of dual study coordinator/direct care provider is now available. Stakeholders such as hospital administrators, physician investigators, nurse managers, and those responsible for clinical trials infrastructure support must have a clear understanding of these roles when building and maintaining a program of clinical research.

Differences in the frequency scores and importance scores showed that nurses are frequently complying with federal regulations related to the conduct of clinical trials but they perceive patient care activities as most important to their role. The ability of nurses to influence the workplace regarding performance of tasks they view as important is a way for nurses to increase autonomy and decrease role conflict. Insights into discrepancies between how often a nurse performs a task and how important tasks are to their role are needed as it relates to control practice and role conflict.

This program of research will continue to investigate the role of the oncology nurse in the clinical research. Investigation into the differences in frequency and importance scores will help gain insight into the concepts of autonomy, job satisfaction and feelings of role conflict. With the power of the internet and social networking, as well as strength of international associations such as ONS and the International Association of Clinical Research Nursing, international trials to evaluate differences and similarities in the role across borders can be conducted. The current study has also sparked collaborations with two large oncology networks within the US to survey
their nurses and demonstrate the role of their nurses within large national cancer research community practice networks.
Appendix A. Clinical Research Nurse Role Delineation Survey

Screening Questions

Q1. Are you a nurse currently practicing in the United States?
   ○ Yes
   ○ No

Q2. Are you a nurse who is currently working in a position that is primarily focused on direct patient care for oncology patients enrolled to clinical trials OR that is primarily focused on coordination aspects of oncology clinical trials OR a combination of both?
   ○ Yes
   ○ No

Main Questions

Q3. This survey includes a list of 59 activities that nurses may assume when working in a clinical research setting. When answering, please consider these activities in the context of your current position. In each question please rate how often you do the activities and the importance of the activity to your role.

Provide direct nursing care to research participants (e.g. interact with research participants to provide nursing care, administration of research interventions, specimen collection, etc.)

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Not part of my practice</th>
<th>Infrequently (1-2 times/year)</th>
<th>Multiple times/year/monthly</th>
<th>More than once/month/weekly</th>
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<tr>
<td>Importance</td>
<td>Not part of my role</td>
<td>Not important to my role</td>
<td>Somewhat important to my role</td>
<td>Important to my role</td>
<td>Very important to my role</td>
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Q4. Participate in research participant recruitment

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<th>Frequency</th>
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<td>Importance</td>
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</table>
Q5. Perform secondary data analysis to contribute to the development of new ideas

<table>
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<tr>
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<th>Infrequently (1-2 times/year)</th>
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Q6. Facilitate scheduling of study procedures

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Q7. Collaborate with the interdisciplinary team to create and communicate a plan of care that allows for safe and effective collection of clinical research data

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<th>Frequency</th>
<th>Not part of my practice</th>
<th>Infrequently (1-2 times/year)</th>
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Q8. Serve as IRB member

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Q9. Support study budget development.

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<th>Q10. Provide nursing leadership within the interdisciplinary team.</th>
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<th>Q11. Collect data on research participant based on study endpoints.</th>
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<th>Q12. Identify questions appropriate for clinical nursing research as a result of study team participation.</th>
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<th>Q13. Contribute to the development of case report forms.</th>
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### Q14. Monitor the research participant for potential adverse events.

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### Q15. Communicate the impact of study procedures on the research participants.

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### Q16. Collaborate with the interdisciplinary team to address ethical conflicts.

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### Q17. Coordinate the collection of research specimens.

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### Q18. Collaborate with the interdisciplinary team to develop innovations in care delivery that have the potential to improve outcomes and accuracy of data collection.

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Q19. Facilitate the processing of research specimens.

Q20. Report potential adverse events to a member of the research team.

Q21. Facilitate the initial informed consent/assent process.

Q22. Provide nursing expertise to the research team during study development.

Q23.
Provide nursing expertise to community-based health care personnel (e.g. referring physician or center) related to study participation.

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Q24.
Record data on official study documents (e.g. case report forms, research/study database, etc.)

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Q25.
Coordinate interdisciplinary meetings and activities in the context of a study.

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Q26.
Participate in the reporting of research trends.

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Q27.
Comply with International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines.

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**Q28. Coordinate referrals to appropriate interdisciplinary services outside the immediate research team.**

**Q29. Manage potential ethical and financial conflicts of interest for self.**

**Q30. Perform quality assurance activities to ensure data integrity.**

**Q31. Serve as a resource to new investigators.**

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1/24/2016
Q32. **Facilitate accurate communication among research sites (i.e. multisite studies)**

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Q33. **Coordinate research participant study visits**

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Q34. **Participate in the screening of potential research participants for eligibility**

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Q35. **Support study grant development**

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Q36. **Serve as an expert in a specialty area (e.g. grant reviewer, editorial board, presenter, etc.)**

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**Q37. Identify clinical care implications during study development (e.g. staff competencies and resources equipment, etc.)**

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**Q38. Support research participant in defining his/her reasons and goals for participating in a study**

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**Q39. Participate in the preparation of reports for appropriate regulatory and monitoring bodies/boards**

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**Q40. Participate in the query of research data to prepare for analysis**

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Q41. Participate in the identification of research trends.

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Q42. Participate in the analysis of research data

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Q43. Provide indirect nursing care (e.g. participation in clinical, unit, and/or protocol rounds; scheduling study related tests, etc.) in the context of research participation

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Q44. Participate in study development

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Q45. Record research data (e.g. document vital signs, administration of a research compound, participant responses, etc.) in approved source document (e.g. the medical record, data collection sheet, etc.)

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### Q46. Develop study specific materials for research participant education

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### Q47. Generate practice questions as a result of a new study procedure or intervention

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</tr>
</tbody>
</table>

### Q48. Participate in site visits and/or audits.

<table>
<thead>
<tr>
<th>Importance</th>
<th>Not part of my role</th>
<th>Not important to my role</th>
<th>Somewhat important to my role</th>
<th>Important to my role</th>
<th>Very important to my role</th>
<th>Essential to my role</th>
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<tbody>
<tr>
<td>Frequency</td>
<td>Not part of my practice</td>
<td>In frequen  tly (1-2 times/year)</td>
<td>Multiple times/year; monthly</td>
<td>More than once/month; weekly</td>
<td>Once/day</td>
<td>Multiple times/day</td>
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</table>

### Q49. Facilitate research participant inquiries and concerns

<table>
<thead>
<tr>
<th>Importance</th>
<th>Not part of my role</th>
<th>Not important to my role</th>
<th>Somewhat important to my role</th>
<th>Important to my role</th>
<th>Very important to my role</th>
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<tr>
<td>Frequency</td>
<td>Not part of my practice</td>
<td>In frequen  tly (1-2 times/year)</td>
<td>Multiple times/year; monthly</td>
<td>More than once/month; weekly</td>
<td>Once/day</td>
<td>Multiple times/day</td>
</tr>
</tbody>
</table>
Q50. **Oversee human resources (people) related to research process**

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not part of my practice</td>
<td>Not part of my role</td>
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<tr>
<td>Infrequently (1-2 times/year)</td>
<td>Not important to my role</td>
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<tr>
<td>Multiple times/year; monthly</td>
<td>Somewhat important to my role</td>
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<td>More than once/month; weekly</td>
<td>Important to my role</td>
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<tr>
<td>Once/day</td>
<td>Very important to my role</td>
</tr>
<tr>
<td>Multiple times/day</td>
<td>Essential to my role</td>
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</tbody>
</table>

Q51. **Disseminate clinical expertise and best practices related to clinical research through presentations, publications and/or interactions with nursing colleagues**

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Importance</th>
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<tbody>
<tr>
<td>Not part of my practice</td>
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<td>Infrequently (1-2 times/year)</td>
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<td>Multiple times/year; monthly</td>
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<td>Once/day</td>
<td>Very important to my role</td>
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<tr>
<td>Multiple times/day</td>
<td>Essential to my role</td>
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</table>

Q52. **Protect research participant data in accordance with regulatory requirements**

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not part of my practice</td>
<td>Not part of my role</td>
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<tr>
<td>Infrequently (1-2 times/year)</td>
<td>Not important to my role</td>
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<tr>
<td>Multiple times/year; monthly</td>
<td>Somewhat important to my role</td>
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<tr>
<td>More than once/month; weekly</td>
<td>Important to my role</td>
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<tr>
<td>Once/day</td>
<td>Very important to my role</td>
</tr>
<tr>
<td>Multiple times/day</td>
<td>Essential to my role</td>
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</table>

Q53. **Coordinate research activities to minimize subject risk**

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Importance</th>
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<tbody>
<tr>
<td>Not part of my practice</td>
<td>Not part of my role</td>
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<tr>
<td>Infrequently (1-2 times/year)</td>
<td>Not important to my role</td>
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<td>Multiple times/year; monthly</td>
<td>Somewhat important to my role</td>
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<td>More than once/month; weekly</td>
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<td>Once/day</td>
<td>Very important to my role</td>
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<tr>
<td>Multiple times/day</td>
<td>Essential to my role</td>
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Q54. **Provide teaching to research participants and family regarding study participation, participant's current clinical condition, and/or disease process**

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Importance</th>
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<tbody>
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<td>Not part of my practice</td>
<td>Not part of my role</td>
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<tr>
<td>Infrequently (1-2 times/year)</td>
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<td>Somewhat important to my role</td>
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<td>More than once/month; weekly</td>
<td>Important to my role</td>
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<tr>
<td>Once/day</td>
<td>Very important to my role</td>
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<tr>
<td>Multiple times/day</td>
<td>Essential to my role</td>
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</tbody>
</table>
Q55. Participate in the set up of a study specific database.

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Not part of my role</th>
<th>Not important to my role</th>
<th>Somewhat important to my role</th>
<th>Important to my role</th>
<th>More than once/month; weekly</th>
<th>Multiple times/year; monthly</th>
<th>Once/day</th>
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<td>Importance</td>
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</table>

Q56. Facilitate communication within the research team

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Not part of my role</th>
<th>Not important to my role</th>
<th>Somewhat important to my role</th>
<th>Important to my role</th>
<th>More than once/month; weekly</th>
<th>Multiple times/year; monthly</th>
<th>Once/day</th>
<th>Multiple times/day</th>
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<tr>
<td>Importance</td>
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</tbody>
</table>

Q57. Facilitate the education of the interdisciplinary team on study requirements

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Not part of my role</th>
<th>Not important to my role</th>
<th>Somewhat important to my role</th>
<th>Important to my role</th>
<th>More than once/month; weekly</th>
<th>Multiple times/year; monthly</th>
<th>Once/day</th>
<th>Multiple times/day</th>
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<tr>
<td>Importance</td>
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</tbody>
</table>

Q58. Mentor junior staff and students participating as members of the research team

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Not part of my role</th>
<th>Not important to my role</th>
<th>Somewhat important to my role</th>
<th>Important to my role</th>
<th>More than once/month; weekly</th>
<th>Multiple times/year; monthly</th>
<th>Once/day</th>
<th>Multiple times/day</th>
</tr>
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<tbody>
<tr>
<td>Importance</td>
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<td></td>
</tr>
</tbody>
</table>
Q59.
Facilitate the handling (storage and shipment) of research specimens

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Not part of my practice</th>
<th>Infrequently (1-2 times/year)</th>
<th>Multiple times/year; monthly</th>
<th>More than once/month; weekly</th>
<th>Once/day</th>
<th>Multiple times/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Importance</td>
<td>Not part of my role</td>
<td>Not important to my role</td>
<td>Somewhat important to my role</td>
<td>Important to my role</td>
<td>Very important to my role</td>
<td>Essential to my role</td>
</tr>
</tbody>
</table>

Q60.
Facilitate the ongoing informed consent/assent process

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Not part of my practice</th>
<th>Infrequently (1-2 times/year)</th>
<th>Multiple times/year; monthly</th>
<th>More than once/month; weekly</th>
<th>Once/day</th>
<th>Multiple times/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Importance</td>
<td>Not part of my role</td>
<td>Not important to my role</td>
<td>Somewhat important to my role</td>
<td>Important to my role</td>
<td>Very important to my role</td>
<td>Essential to my role</td>
</tr>
</tbody>
</table>

Q61.
Provide nursing expertise to the research team during study implementation

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Not part of my practice</th>
<th>Infrequently (1-2 times/year)</th>
<th>Multiple times/year; monthly</th>
<th>More than once/month; weekly</th>
<th>Once/day</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Importance</td>
<td>Not part of my role</td>
<td>Not important to my role</td>
<td>Somewhat important to my role</td>
<td>Important to my role</td>
<td>Very important to my role</td>
<td>Essential to my role</td>
</tr>
</tbody>
</table>

Block 2

Q62. Please check the response that best applies to your current practice.

- My role is primarily focused on providing direct patient care to research participants who come to my facility.
- My role is primarily focused on coordination of aspects of specific clinical trials.
- My role is a combination of providing direct patient care to research participants and coordination of clinical trials.

Q63. Select your current nursing degree

- LVN/LPN
- ADN, RN
- BSN, RN

Q64. Approximately how long have you been practicing in your current role?

- < 5 years
- >= 5 years
- Click to write Choice 3

Q65. Are you currently working full time or part time?

- Full-time
- Part-time
- Other (please specify)

Q66. What region of the United States do you currently practice?

- North East
- Southwest
- Northeast
- Southeast
- Central
- Midwest

Q67. In your current role, do you provide direct care to research participants?

- yes
- No

Q68. How would you describe your primary patient population?

Q69. Which population do you primarily serve? (Check all that apply)
- Hematology/oncology
- Surgical oncology
- Medical oncology
- Radiation oncology
- Palliative care/symptom management
- Other (please specify)

Q70. How long have you been practicing as a nurse?
- <1 year
- 1-2 years
- 3-5 years
- 6-10 years
- 11-15 years
- 16-20 years
- >20 years

Q71. Age range
- 20-29
- 30-39
- 40-49
- 50-59
- >60

Q72. Gender
- Male
- Female

Q73. What training or education have you participated in or received specific to clinical research (select all that apply)?

- None
- Organization/center specific
- Academic/college course(s), no degree
- Academic/college course(s), degree
- Certification program
- Other (please specify)

[Box for Other specification]
Appendix B. Updated Oncology Clinical Trials Nurse Role Delineation Survey- Importance

Section I: Screening Questions:
1. Are you a nurse currently practicing in the United States?
2. Are you a nurse who is currently working in a position that is primarily focused on direct patient care for oncology patients enrolled to clinical trials OR that is primarily focused on coordination aspects of oncology clinical trials OR a combination of both?

Section II: Main Questions
This survey includes a list of 57 activities that nurses may assume when working in a clinical research setting. When answering, please consider these activities in the context of your current position. In each question please rate how often you do the activities.

1. Provide direct nursing care to research participants (e.g. interact with research participants to provide nursing care, administration of research interventions, specimen collection, etc.)
   - Not part of my role
   - Not important to my role
   - Somewhat important to my role
   - Important to my role
   - Very important to my role
   - Essential to my role

2. Participate in research participant recruitment
   - Not part of my role
   - Not important to my role
   - Somewhat important to my role
   - Important to my role
   - Very important to my role
   - Essential to my role

3. Perform secondary data analysis to contribute to the development of new ideas
   - Not part of my role
   - Not important to my role
   - Somewhat important to my role
   - Important to my role
   - Very important to my role
   - Essential to my role

4. Facilitate scheduling of study procedures
   - Not part of my role
   - Not important to my role
   - Somewhat important to my role
   - Important to my role
   - Very important to my role
   - Essential to my role

5. Collaborate with the interdisciplinary team to create and communicate a plan of care that allows
for safe and effective collection of clinical research data

6. Support study budget development

7. Provide nursing leadership within the interdisciplinary team

8. Collect data on research participant based on study endpoints

9. Identify questions appropriate for clinical nursing research as a result of study team participation

10. Contribute to the development of case report forms
11. Monitor the research participant for potential adverse events
   - Not part of my role
   - Not important to my role
   - Somewhat important to my role
   - Important to my role
   - Very important to my role
   - Essential to my role

12. Communicate the impact of study procedures on the research participants
   - Not part of my role
   - Not important to my role
   - Somewhat important to my role
   - Important to my role
   - Very important to my role
   - Essential to my role

13. Collaborate with the interdisciplinary team to address ethical conflicts
   - Not part of my role
   - Not important to my role
   - Somewhat important to my role
   - Important to my role
   - Very important to my role
   - Essential to my role

14. Coordinate the collection of research specimens
   - Not part of my role
   - Not important to my role
   - Somewhat important to my role
   - Important to my role
   - Very important to my role
   - Essential to my role

15. Collaborate with the interdisciplinary team to develop innovations in care delivery that have the potential to improve outcomes and accuracy of data collection
   - Not part of my role
   - Not important to my role
   - Somewhat important to my role
   - Important to my role
   - Very important to my role
   - Essential to my role

16. Handling and collection of research specimens
   - Not part of my role
   - Not important to my role
   - Somewhat important to my role
   - Important to my role
   - Very important to my role
   - Essential to my role
17. Report potential adverse events to a member of the research team

☐ Not part of my role
☐ Not important to my role
☐ Somewhat important to my role
☐ Important to my role
☐ Very important to my role
☐ Essential to my role

18. Facilitate the informed consent/assent process

☐ Not part of my role
☐ Not important to my role
☐ Somewhat important to my role
☐ Important to my role
☐ Very important to my role
☐ Essential to my role

19. Provide nursing expertise to the research team during study development

☐ Not part of my role
☐ Not important to my role
☐ Somewhat important to my role
☐ Important to my role
☐ Very important to my role
☐ Essential to my role

20. Provide nursing expertise to community-based health care personnel (e.g. referring physician or center) related to study participation

☐ Not part of my role
☐ Not important to my role
☐ Somewhat important to my role
☐ Important to my role
☐ Very important to my role
☐ Essential to my role

21. Record data on official study documents (e.g. case report forms, research/study database, etc.)

☐ Not part of my role
☐ Not important to my role
☐ Somewhat important to my role
☐ Important to my role
☐ Very important to my role
☐ Essential to my role

22. Coordinate interdisciplinary meetings and activities in the context of a study

☐ Not part of my role
☐ Not important to my role
☐ Somewhat important to my role
☐ Important to my role
☐ Very important to my role
23. Participate in the reporting of research trends

- Essential to my role
- Not part of my role
- Not important to my role
- Somewhat important to my role
- Important to my role
- Very important to my role
- Essential to my role


- Essential to my role
- Not part of my role
- Not important to my role
- Somewhat important to my role
- Important to my role
- Very important to my role
- Essential to my role

25. Coordinate referrals to appropriate interdisciplinary services outside the immediate research team

- Essential to my role
- Not part of my role
- Not important to my role
- Somewhat important to my role
- Important to my role
- Very important to my role
- Essential to my role

26. Manage potential ethical and financial conflicts of interest for self.

- Essential to my role
- Not part of my role
- Not important to my role
- Somewhat important to my role
- Important to my role
- Very important to my role
- Essential to my role

27. Serve as a resource for new investigators

- Essential to my role
- Not part of my role
- Not important to my role
- Somewhat important to my role
- Important to my role
- Very important to my role
- Essential to my role

28. Facilitate accurate communication among research sites (i.e. multisite studies)

- Essential to my role
- Not part of my role
- Not important to my role
- Somewhat important to my role
- Important to my role
29. Coordinate research participant study visits

- Not part of my role
- Not important to my role
- Somewhat important to my role
- Important to my role
- Very important to my role
- Essential to my role

30. Participate in screening of potential research participants for eligibility

- Not part of my role
- Not important to my role
- Somewhat important to my role
- Important to my role
- Very important to my role
- Essential to my role

31. Support study grant development

- Not part of my role
- Not important to my role
- Somewhat important to my role
- Important to my role
- Very important to my role
- Essential to my role

32. Serve as an expert in a specialty area (e.g. grant reviewer, editorial board, presenter, etc.)

- Not part of my role
- Not important to my role
- Somewhat important to my role
- Important to my role
- Very important to my role
- Essential to my role

33. Identify clinical care implications during study development (e.g. staff competencies and resources, equipment, etc.)

- Not part of my role
- Not important to my role
- Somewhat important to my role
- Important to my role
- Very important to my role
- Essential to my role

34. Support research participant in defining his/her reasons and goals for participating in a study

- Not part of my role
- Not important to my role
- Somewhat important to my role
35. Participate in the preparation of reports for appropriate regulatory and monitoring bodies/boards

☐ Not part of my role
☐ Not important to my role
☐ Somewhat important to my role
☐ Important to my role
☐ Very important to my role
☐ Essential to my role

36. Participate in the query of research data to prepare for analysis

☐ Not part of my role
☐ Not important to my role
☐ Somewhat important to my role
☐ Important to my role
☐ Very important to my role
☐ Essential to my role

37. Participate in the identification of research trends

☐ Not part of my role
☐ Not important to my role
☐ Somewhat important to my role
☐ Important to my role
☐ Very important to my role
☐ Essential to my role

38. Participate in the analysis of research data

☐ Not part of my role
☐ Not important to my role
☐ Somewhat important to my role
☐ Important to my role
☐ Very important to my role
☐ Essential to my role

39. Provide indirect nursing care (e.g. participation in clinical, unit, and/or protocol rounds; scheduling study relates tests, etc.) in context of research participation

☐ Not part of my role
☐ Not important to my role
☐ Somewhat important to my role
☐ Important to my role
☐ Very important to my role
☐ Essential to my role

40. Participate in study development

☐ Not part of my role
☐ Not important to my role
41. Record research data (e.g. document vital signs, administration of a research compound, participant responses, etc.) in approved source document (e.g. the medical record, data collection sheet, etc.)

42. Develop study specific materials for research participant education

43. Generate practice questions as a result of a new study procedure or intervention

44. Participate in site visits and/or audits

45. Facilitate research participant inquiries and concerns

46. Oversee human resources (people) related to research process
47. Disseminate clinical expertise and best practices related to clinical research through presentations, publications and/or interactions with nursing colleagues

48. Protect research participant data in accordance with regulatory requirements

49. Coordinate research activities to minimize subject risk

50. Provide teaching to research participants and family regarding study participation, participant’s current clinical condition, and/or disease process

51. Participate in the set up of a study specific database
52. Facilitate communication within the research team
   - Not part of my role
   - Not important to my role
   - Somewhat important to my role
   - Important to my role
   - Very important to my role
   - Essential to my role

53. Facilitate the education of the interdisciplinary team on study requirements
   - Not part of my role
   - Not important to my role
   - Somewhat important to my role
   - Important to my role
   - Very important to my role
   - Essential to my role

54. Mentor junior staff and students participating as members of the research team
   - Not part of my role
   - Not important to my role
   - Somewhat important to my role
   - Important to my role
   - Very important to my role
   - Essential to my role

55. Facilitate the handling (storage and shipment of research specimens)
   - Not part of my role
   - Not important to my role
   - Somewhat important to my role
   - Important to my role
   - Very important to my role
   - Essential to my role

56. Facilitate the ongoing informed consent/assent process
   - Not part of my role
   - Not important to my role
   - Somewhat important to my role
   - Important to my role
   - Very important to my role
   - Essential to my role

57. Provide nursing expertise to the research team during study implementation
   - Not part of my role
   - Not important to my role
   - Somewhat important to my role
   - Important to my role
   - Very important to my role
   - Essential to my role
Section III: Demographic Questions

Please check the response that best applies to your current practice.

☐ My role is primarily focused on providing direct patient care to research participants who come to my facility.
☐ My role is primarily focused on coordination of aspects of specific clinical trials.
☐ My role is a combination of providing direction patient care to research participants and coordination of clinical trials.

Select your current nursing degree
LVN/LPN
ADN, RN
BSN, RN
MSN, RN
Nurse Practitioner DNP, RN
PhD, RN
Other (please specify)

Approximately how long have you been practicing in your current role?
< 5 years
≥ 5 years

Are you currently working full time or part time?
Full-time Part-time
Other (please specify)

What region of the United States do you currently practice?
Northwest
Southwest
Northeast
Southeast
Central
Midwest

In your current role, do you provide direct care to research participants?

Yes
No

How would you describe your primary patient population?

Pediatrics (0-17 years)
Adults (18+)

Which population do you primarily serve? (check all that apply)

☐ Hematology/oncology
☐ Surgical oncology
☐ Medical oncology
☐ Radiation oncology
☐ Palliative care/Symptom Management
☐ Other (please specify)

How long have you been practicing as a nurse?
○ <1 year
○ 1-2 years
○ 3-5 years
○ 6-10 years
○ 11-15 years
○ 16-20 years
○ >/= 20 years

Age range
○ 20-29
○ 30-39
○ 40-49
○ 50-59
○ >/= 60

Gender
○ Male
○ Female

Appendix C. Updated Oncology Clinical Trials Nurse Role Delineation Survey- Frequency

Section I: Screening Questions:
1. Are you a nurse currently practicing in the United States?
2. Are you a nurse who is currently working in a position that is primarily focused on
Section II: Main Questions
This survey includes a list of 53 activities that nurses may assume when working in a clinical research setting. When answering, please consider these activities in the context of your current position. In each question please rate how often you do the activities.

58. Provide direct nursing care to research participants (e.g. interact with research participants to provide nursing care, administration of research interventions, specimen collection, etc.)

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year;monthly
- More than once/month;weekly
- Once/day
- Multiple times/day

59. Participate in research participant recruitment

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year;monthly
- More than once/month;weekly
- Once/day
- Multiple times/day

60. Perform secondary data analysis to contribute to the development of new ideas

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year;monthly
- More than once/month;weekly
- Once/day
- Multiple times/day

61. Facilitate scheduling of study procedures

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year;monthly
- More than once/month;weekly
- Once/day
- Multiple times/day

62. Collaborate with the interdisciplinary team to create and communicate a plan of care
that allows for safe and effective collection of clinical research data

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

63. Support study budget development

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

64. Provide nursing leadership within the interdisciplinary team

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

65. Collect data on research participant based on study endpoints

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

66. Contribute to the development of case report forms

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day
67. Monitor the research participant for potential adverse events

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

68. Communicate the impact of study procedures on the research participants

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

69. Collaborate with the interdisciplinary team to address ethical conflicts

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

70. Coordinate the collection of research specimens

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

71. Collaborate with the interdisciplinary team to develop innovations in care delivery that have the potential to improve outcomes and accuracy of data collection

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day
72. Handling and collection of research specimens

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

73. Report potential adverse events to a member of the research team

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

74. Facilitate the informed consent/assent process

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

75. Provide nursing expertise to the research team during study development

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

76. Record data on official study documents (e.g. case report forms, research/study database, etc.)

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day
77. Coordinate interdisciplinary meetings and activities in the context of a study

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

78. Participate in the reporting of research trends

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

79. Comply with International Conference of Harmonization (ICH) Good Clinical Practice (GCP) guidelines.

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

80. Coordinate referrals to appropriate interdisciplinary services outside the immediate research team

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

81. Manage potential ethical and financial conflicts of interest for self.

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day
82. Serve as a resource for new investigators

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

83. Facilitate accurate communication among research studies (i.e. multisite studies)

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

84. Coordinate research participant study visits

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

85. Participate in screening of potential research participants for eligibility

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

86. Support study grant development

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

85
87. Identify clinical care implications during study development (e.g. staff competencies and resources, equipment, etc.)

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

88. Support research participant in defining his/her reasons and goals for participating in a study

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

89. Participate in the preparation of reports for appropriate regulatory and monitoring bodies/boards

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

90. Participate in the query of research data to prepare for analysis

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

91. Participate in the identification of research trends

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
92. Participate in the analysis of research data

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

93. Provide indirect nursing care (e.g. participation in clinical, unit, and/or protocol rounds; scheduling study relates tests, etc.) in context of research participation

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

94. Participate in study development

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

95. Record research data (e.g. document vital signs, administration of a research compound, participant responses, etc.) in approved source document (e.g. the medical record, data collection sheet, etc.)

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

96. Develop study specific materials for research participation education

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
97. Generate practice questions as a result of a new study procedure of intervention

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

98. Participate in site visits and/or audits

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

99. Facilitate research participant inquiries and concerns

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

100. Oversee human resources (people) related to research process

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

101. Protect research participant data in accordance with regulatory requirements

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
102. Coordinate research activities to minimize subject risk

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

103. Provide teaching to research participants and family regarding study participation, participant’s current clinical condition, and/or disease process

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

104. Participate in the set up of a study specific database

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

105. Facilitate communication within the research team

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

106. Facilitate the education of the interdisciplinary team on study requirements

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
107. Mentor junior staff and students participating as members of the research team

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

108. Facilitate the handling (storage and shipment) of research specimens

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

109. Facilitate the ongoing consent/assent process

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

110. Provide nursing expertise to the research team during study implementation

- Not part of my practice
- Infrequently (1-2 times/year)
- Multiple time/year; monthly
- More than once/month; weekly
- Once/day
- Multiple times/day

Section III: Demographic Questions

Please check the response that best applies to your current practice.

- My role is primarily focused on providing direct patient care to research participants who come to my facility.
- My role is primarily focused on coordination of aspects of specific clinical
My role is a combination of providing direction patient care to research participants and coordination of clinical trials.

Select your current nursing degree
LVN/LPN
ADN, RN
BSN, RN
MSN, RN
Nurse Practitioner DNP, RN
PhD, RN
Other (please specify)

Approximately how long have you been practicing in your current role?
< 5 years
>= 5 years

Are you currently working full time or part time?
Full-time Part-time
Other (please specify)

What region of the United States do you currently practice?
Northwest
Southwest
Northeast
Southeast
Central
Midwest

In your current role, do you provide direct care to research participants?
Yes
No

How would you describe your primary patient population?

Pediatrics (0-17 years)
Adults (18+)

Which population do you primarily serve? (check all that apply)

Hematology/oncology
Surgical oncology
Medical oncology
Radiation oncology
Palliative care/Symptom Management
☐ Other (please specify)

How long have you been practicing as a nurse?
- <1 year
- 1-2 years
- 3-5 years
- 6-10 years
- 11-15 years
- 16-20 years
- >= 20 years

Age range
- 20-29
- 30-39
- 40-49
- 50-59
- >= 60

Gender
- Male
- Female
November 30, 2015

Dear Ms. Purdom,

Your request to conduct the study: *Validating a Taxonomy of Nursing Practice for Oncology Clinical Trial Nurses*, IRB #F2015-24 has been approved by The University of Texas at Tyler Institutional Review Board as a study exempt from further IRB review. This approval includes a waiver of signed, written informed consent. In addition, please ensure that any research assistants are knowledgeable about research ethics and confidentiality, and that co-investigators have completed human protection training within the past three years, and have forwarded their certificates to the IRB office (G. Duke). Please review the UT Tyler IRB Principal Investigator Responsibilities, and acknowledge your understanding of these responsibilities and the following through return of this email to the IRB Chair within one week after receipt of this approval letter:

- Prompt reporting to the UT Tyler IRB of any proposed changes to this research activity
- Prompt reporting to the UT Tyler IRB and academic department administration will be done of any unanticipated problems involving risks to subjects or others
- Suspension or termination of approval may be done if there is evidence of any serious or continuing noncompliance with Federal Regulations or any aberrations in original proposal.
- Any change in proposal procedures must be promptly reported to the IRB prior to implementing any changes except when necessary to eliminate apparent immediate hazards to the subject.

Best of luck in your research, and do not hesitate to contact me if you need any further assistance.

Sincerely,

Gloria Duke, PhD, RN
Chair, UT Tyler IRB
RE: Permission request for Clinical Research Role Delineation Measure

From: Hastings, Clare (NIH/CC/NURS) [E] (CHastings@cc.nih.gov)
Sent: Tue 3/17/15 3:56 PM
To: 'Michelle Purdom' (mpurdom@hotmail.com)
Cc: Bevans, Margaret (NIH/CC/NURS) [E] (MBevans@cc.nih.gov), Wallen, Gwerynth (NIH/CC/NURS) [E] (GWallen@cc.nih.gov)

2 attachments
RDS Demographics Questionnaire_10.21.11.pdf (361.3 KB), NIH CRN Role Delineation Measure Questionnaire_10.21.11.pdf (467.5 KB)

Hello Michelle,

Here are the measures used for the 2011 Role Delineation Survey. You can feel free to use them in any way that is helpful to move your project forward. No need to request additional permission for a second use, although we would certainly be interested in any information you get about reliability, validity, etc. in a new sample (if you can share it.) Please use the 2011 article as the citation when crediting the use of the instrument.

Best - Clare

Clare Hastings, PhD, RN, FAAN
Chief Nurse Officer
NIH Clinical Center
National Institutes of Health
Building 10, Room 6-1484
Bethesda, MD 20892
301-435-3489

https://bay174.mail.live.com/ol/mail.mvc/PrintMessages?mkt=en-us 4/7/2015
From: Michelle Purdom [mailto:m_purdom@hotmail.com]
Sent: Tuesday, March 17, 2015 2:05 PM
To: Hastings, Clare (NIH/CC/NURS) [E]
Subject: Permission request for Clinical Research Role Delineation Measure

Good Afternoon Dr. Hastings,

I would like to request permission for use of the Clinical Research Role Delineation Measure used in the Bevans et al. (2011) study looking at frequency and importance of activities. At this time the instrument will only be used in preparation of my draft dissertation proposal. It is not yet clear if it will be used for my study. I can update you at that time if different permission is needed to utilize the survey for a future study.

Let me know if you have any questions and I appreciate your help.

Take Care,
Michelle

Michelle A. Purdom RN, MSN
713-416-7487

https://bay174.mail.live.com/o1/mail.mvc/PrintMessages?mkt=en-us
Appendix F.

Biographical Sketch

BIOGRAPHICAL SKETCH

NAME: Purdom, Michelle Anne

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: MSN RN

EDUCATION/TRAINING

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE</th>
<th>MM/YYYY</th>
<th>FIELD OF STUDY</th>
</tr>
</thead>
<tbody>
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<td>Pace University</td>
<td>BSN</td>
<td>6/1997</td>
<td>Nursing</td>
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<tr>
<td>The University of Texas Medical Branch</td>
<td>MSN</td>
<td>05/2010</td>
<td>Nursing Leadership</td>
</tr>
<tr>
<td>The University of Texas at Tyler</td>
<td>PhD</td>
<td>Candidate</td>
<td>Nursing</td>
</tr>
</tbody>
</table>

A. Personal Statement

The goal of the proposed research was to investigate the role of the oncology clinical trials nurse. We measured the frequency and importance of activities of the nurse. We also examined the differences in the role of the direct patient care providers versus the nurse coordinator versus those nurses with a dual role. My over 10 years’ of oncology experience as a research nurse coordinator and nurse manager as well as drug development experience in the pharmaceutical industry enabled me to successfully carry out the study.

B. Positions and Honors

Positions and Employment

2014-Present. Director, Medical Affairs. TG Therapeutics, New York, NY
2011-2014. Sr. Manager, Medical Information and Communications, Seattle Genetics, Bothell, WA
2009-2011. Clinical Sales Specialist. Allos Therapeutics, Field Based
2001-2009. Research Nurse, Manager of Clinical Trials Administration, Research Nurse Manager. The University of Texas MD Anderson Cancer Center, Houston, TX

Other Experience and Professional Memberships

Oncology Nurse Society
International Association of Clinical Research Nurses
American Society of Clinical Oncology