

Exploring the Role and Perceived Impact of Clinical Research Nurses on
Pharmaceutical Drug Research and Development

by

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ABSTRACT OF THE DISSERTATION

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Many new drugs and treatments come to clinical practice as a result of the combined and coordinated efforts of skilled multidisciplinary team in the pharmaceutical drug research and development process. Although Clinical Research Nurses (CRNs) contribute to this process, the role of the CRN who works at many places along the continuum of pharmaceutical drug research and development has not been described from the CRN perspective.

The purpose of this study was to explore and describe the role experiences and perceived impact of the CRN, other than a research study coordinator, who works within the pharmaceutical industry. A focused ethnography methodology was used to examine the ordinary conscious experience of the work life of the CRN and their views of this non-traditional nursing role. Rutgers University IRB approval was obtained prior to study initiation. Twenty-one participants whose roles included, drug safety and risk management, clinical trials, regulatory management, and data dissemination, were interviewed to discover their perspectives of working in a non-traditional nursing role within pharmaceutical drug research and development.

Four main themes emerged from the data: Work environment, The goal of the role, Being in the role of clinical researcher and Being a nurse in the role of clinical researcher. The highly demanding, and changing work environment is based on a business rather than a clinical model. In this setting the CRNs' role was not about direct patient care but about caring for the larger population, both research subjects and product consumers. The goal of the CRN role is to ensure the integrity of clinical research so that only safe and effective treatments reach the clinical setting. The roles that nurses enact are varied but all require multidisciplinary collaboration and communication. Nurses in this role put patients in the forefront and use their nursing knowledge, training, and professional judgement to ensure the safe and ethical conduct of clinical research.

This study illustrates a unique role for nurses within the pharmaceutical industry to care for the public's health. The changing business focused environment impacts their role but they use their nursing experience to advocate for study patients and patient consumers.

DEDICATION

We have been created for greater things. Not just to be a number in the world. Not just to go for diplomas and degrees. This work and that work. We have been created in order to love and to be love.

Mother Teresa

I dedicate this dissertation to those whom I have loved dearly and who have shown great love to me during these last years as I pursued my doctorate. To my parents, William and Bridget Bennett, who showed me by example what true love is and instilled in me a love for life-long learning. To my sister, Dr. Anna Marie Tracy, who has been my rock. She has listened patiently and supported me through all life has given me. To my children who I love with all my heart. David who never ceases to amaze me with his intelligence, constant energy, and ability to work through any problem. To my daughter Kristin, who is my heart. She is the light of my world with her kindness and ability to give all she meets sunshine through any darkness. To my angel, Tom, he is the reason for this journey as he guides me daily through this life. To my Joe, who will always be my baby although he has graduated college and law school while I was still working on this degree. He is the best editor-in-chief and may now know more about clinical research after repeatedly reading this dissertation than any CRN. To TFox and Jess who let me know that love continues to grow. To my granddaughter, Madeline, who is the future of my world. To my husband, Dave, my love, my best friend, my partner, my constant support. It is with his love that together we have accomplished this goal. And lastly to God. It is through His grace that all good comes.

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My sincere gratitude to the study participants who willingly gave of their time and shared their stories to give voice to this non-traditional career choice for nurses. I am truly thankful for these fellow clinical research nurses.

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Chapter 1: Introduction and Problem

The nurse sat quietly with her family watching television. During the program a commercial came on showing a smiling middle aged female walking briskly with a female companion, the announcer commented that the female was now able to live life to the fullest due to the inhaled medication prescribed by her physician to improve her breathing. The nurse softly smiled and told her family, I helped test that drug before it was even given a name. She felt a great sense of accomplishment, a sense of having contributed in a small way to the improved health of the patients who would benefit from the drug. She was part of the cutting edge of science. She was the person who ensured the testing of this drug was performed according to the prescribed plan so the research could be replicated. She was the one who assessed the study participants for adverse events. She was proud she was a Clinical Research Nurse (CRN). The next day, the CRN was in a forum with peers where they discussed their nursing roles. After stating her CRN role function, a fellow nurse commented, "I have worked in teaching facilities where data collection was done by any of the staff. Additionally I did not experience anything intricately limited to nursing about the research nurse role when my mother was involved in a breast cancer research study." The CRN left the discussion feeling devalued. Her contributions to clinical research were not viewed as valuable by her peers. She felt she was *only* a CRN.

Introduction to the Problem

We are in a time of great scientific discovery (Callard, 2011). It is imperative that the newest treatments and biological discoveries are evaluated for safety and efficacy and

quickly brought to clinical settings. Pharmaceutical medicine is an evolving specialty which encompasses many disciplines, including nursing, whose ultimate responsibility is to interpret clinical data to determine whether drugs should be or should continue to be marketed to the public (Gabbay, 2003). Regardless of the discipline, Freunscht and Van Dermark (2011, p. 17) believe all clinical researchers “share a common purpose in helping to develop safe and effective therapies supported by high integrity data and generated in environments where the rights, welfare, and safety of the clinical research subjects have been protected with diligence.” Nurses have long been part of the clinical research enterprise working in collaboration with other disciplines (Davis et al, 2002; Hastings, 2012).

Many new treatments come to clinical practice as a result of the pharmaceutical drug research and development process. This process has as its ultimate goal the improvement of the standard of health care by providing new or improved therapies for the prevention and treatment of illnesses (Linberg, 1999). Since the 1940's pharmaceutical drug research and development have been responsible for the introduction of broad-spectrum antibiotics, drugs based on receptor theory, the first biotechnology products, new approaches to drug design and targeting and the first gene therapy products (Gabbay, 2003). There continues to be a constant search for new drug therapies, their development and the evaluation of their performance to improve the public health (Gabbay, 2003). Drug research, development, and continued safety monitoring takes the combined and coordinated efforts of a highly skilled team of professionals (Gabby, 2003; Kenkre, 2003; Ognibene, 2012). The multidisciplinary team of scientists and staff who work to bring new drugs and therapies to the clinical setting are well trained and qualified

persons in their respective fields with each team member doing their part to ensure only safe and effective therapies are brought to the public. Disciplines involved in this process include biologists, chemists, physicians, pharmacists, lawyers, regulatory specialists, statisticians, epidemiologists, bioinformatics experts and nurses (Gabbay, 2003, Ognibene, 2012).

Among the major factors to be considered during drug research and development are safety, efficacy, cost, and time (Linberg, 1999). With the increasing complexity of drug development as well as increased regulatory requirements, there is a high cost in both time and money in drug research and development (Levine, 2012). It reportedly costs approximately \$1.2 billion to develop a new drug that will be brought to the clinical setting (Center for Drug Development, 2013). Additionally, it takes an average of greater than 13 years to bring a drug to market (Levine, 2012). This financial investment in drug research and development underscores the importance of having interdisciplinary coordination ensuring the timely delivery of safe and effective products to the public. Each person contributing to the research and development of pharmaceutical products at any point along the continuum must perform their job in a timely and cost effective manner. Multidisciplinary team members may work within one of many groups or departments that contribute to this process which may include: private or public funding organizations, government agencies, academic medical centers, investigative research sites, pharmaceutical and biotechnology companies, device manufacturers, research organizations, clinical research teams (investigators, nurse coordinators and clinical data managers), regulatory agencies, institutional review boards, or payers and purchasers of the pharmaceutical drug (Ness, Parreco, Galassi, and O'Mara, 2012). CRNs may be a

member of any of these groups which contribute to the pharmaceutical drug research and development process.

Clinical trials are one portion of the drug development process. According to Tonkens (2005), the clinical research / clinical trials portion of drug development is the most costly and time consuming part of drug development. ClinicalTrials.gov, a website maintained by the United States Federal Drug Administration (FDA), indicates there were approximately 201,149 studies with locations in all 50 states and in 190 countries listed on October 24, 2015 involving pharmaceutical drugs worldwide (FDA, n.d). Nurses have historically been an essential part of the clinical research infrastructure often working as study coordinators implementing clinical trials at investigative sites (Hastings, 2012). Nurses who coordinate clinical trials are often described as the most important members of the clinical research team (Fisher, 20006; Spilsbury et al, 2008). It is this role of nurse study coordinators in clinical research that is most frequently addressed in the literature. However, during the clinical trial process CRNs may also work as part of the multidisciplinary team contributing to other aspects of clinical trials including: study protocol development, writing of consent forms, recruiting subjects, explaining the study to subjects, coordinating with hospital services, collecting and maintaining clinical data and serving as the main contact for subjects during a trial (Davis et al, 2002). While the role of the CRN working as a study coordinator is described in the literature there is a dearth of literature describing the role or contribution of nurses who work at other points along the continuum of pharmaceutical drug research and development.

Statement of the Problem

Translating basic science findings into clinically relevant treatments for the public good demands a multidisciplinary team with each member adding their expertise to the process. The research infrastructure to accommodate that translational process includes nurses at many places along the continuum of pharmaceutical drug research and development yet the role and the perceived impact of the CRN other than that of a study coordinator has not been fully explored from the perspective of the CRN. Over time, clinical trials have increased in number and complexity and now require a highly skilled research team to test new treatments and recognize the potential side effects and possible complications (Catania et al, 2008). With this increased intricacy and volume of clinical research, many believe that CRN's nursing knowledge and training have become essential to the research process (Lubejko et al, 2011). According to Hastings (2012), CRNs are intimately involved in all aspects of clinical research from management and planning to evaluation of current practice to assess relevance of the new treatment. However, the vast majority of literature that addresses nursing's involvement in the pharmaceutical research and development process focuses on the role of the study coordinator at the investigative site (Davis, Hull, Grady, Wilfond and Henderson, 2002; Fisher, 2006; Gwede, Johnson, Roberts & Cantor, 2005; Hill & MacArthur, 2006; Instone, Mueller & Gilbert, 2008; Isaacman & Reynolds, 1996;; Mueller, 2001 Isaacman & Reynolds, 1996;Roberts, Rickared, Foote & McGrail, 2006; Spilsbury et al, 2008; Xanthos, Carp, & Geromanos, 1998). This is only one of the roles in which a CRN may be employed in the drug research and development process. Other roles that employ nurses in the pharmaceutical drug environment include: regulatory roles,

pharmacovigilance roles, clinical research operations roles or data dissemination roles. There remains a paucity of literature examining the role experience and perceived impact of CRNs at these other points along the continuum of pharmaceutical drug research and development.

The concern addressed in this study is the lack of understanding of the role experiences and perceived impact of the Clinical Research Nurse (CRN) who works within an interdisciplinary team involved in the pharmaceutical drug research and development process outside the role of the research study coordinator. Although much has been written about the role of the CRN, especially the research study coordinator, the majority of the literature is anecdotal or opinion based rather than rigorous empirical evidence (Castro et al, 2011; Denninger, 2008; National Council, 2008). The role of the CRN within the pharmaceutical drug research and development process is often hidden and invisible, remaining unknown and not well understood by other healthcare workers, even those in the nursing profession (Gwede et al, 2005). Hastings (2012) reports that although the discipline of nursing has long played an active part in industry-sponsored clinical research, the nurse's role has not been fully or routinely documented. Little is written about the experiences, responsibilities and effectiveness of all aspects of the CRN role despite the acceptance of their widespread existence (Stephens-Lloyd, 2004).

The current number of nurses working in various capacities within clinical research remains unknown. Rodrigo (2013) opines that although there is no consensus on exact numbers, CRNs who play a crucial role in research and development are in short supply.

The specialty of clinical research nursing is unknown even within the discipline of nursing. Clinical research nursing has been defined as “clinical nursing practice with a specialty focus on research implementation and care of subjects participating in clinical research” (Hastings, 2012 p.650). Another definition put forth by Gibbs and Lowton (2012,p.37) indicates that CRNs are “registered nurses who ...work as members of multidisciplinary study teams that can consist of physicians, pharmacists and staff from other disciplines who have a specific interest in the clinical study.” McCabe and Cahill (2007, p. 13) define CRNs as “specially trained nurses responsible for safeguarding research subjects and maintaining the integrity of the research study in settings ranging from ambulatory to inpatient with healthy to acutely ill subjects.”

According to the American Nurses Association’s (ANA) document *Recognition of a Nursing Specialty*, nursing specialization involves focusing on nursing practice in a specific area, identified from within the whole field of professional nursing (ANA, 2010). Nursing specialties involve education, knowledge, skills, abilities, and competence developed through experience in a specialty area of practice (Deininger, 2008). Although the discipline of nursing has long been a part of the drug research and development process with a unique knowledge and skill set, the specialty of clinical research nursing is still evolving. This nursing specialty will continue to be unknown even within the discipline of nursing as long as the role experience and perceived impact of CRNs is not well defined or documented in the literature (Hastings, 2012).

Phenomenon of Concern

The phenomenon of concern in this study is the role experiences and perceived impact of clinical research nurses working within the pharmaceutical drug research and

development environment other than a research study coordinator. The literature reflects an evolution in the CRN role over the last few decades (Hill & McArthur, 2006; Pitler et al, 2009). Medical doctors in the past conducted all aspects of medical research (Fox, 1998). Today, physicians delegate many of the tasks and responsibilities of clinical research thus creating a unique role for the CRN (Mueller, 2001). Traditional roles and responsibilities for nurses in some practice areas such as clinical research have shifted (Stephens-Lloyd, 2004). The CRN job functions include the components of clinician, educator, advocate, administrator, and direct care giver (Ehrenberger & Lillington, 2004; Green, 2011). Stephens- Lloyd (2004) notes that nurses in the drug development and research field require diverse expertise, with roles encompassing clinical, managerial, educational, professional and research responsibilities. Raja-Jones (2002) additionally states that CRNs must have a wide range of skills and practice with great autonomy in decision-making and problem solving, while simultaneously working within a team setting. A CRN must be highly organized, detailed oriented, and have a passion for patient advocacy in order to practice in the specialty of clinical research and act with great autonomy and independence (Nagel, Gender, & Bonner, 2010; Poston & Buescher, 2010).

This study explored the role experiences and perceived impact of CRNs working in the pharmaceutical drug research and development environment other than the role of the study coordinator. Through in depth interviewing, the researcher elicited a rich description of individual experiences of these CRNs to better understand the CRN role throughout the continuum of pharmaceutical drug research and development and their perceived impact on product development. .

Purpose of the Study

The purpose of this research was to explore and describe the role experiences and perceived impact of the CRN, other than a research study coordinator, on pharmaceutical drug research and development. Through this study, the researcher provides a fuller description and better understanding of the full spectrum of the CRN role. The researcher explored how CRNs perceive this nursing role and the impact on pharmaceutical drug research and development. In describing the experiences of the CRN's role and its impact as viewed by the CRN, the researcher added further insight into the atypical nursing specialty of clinical research. The researcher investigated and articulated what it means to be a CRN from the perspectives of the CRNs themselves and elucidated the CRNs' role experience, perceived role and impact within the pharmaceutical clinical research environment. While it has been reported many times in literature that nurses play an integral role in the clinical research enterprise (Castro et al, 2011), the perspective of the CRN outside the role of the study coordinator had not been fully explored. This researcher conducted a focused ethnography study to describe the experience and perceived impact of being a CRN as articulated by the CRN answering the question, "What are the role experiences, and perceived impact of the CRN working in the pharmaceutical drug research and development environment in a role other than a research study coordinator?"

Significance of the Study

In this time of great medical discoveries, there is a great need to quickly translate basic science to treatments that can benefit the public health. This movement of science from the bench to the bedside requires translational research and a skilled

multidisciplinary team of qualified persons to bring new discoveries to the public. Along this continuum of pharmaceutical drug research and discovery, nurses have become an integral team member. However, the CRN's role often remains unknown even to fellow nurses. The number and complexity of clinical trials continues to increase as regulatory and economic pressures push for more and better treatments (Joshi & Ehrenberger, 2001). With the need to test the growing number of preventative, palliative, and curative treatments for the population, there is a great need for qualified research teams (Harris Interactive, 2001). The increased need for clinical research was highlighted when the American Recovery and Reinvestment Act of 2009 which was signed into law on February 17, 2009, provided over one billion dollars for comparative effectiveness research. One of President Obama's principles in his quest to Transform and Modernize the U.S. Health Care System is to "expand research comparing the effectiveness of medical treatments to give patients and physicians better information on what works best" (Office of Management and Budget, 2009, p.67). Along with the great need for clinical research is the need for qualified persons to conduct this research. Castro et al, (2011, p.72) concluded that "to ensure the protection of human subjects and scientific integrity amidst the complexities of the clinical research process, the expertise of various disciplines is required."

According to Poston and Buescher (2010), nurses possess a foundational knowledge of both pharmacology and pathophysiology which allows them to be critical members of the clinical research team. Although nurses have long been involved in clinical research, only recently has this nursing specialty begun to be defined (Castro et al., 2008). The study reported here explored and described the role experiences and

perceived impact of the CRN working within the pharmaceutical drug research and development environment outside the role of the study coordinator. There was a need for this qualitative study as there was a lack of knowledge and understanding of the role experiences and perceived impact of CRNs working as members of the multidisciplinary team conducting drug research and development other than the role of study coordinator. Through this study, the researcher added to nursing knowledge by offering a view of the role experience and perceived impact of the CRN who works within the multidisciplinary team at many points along the continuum of the pharmaceutical drug research and development process. Nursing practice and research benefited by being informed of the full spectrum of this non-traditional yet developing nursing role and its impact on pharmaceutical drug research and development. Through this study, the researcher increased awareness of the role of the CRN, and explored the variety of CRN roles. The researcher addressed how CRNs perceive their impact pharmaceutical drug research and development through actions such as ensuring patient safety, protecting clinical research subjects, or increasing research protocol adherence.

Summary

This qualitative study was conducted to describe the role experiences and perceived impact of the CRN (other than the study coordinator) who works within the pharmaceutical drug research and development environment and describe the ordinary conscious experience of the work life of the CRN. The findings of this study allowed for further insight into the relatively new nursing specialty of clinical research by providing experiences and perceptions of these nurses thus adding to the body of nursing knowledge. Through this study, the researcher raised awareness of the role of the CRN

and articulated the perceived impact of the CRN on pharmaceutical drug research and development. The study was done to articulate the impact that CRNs with their intimate knowledge of clinical research utilizing their nursing skills and knowledge have on public health and improved patient outcomes through their contributions as members of the multidisciplinary team discovering and developing new pharmaceutical products.

Chapter 2: Literature Review and Conceptual Framework

In recent years, the healthcare environment and the clinical research environment have increased in size, scope and complexity (Perrillo, 2001). It has also been a time of great discovery creating a demand for scientific discoveries that benefit the health of the public. The pharmaceutical industry seeks to fulfill this demand through the discovery of new drugs and treatments. Bringing new pharmaceutical drugs from discovery at the laboratory bench to clinical use at a patient's bedside requires sequential movement of the pharmaceutical product through a translational research process. This process is necessary to provide the strong scientific data required to establish a drug's safety and efficacy profile as well as to ensure an acceptable benefit to risk ratio. Throughout this translational research process, both interdisciplinary contribution and interdisciplinary collaboration are critical to bringing a drug to the public (Woods & Magyary, 2010). One of the disciplines that is involved in this process is nursing. The changes in the healthcare environment and the increased need for interdisciplinary collaboration in the drug development process have allowed for a new specialty in nursing to emerge, Clinical Research Nursing. As this nursing specialty is still evolving and defining itself, exploring the role experiences and perceived value of nurses working in positions supporting pharmaceutical drug research and development through all phases of clinical development will allow for better understanding of the role of the clinical research nurse (CRN). As the role of the study coordinator has previously been explored, the purpose of this study is to explore and describe the role experiences and perceived impact of the Clinical Research Nurse who works in a role other than study coordinator in the pharmaceutical drug research and development environment.

This chapter reviews the relevant literature addressing the nurse involved in the pharmaceutical drug research and development process. This literature review provides a synthesis of the current state of knowledge about the role of the CRN in this nontraditional nursing specialty thus providing a background for the further exploration of this subject. The review establishes the context for exploring how CRNs' describe their role experience and perceived value within the pharmaceutical industry's drug research and development environment. As the concept of role is multidimensional and may be viewed from multiple perspectives including the perspective of the role occupant, Role Theory is addressed in this chapter to provide a theoretical lens through which to view the CRN's perception of their atypical role (Conway, 1988).

Purpose of the Literature Review in Qualitative Inquiry

Nursing's unique body of knowledge and development of that knowledge defines nursing as a specialty within society (Chinn, 1995). As nursing research seeks to explore, examine, and answer questions of interest, epistemological approaches taken by researchers may vary to reflect the dynamic and changeable nature of knowledge. This epistemic diversity allows for different ways of knowing as nursing knowledge progresses and matures (Meleis, 2007). The present level or state of the scientific knowledge regarding the phenomenon of interest guides the epistemological approach (Meleis, 2007). A literature review is necessary to establish the current state of knowledge regarding a phenomenon thus providing rationale for further research. A literature review's synthesis of literature will also guide the researcher to the appropriate paradigm for further research.

Strauss and Corbin (1997) note that for qualitative researchers a literature review may inform the researcher on a research topic, help to formulate a research plan, and raise awareness of subtleties found in previous research. Creswell (2013) indicates the use of a literature review will help to frame the problem in context of what is known in the larger field of research surrounding the topic. Thus the present state of the literature surrounding the role of the clinical research nurse will be explored in this chapter to guide the research in this study.

Background of the Phenomenon

The phenomenon of interest in this study is the role experience and perceived impact of the CRN working within an environment supporting pharmaceutical industry drug research and development. As part of a multidisciplinary team nurses work in many capacities along the continuum of translational drug research and development. Many of these roles remain unknown to others. Even fellow nurses working at different places on the continuum of drug research and development are unaware of the contribution or role of nurses at other points in the drug discovery process. This researcher explored and described the role experience and perceived impact of these nurses other than study coordinators who work in this nontraditional nursing environment and answered the question “What are the role experiences and perceived impact of the CRN working in the pharmaceutical drug research and development environment in a role other than a research study coordinator?” It is important to the discipline of nursing to study this question in order to illuminate the role and impact of nursing as a member of the multidisciplinary team conducting pharmaceutical research and development.

Title of Clinical Research Nurse

Throughout the literature, neither the role nor the title of Clinical Research Nurse is standard. The National Council for the Professional Development of Nursing and Midwifery (2008) in Ireland in their *Report on the role of the nurse or midwife in medical-led clinical research* reported that job titles in the literature include: research nurse, research coordinator, ICU research coordinator, manager, officer, fellow, nurse, research practitioner, clinical trials nurse, research assistant, research sitter, clinical research nurse, and clinical trials with no consensus in the literature over the past 20 years. Bevans et al. (2011) suggests that there are two distinct roles and titles for nurses involved in the clinical research environment; the clinical research nurse and the clinical research coordinator. They state that the title CRN applied to the “staff nurse” or “clinical nurse” whereas the title of RNC (Research Nurse Coordinator) applied to the “study coordinator” or “clinical trials nurse” (Bevans et al., 2011). Offenhartz, McClary, and Hastings (2008) state that a CRN is also known as research nurse coordinator, study coordinator, research nurse, or clinical trials coordinator. Castro et al. (2011) reports that internationally CRN titles include research coordinator, clinical research coordinator, clinical trials nurse (CTN), or study coordinator. Bell (2009) reports that CRNs are also referred to as clinical research nurses, research coordinators, study coordinators or research assistants. With the lack of title consensus, it is difficult for other disciplines and other nurses to recognize the role of the CRN.

Just as the title clinical research nurse varies in the literature so does the definition of the CRN. Scott, White, Johnson, and Roydhouse (2011, p.1112) describe the CRN as “nurses who provide clinical expertise throughout the entire trial process, from initial

screening and consent to trial follow up and completion” while Green (2011, p.37) defines the CRN as a “generic title for nurses involved in clinical therapeutic trials.” Bell (2009, p.4) describes CRNs as “nurses employed to assist in the management and conduct of clinical trials and clinical research.” Gibbs and Lowton (2012, p.37) offer a broader definition of clinical research nursing stating this nursing specialty combines “the more familiar nursing responsibilities of holistic patient care with the world of clinical research protocols, governance and management.”

Additionally, the CRN is often confused with the nurse researcher although they are very different roles (Johnson & Stevenson, 2010). According to Johnson and Stevenson, the nurse researcher is an independent researcher leading nursing focused research who has been trained in the theoretical principles of nursing research, whereas a CRN is a nurse who undertakes work associated with the efficient and successful conduct of clinical trials. The skill set associated with each role is different although those in both roles develop considerable skills in the practice of research.

The lack of a consensus on a definitive title and definition for the role of the CRN adds to the confusion of defining who is a CRN. As the new specialty of clinical research nursing is evolving, there is a need for CRNs to establish a clear identity and position within nursing and within the clinical research environment (Bell, 2009; Raja-Jones, 2002; Stephens-Lloyd, 2004;). In this study, a clinical research nurse is defined as a registered nurse who is working in any role, in any environment along the pharmaceutical drug research and development continuum.

Both qualitative and quantitative empirical research on the role of the CRN other than the role of the study coordinator is limited. Literature addressing the CRN’s role

experience and perceived impact in roles spanning the continuum of the pharmaceutical drug research and development process is extremely limited. Hastings, Fisher, and McCabe (2012) regard clinical research nursing as a critical resource in the national research enterprise, stating that nurses have important roles across the knowledge creation and translation process from concept to dissemination of research. However, they state there is essentially no formal evaluation research that demonstrates the impact of nurses in a research setting on specific quality, safety or efficiency outcomes (Hastings et al, 2012).

CRN as a Nursing Specialty

The American Nurses Association (ANA) is a key professional organization representing the interests of the United States cohort of registered nurses. In 2002, the ANA defined nursing as “the pivotal health care profession, highly valued for its specialized knowledge, skill, and caring in improving the health status of the public and ensuring safe, effective, quality care” (ANA, 2010). Nursing’s single scope of practice encompasses a range of nursing activities (ANA, 2010). However, the ANA (2010, pg.15) goes on to state that the “depth and breadth to which individual nurses engage in the total scope of professional nursing practice is dependent on their education preparation and self-development their experience, their role, the setting, and the nature of the populations they serve.” This broad perspective allows for inclusion of nurses working in atypical roles such as drug research and development environment. Nurses work within the pharmaceutical drug research and development environment in many different roles as part of a multidisciplinary team working to bring safe and effective new treatments to patients thus improving the status of the public health. Although there is

literature about the role of the CRNs involvement in the conduct of clinical trials, there is surprisingly little empirical research on the topic of nursing's involvement throughout the entire continuum of drug research and development (Castro et al., 2011). The majority of the published literature contains anecdotal reports and opinion based commentaries discussing nurses' involvement in clinical research and the tasks they perform (Johnson & Stevenson, 2010). (See table 1)

Table 1 Overview of Published Literature

| Year | Author | Title |
|------|---|---|
| 1988 | Cowley, S., Somelofski, C., Hill, M., Smith, J., & Buchwald, H. | Nursing and cardiovascular clinical trial research: Collaboration for successful outcomes |
| 1994 | Arrigo, C., Gall, H., DeLongne, A., & Molin, C. | The involvement of nurses in clinical trials |
| 1997 | Raybuck, J. | The clinical nurse specialist as research coordinator in clinical drug trials |
| 1999 | Sadler, G., Lantz, J. Fullerton, J., & Dault, Y. | Nurse' unique roles in randomized clinical trials |
| 2001 | Joshi, T., & Ehrenberger, J. | Cancer clinical trials in the new millennium: Novel challenges and opportunities for oncology nursing |
| 2002 | Barrett, R. | A Nurse's primer on recruiting participants for clinical trials |
| 2003 | Rath, L., Hitchcock, A., Oakley, M., & Graham, J. | Clinical drug trials and the role of the nurse |
| 2004 | Stephens-Lloyd, A. | The extended role of the clinical research nurse: Building an evidence base for practice |
| 2008 | Chatfield | Role of the specialized neuro intensive care nurse in neuroscience research |
| 2009 | Bell, J. | Towards clarification of the role of research nurses in New Zealand: A literature review |
| 2009 | Grady, C., & Edgerly, M. | Science, Technology, and Innovation: Nursing responsibilities in clinical research |
| 2010 | Poston, R. & Buescher, C. | The Essential role of the clinical research nurse |
| 2011 | Green, L. | Explaining the role of the nurse in clinical trials |
| 2011 | Hosie, A. et al | Palliative care clinical trials: How nurses are contributing to integrated, evidence-based care |
| 2012 | Catania, C. | Clinical trial nurse's role in safety reporting |
| 2012 | Gibbs, C. & Lowton, K. | The role of the clinical research nurse |
| 2013 | Barlow, C. & Farrar, H. | The role of the clinical trial nurse in Oklahoma |

| | | |
|------|----------------------------|---|
| 2013 | Hemingway, B. & Storey, C. | Role of the clinical research nurse in tissue viability |
|------|----------------------------|---|

There is scant empirical evidence reflecting the CRN's contribution to the drug development process other than in the role of the study coordinator (Rickard & Roberts, 2008). Despite the amount of anecdotal literature, the role of the CRN is often hidden and invisible, remaining unknown and not well understood by other healthcare workers, even those in the nursing profession or those involved within the clinical research environment (Gwede, Johnson, Roberts, & Cantor, 2005). How CRNs use their specialized nursing skills, knowledge and professional judgment in the specific domain of pharmaceutical drug research and development remains unclear. The impact of specialized nursing skills on outcomes specific to the domain of clinical research is also not well defined or documented in the literature.

The ANA facilitates the development of the standards of nursing practice and aids in the development of specialty nursing groups to facilitate focused continuing education and professional resources. The ANA has defined criteria for recognition of a nursing specialty in its document *Recognition of a nursing specialty, approval of a specialty nursing scope of practice statement and acknowledgment of specialty nursing standards of practice* (ANA, 2010). Currently, there is no ANA accredited nursing specialty established for clinical research nursing. However, Hastings, Fisher, and McCabe (2012, p156) have made recommendations for the development of a specialty of clinical research nursing, stating "Clinical research nurses have a unique skill set and knowledge base that positions them to make significant and essential contributions to the clinical research enterprise."

Role Competencies and Domains of Practice

The role of the nurse with specialized clinical research skills is best documented and described within the specialty of oncology (Bevans et al., 2011; Lubejko et al., 2011). Oncology research nurses have become a vital part of the cancer research team over the past few decades with increasing efforts to document their contributions in this therapeutic area (Larkin et al., 2012; Lubejko et al., 2011; Ocker and Plank, 2000, ONS, 2010). The Oncology Nursing Society (ONS) (2010, p.5) defines the CRN as the “specialty nursing role requiring a unique framework of knowledge for working with patients involved in clinical research trials” and believes that coordination of clinical trials is best performed by Registered Nurses who are educated in oncology and research.

In 2010, The ONS published the Oncology Clinical Trials Nurse Competencies. This document states the core values of the CRN role include: advocate for patient safety and trial integrity, advance evidence based oncology care through scientifically sound research, and recognize the unique value that professional nurse contribute to the successful conduct and outcome of clinical trials. The nine functional competencies were: protocol compliance, clinical trials related communication, informed consent process, management of clinical trial patients, documentation, patient recruitment, ethical issues, financial implications and professional development. These competencies were accompanied by 54 competency statements within the functional areas. The ONS developed these core competencies in response to requests from ONS members for a comprehensive curriculum on clinical trials and standardization of role expectations (Lubejko et al., 2011).

An NIH publication, *Building the foundation for clinical research nursing* articulated the important role CRNs play in “assuring participant safety, integrity of protocol data and ongoing maintenance of informed consent, all within the context of effective and appropriate clinical care” (CRN, 2010¹, p. 2). A project in 2007 at The National Institute of Health Clinical Center sought to define a Domain of Practice for the specialty of clinical research nursing (CRN, 2010²). The first step in this process was to develop a taxonomy in order to classify concepts and roles within the specialty domain of practice. A team of nurses with experience in clinical research who actively provided or supervised clinical research care identified three levels within this taxonomy. The broadest level was the domain titled “clinical research nursing.” This domain was intended to represent the full spectrum of nursing practice in the clinical research setting. Through literature review, academic curricula, professional guidelines, position descriptions and expert opinion, the team identified five dimensions within the clinical research nursing domain of practice: clinical practice, study management, care coordination and continuity, human subjects protection, and contributing to the science. They also identified 49 unique activities performed by research nurses each of which were placed into a specific dimension (Castro et al, 2011). Although the authors state the expert team had research experience, a thorough explanation of the qualifications or the clinical research roles of the team performing the taxonomy was not provided.

The second step in the process of defining a domain of practice for the specialty of clinical research nursing was to validate the proposed taxonomy using a Delphi approach. The Delphi method included the use of three sequential surveys in an iterative process collected over 5 months to gain consensus on the dimensions and activities of

clinical research nurses in this study. The sample for this study was a purposefully selected panel of 30 expert nurses. The definition for expert nurse in this study was broad. This allowed for a heterogeneous sample of nurses who had at least two years of active experience in the clinical research environment in the United States. Therapeutic areas included pediatrics, gerontology, and oncology. The study did not indicate the work environment such as academic medical center, government institution, or private employer. Nor did it indicate the role of the expert nurses. Therefore it is not known if nurses who worked in the pharmaceutical drug research environment were included as nurse experts. This study concluded that the specialty of clinical research nursing competences included both care provided to research participants as well as activities that support protocol implementation, data collection, and human research protection (Castro et al, 2011).

Bevans et al (2011) conducted a web based survey of 412 nurses working in clinical research at the NIH intramural campus. This role delineation study described the frequency and importance of activities within each of the dimensions of the clinical research nursing domain and confirmed there were two research nursing roles, CRN and research nurse coordinator (RNC), within the nursing model of care used at the NIH Clinical Center. The instrument used in this study, the “CRN role delineation measure,” was based on the previously validated survey articulating the clinical research nursing domains of practice and demonstrated robust reliability for ratings of frequency and importance of activities performed (Bevans et al, 2011). The most frequently performed and most important activities were providing direct care to research participants and monitoring for potential adverse events in research participants. This study found that

research nursing activities are multidimensional, span clinical specialties, and make important contributions to research integrity, patient care, care coordination and human subjects' protection. The study sample only included nurses working at the NIH clinical Center, therefore the findings may not be transferable to other research settings.

The NIH Clinical Center Model of Care defined the CRN as a “clinical research nurse with expertise in clinical research implementation who practices in a specific clinical care area” while the RNC was defined as an “experienced clinical research nurse who assumes responsibility as the nursing specialty team leader for a group of research participants based on a set of related protocols within a patient care unit or ambulatory program” (CRN, 2010¹, p.3). Both of these roles share common expertise and competencies but allow for different areas of emphasis.

In the United Kingdom, the National Health Service (NHS, 2011) developed a competency framework for CRN which offered clearly defined competencies linked to their research roles for nurses. They define a CRN as “any nurse employed principally to undertake research within the clinical environment” (NHS, 2011, p.9). CRN competencies included: 1) to demonstrate understanding of the historical background, political influence and strategy regarding clinical research in the UK 2) to work within the regulation framework including understanding the role and remit of research ethics committees in the UK, and contributing to the preparation of submissions for regulatory reviews, 3) to understand, apply and promote the principles and practice of obtaining and maintaining valid informed consent, and 4) to apply professional knowledge and skills to facilitate efficient, safe and participants focused clinical research including contributing to the development and facilitation of clinical research, contributing to effective and

efficient use of resources, facilitating the delivery of clinical research, and contributing to the safe collection and storage of data and accurate completion of study documentation. The report does not specify the methodology used to arrive at the competencies only that they were authored by a Competency Working Group.

In 2008, the Irish National Council for the Professional Development of Nursing and Midwifery presented a Report on the Role of the Nurse or Midwife in Medical-led Clinical Research (National Council for the Professional Development of Nursing and Midwifery, 2008). This report was issued in response to an Irish governmental policy seeking to provide patients access to cutting-edge treatments for their conditions. This included creating an environment in which research could thrive. The report acknowledges that central to the success of clinical research is the role of the research nurse or midwife. The CRN was defined as “nurses or midwives involved in research for purposes other than nursing or midwifery” (National Council for the Professional Development of Nursing and Midwifery, 2008, p.6). The first part of this project was a literature review of the international experiences of nurses’ and midwives’ role in medical clinical trials. The second part was research site visits and the third part was comprised of interviews with research nurses. The interview portion of the project included a sample size of 41 which included interviews with 13 individuals and eight groups of nurses and midwives whose primary role was defined as being in medical led clinical research. Participants for the interviews were obtained through snowball sampling. Content analysis revealed regular hours, autonomy, respect and being part of cutting edge of science as attractions to the role of research nurse. The researchers report that much role diversity exists. The most common activities cited by the research nurses

were patient identification recruitment, eligibility screening, interpreting for consent, performing an intervention or organizing the monitoring and collecting of data per the protocol and educating others about the trial. Patient information was deemed to be the “bedrock of it all” (National Council for the Professional Development of Nursing and Midwifery, 2008, p.31). The qualitative study within this report addressed tasks performed by CRNs but the sample is limited to research centers within Ireland.

Although CRNs have demonstrated unique skills and knowledge that allows them to make significant and essential contributions to the clinical research enterprise, the specialty of clinical research nursing remains largely undefined and unrecognized.

Professional Associations

As CRNs seek to establish a nursing specialty creating a professional identity is critical. In 2009, the first professional association for research nurses, the International Association of Clinical Research Nurses (IACRN) was founded. This organization’s mission is to “define, validate and advance clinical research nursing as a specialty practice and to support the professional development of registered nurses who directly or indirectly impact the care of clinical research participants” (IACRN, 2012 home page). The IACRN (2012, scopes and standards committee page) defines clinical research nursing as “the specialized practice of professional nursing focused on maintaining equilibrium between care of the research participant and fidelity to the research protocol.” According to the IACRN the process of clinical research nursing includes: providing and coordinating clinical care in the context of a research study, assuring participant safety, maintaining ongoing informed consent, managing protocol implementation, and assuring accuracy of data collection and recording.

Professional non-nursing organizations such as the Association of Clinical Research Practitioners (ACRP, 2003), the Society of Clinical Research Associates (SoCRA, 2014) and Drug Information Association (DIA, 2014) represent research professionals belonging to many disciplines. These organizations represent all persons engaged in the research community and do not specifically define a role for the Clinical Research Nurse although many nurses are among their members.

Drug Research and Development

In order to fully understand the roles that nurses assume in the drug research and development process, a review of this process is included in this literature review. The ultimate goal of the pharmaceutical development process is to universally improve the standard of public health by providing proven drug therapies for the prevention and treatment of illness (Linberg, 1999). Drug development is a complicated, costly and time consuming process occurring along a continuum starting with a molecule on the scientist's bench progressing to integration in medical practice (Linberg, 1999). At all points along this continuum, newly discovered drugs and treatments need to be evaluated for safety and efficacy with those having a proven positive benefit: risk ratio being quickly brought to clinical setting (Tolme, Munhall, Loudon, Lindsar, & Gaw, 2004). According to Linberg (1999), major factors to be considered during drug research and development are safety, efficacy, cost, and time. The increasing complexity of the science underlying drug development as well as increased regulatory requirements has increased the cost and length of time it takes to bring a drug to market (Levine, 2012). Levine (2012) reports that only 10% (1/10) chosen for market will be a clinical success. . With each new drug bearing a high cost of development in both time and money, it is key to

have all persons who work anywhere along the drug research and development continuum trained and qualified to perform their job in a timely and cost effective manner. Multidisciplinary team members may work within one of many groups or departments that contribute at some point along the drug discovery and development continuum. These groups may include private or public funding organizations, government agencies, academic medical centers, investigative research sites, pharmaceutical and biotechnology companies, device manufacturers, research organizations, clinical research teams (investigators, nurse coordinators and clinical data managers), regulatory agencies, institutional review boards, or payers and purchasers of the pharmaceutical drug (Ness, Parreco, Galassi, and O'Mara, 2012). CRNs may be a member of any of these groups.

There are three major phases in the drug development process: pre-clinical, clinical, and post marketing (Mathieu, 2005; Tonkens, 2005). The pre-clinical phase includes drug discovery or bench science and animal testing. It is here that molecular targets are identified, assays are developed and compounds are invented or discovered. Scientists may look at thousands of new molecular entities to identify one promising target compound (Ehrenberger and Joshi, 2003). The chemical makeup, the stability and the solubility of the compound must be established during this stage. During this preclinical stage laboratory and animal testing is performed to test the kinetics, toxicity and carcinogenicity of the drug (Tonkens, 2005). It is in this stage that bench scientists collect data through both *in vitro* and *in vivo* testing which will provide essential information prior to human testing (Mathieu, 2005). In the pre-clinical phase there is a

limited role for CRNs. However, knowledge and understanding of pre-clinical studies and their potential clinical application is important for CRNs (Hastings, 2012).

At this point in the drug development process, a sponsor decides if the drug should be developed further based on pre-clinical results, scientific rationale, clinical need and economics (Greener, 2010). Of every twelve compounds that enter preclinical development only five will enter clinical development (Greener, 2010). If a drug shows promise in the pre-clinical stage, a clinical development plan with very clear goals is then created and submitted to regulatory authorities (Lawry, 1999). In the United States this regulatory authority is the Food and Drug Administration (FDA). Regulatory approval ensures an adequate drug development program is in place prior to human testing (Linberg, 1999; Tokens, 2005). Additionally, local ethics committees must grant permission prior to initiation of any clinical trial to ensure the study is ethical and that the rights of study participants are protected (Mahendra and Bisht, 2011). Nurses may have roles within the regulatory environment or the ethical oversight environment such as regulatory liaison, product labeling, or IRB manager. Following regulatory approval, a drug enters the second stage of the drug development process which is clinical research.

Clinical research is the essential link between basic science and medical therapy as drugs are brought from molecule to clinical practice. Clinical research is defined by the National Institutes of Health as a biomedical or behavioral research study of human subjects designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices) (Office of Extramural Research, n.d.). The NIH also defines clinical research as “research that directly involves a particular person or group of people, or that uses

materials from humans, such as the behavior of samples of their tissue” (NIH, 2012, “Clinical Trials & Clinical Research,” para. 1).

This stage of drug development encompasses the time from the beginning of human trials until a regulatory marketing application is complete. It is the most costly, time consuming and critical part of the drug development process (Tonkens, 2005). Clinical research for a product often lasts from two to ten years (Mathieu, 2005, Linberg, 1999). As far back as the 1920’s randomized, controlled trials were used and are still considered to be the “gold standard” for the evaluation of clinical outcomes (Sadler, Lantz, Fullerton, & Dault, 1999).

Clinical trials ensure that a drug or therapy acts as anticipated and that all side effects and positive benefits are closely monitored and recorded, thus providing the empirical evidence for new or existing treatments that may be used in clinical practice to improve the quality of health for many populations. CRNs often contribute to clinical study design defining what safety and efficacy data is to be collected to define the benefit: risk ratio of a pharmaceutical product. Data obtained from these studies is critical as it is the basis for approval allowing a drug to be marketed. CRNs are involved in many aspects of clinical trial data collection and evaluation. Continual monitoring of the safety and efficacy of investigational products is of utmost importance throughout the clinical research process. The knowledge obtained from clinical trials allows for the translation of scientific discovery and technical advancement into improved treatment or procedures that offer the prospect of a better life for patients. There are strict requirements for standardization, consistency, and compliance of clinical research. In the United States, the conduct of clinical trials is regulated according to the Code of Federal Regulations

(CFR). The CFR mandates standards for the conduct of all clinical research regulated by the FDA in the United States. Additionally, there are national and international non-binding guidelines for the conduct of clinical research called Good Clinical Practice (GCP) guidelines. These guidelines are ethical and scientific quality standards for the design, conduct, recording and reporting of clinical trials that involve human subjects (FDA, 2014). Adherence to GCP guidelines ensures that clinical trials are credible and that the rights, safety, and well-being of human subjects are protected (Howland, 2008). Compliance with the CFR and GCP provides the public with assurances that clinical trial data is credible. In keeping with these standards, the US Federal Drug Administration (FDA) routinely issues guidance on conducting clinical research which reflect the Agency's current thinking on good clinical practice (GCP) and the conduct of clinical trials. Knowledge of the regulations and guidance are key to ensuring the proper conduct of clinical trials.

Clinical trials are commonly classified into phases according to the drug's stage of development (Piantadosi, 2005). Phases 0 through phase 3 studies are part of the clinical test stage while phase 4 studies are completed following marketing approval. A phase 0 clinical trial is a newer designation for a first in human study which is designed using micro dosing to verify that a drug behaves in human subjects as was anticipated from preclinical studies (FDA, 2006). Phase 0 studies provide no safety or efficacy data but do provide data which may be used in deciding if a drug will progress further in the development process. Phase 1 studies are first in human studies which normally involve a small (10 – 80) group of healthy volunteers to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of a drug (Mahendra and Bisht, 2011;

Tonkens, 2005). These trials often take place in small specialized inpatient units where patients can be closely observed.

Phase 2 clinical trials usually involve a larger (100 – 300) group of patients who have the disease under study to assess the efficacy of the drug as well as optimal dosing and continued safety monitoring (Ehrenberger and Joshi, 2003, Mahendra and Bisht, 2011). Phase 3 clinical trials are usually randomized controlled multicentered trials in large groups (300 – 3,000 or more) of patients. These trials address the overall benefit: risk relationship of the drug as well as assessing adverse events in a larger group of patients over a longer period of exposure (Friedman, Furberg and DeMets, 2010). Trials in this phase confirm the safety and efficacy of the drug for the indication proposed and are often referred to as “pivotal trial(s)” because the study results will determine if a company moves forward with a regulatory submission to market the drug (Ehrenberger and Joshi, 2003). It is after pivotal trials prove the safety and efficacy of a drug that companies submit to the regulatory authorities for approval (Mathieu, 2005; Tonkens, 2005).

Phase 4 in drug development is the post marketing phase. Following marketing approval, comparative effectiveness research and community based research continues as treatment with a new drug is integrated into widespread clinical practice (Friedman, Furberg and DeMets, 2010). Additionally, this stage of drug development may include phase 4 studies which supplement earlier trials by providing additional safety data in a larger population for a longer period of time and are frequently referred to as post marketing surveillance trials. Phase 4 trials may also be completed by companies to find

a new market for a drug, to test for interactions with other drugs used in the general population, or to detect any rare or long-term adverse effects (Mahendra & Bisht, 2011).

According to Hastings (2012), CRNs play a critical role during all phases of clinical trials being responsible for among other things: subject recruitment, study management, regulatory compliance, administration of study intervention and monitoring, assessment of adverse effects, sample collection and processing, management of research data and subject education.

Pharmacovigilance which includes identifying and evaluating safety signals for a marketed drug continues long after a drug is marketed (FDA, 2005). This continuous safety surveillance requires the expertise of health professionals including nurses to constantly review data to detect any new safety data which may change the benefit: risk ratio of a drug. Additionally, regulatory scrutiny of a drug continues after marketing approval as most countries require periodic safety reports to be filed as long as the drug is marketed (Tonkens, 2005). Pharmaceutical scientists including physicians and nurses provide this continued drug safety monitoring by investigating adverse event frequencies in the population after a drug has been given to many patients in the community (Gabbay, 2003). Post marketing pharmacovigilance includes the collection, detection, monitoring, and assessment of adverse events as well as unintended lack of efficacy in a broader population. As clinical trials only allow exposure of a new drug or treatment exposure to a narrowly defined population, post marketing surveillance allows for detection of adverse drug reactions in the larger population through pharmacovigilance and possible continuing safety and efficacy studies. Continual post marketing surveillance ensures the benefit: risk ratio of a new drug remains satisfactory.

Assimilating a new drug into practice involves education and support for healthcare providers who will be providing the new drug to patients. Medical affairs professionals provide the medical and clinical expertise needed to disperse educational and scientific communication regarding new drugs to the medical community. Nurses often assume roles of medical science liaisons, nurse educators, or marketing representatives following regulatory approval. There is no literature addressing nurses in this role.

The journey of an investigational product through the clinical research process from preclinical through market approval to integration in clinical practice requires the knowledge and skill of a multidisciplinary team of researchers. The literature clearly and repeatedly states that nurses are an integral part of the interdisciplinary team conducting clinical trials (Davis et al., 2002; Poston and Buescher, 2010; Spilsbury et al., 2008; Xanthos, Carp, and Geromanos, 1998). Mueller (2001) states that historically nurse have been a part of the research process but mainly in the role of coordinating and implementing clinical trials. According to Hastings (2012), CRNs are intricately involved in all aspects of clinical research from management and planning to evaluation of current practice to assess relevance of the new treatment.

Throughout the process of drug research and development there are many roles which nurses currently fulfill. However, the empirical literature documenting the impact of having a nurse with a specific knowledge base fill these roles remains limited, identifying a need for further exploration of nursing's experience, role and perceived impact within the pharmaceutical drug research and development process.

Review of Empirical Literature

The CRN is able to integrate nursing knowledge and skills into the clinical research process allowing them to be a crucial member of the multi-disciplinary research team contributing to the pharmaceutical drug research and development process (Nagel, Gender, & Bonner, 2010; Poston & Buescher, 2010). A review of literature from 1994 to 2015 was performed using the search terms: Pharmaceutical Nurse or Clinical Research Nurse and Drug development or Drug research. Databases searched included the Nursing databases: CINAHL with Full Text, Health Source, MEDLINE, Nursing & Allied Health Collection: Comprehensive, PubMed, BIOSIS Previews, Biomedical Reference Collection: Comprehensive, and Healthstar (Ovid). Additional databases searched included the Pharmaceutical Sciences databases: The Cochrane Library, International Pharmaceutical Abstracts, MEDLINE, PubMed, Biomedical Reference Collection: Comprehensive, Industrial and Applied Microbiology Abstracts (Microbiology A), Toxicology Abstracts, TOXLINE, and ScienceDirect. Additionally, the database Web of Science (Arts & Humanities, Social Sciences and Science Citation Indexes) was searched using the above terms. Each article identified in this search was reviewed for relevance to the phenomenon of interest in this study. References from the articles were also reviewed to identify any additional studies. There were limited empirical research studies and a plethora of nonempirical literature identified which focused on the role of the nurse working in the pharmaceutical drug research and development environment. An additional search of the dissertation database identified two doctoral dissertations which focused on nurses working within the pharmaceutical drug research and development environment.

Study Coordinator Role

The empirical evidence regarding the role of the CRN presented in literature almost exclusively looks at nurses employed as study coordinators at investigative sites who assist in conducting clinical trials for pharmaceutical drug research and development. (Davis, Hull, Grady, Wilfond and Henderson, 2002; Fisher, 2006; Gwede, Johnson, Roberts & Cantor, 2005; Hill & MacArthur, 2006; Instone, Mueller & Gilbert, 2008; Isaacman & Reynolds, 1996; Mueller, 2001; Roberts, Rickared, Foote & McGrail, 2006; Spilsbury, 2008; Xanthos, Carp, & Geromanos, 1998). The role of study coordinator is only one of many roles in which a CRN may be employed throughout the continuum of the drug research and development process. However, the vast majority of studies as described below explore only the study coordinator role.

Qualitative Research on Study Coordinator Role

Mueller (2001) examined the role of nurses working as study coordinators in clinical research. She used convenience, snowball sampling to recruit participants for two qualitative, interview studies with nurse coordinators looking at the role, their work and their career trajectories. A total of 38 nurse trial coordinators were interviewed with data presented from 32 due to the loss of audio tapes for six participants. These nurses were employed in one of four hospital-based medical centers. None of the participants had received formal education on clinical trials prior to the present position but rather learned on the job. Themes emerging from this study were: development of occupational processes with the creation of role boundaries and definition including workplace assimilation of skills and knowledge by nurses, the strategic interactional involvement of nurses with others on the clinical research team, and the need to formalize the nurse's

role through specialty training. The author describes how CRNs address clinical issues that may arise with participants in clinical research by conferring with the physician principal investigator of the study or with the sponsoring organizations physician. CRNs in this study described how they address ethical issues that occur while coordinating clinical trials with many stating they see their role as a patient advocate. The CRN's attributed their ability to apply the principle of patient advocacy and provide patient education to study subjects to their training and experience in nursing. The author in this study does neither address data saturation nor investigator bias. The methodology does not qualify if the interviews were structured, semi structured or open. This information is critical for the reader to understand the robustness of the data. This study is limited to nurses who work as study coordinators implementing a predefined study protocol and does not address nurses who work in other areas of clinical research.

Davis, Hull, Grady, Wilfond and Henderson (2002) examined the role of the study coordinator as it relates to human subjects protection using structured, vignette based focus groups (n=45), 68% of participants had nursing backgrounds. Other backgrounds of study coordinators included: social work, genetic counseling, general baccalaureate, and public health. Data was appropriately reduced using and iterative qualitative process. Analysis showed that study coordinators hold a central position in the conduct of clinical trials dealing with complex relationships, role expectations, and a potential for role conflict. This qualitative study noted that clinical research was a good job for nurses as nurses possess hands on skills, clinical expertise and psycho social skills all of which may be used in coordinating a clinical study. However it was also noted by the non-nurse participants in this study that at times it was hard for nurses to deviate from

standard of care and get in the “research mode” (Davis et al, 2002 p.414). The focus groups identified three critical roles of a study coordinator: patient advocacy, study participant advocacy, and study advocacy. Balancing of these three advocacy roles was found to be difficult by the study coordinators and had the potential to lead to role conflict. The authors concluded that in balancing these three advocacies the study coordinator was uniquely placed to further the goals of human subjects protection. This study did not address data saturation and was limited to coordinators not all of whom were nurses. Using vignette based focus groups methodology limited the data received in this study as participants may not have provided robust descriptions of their roles. This study did not examine any CRN roles outside of study coordinating.

Roberts, Rickared, Foote and McGrail (2006) sought the perspective of CRNs regarding the best and worst aspects of the research coordinator role. They conducted a cross-sectional web-based cohort study collecting free text information from research coordinators working in ICUs in Australia and New Zealand. A questionnaire was used to collect demographic information, identification of roles and responsibilities using predetermined categories, followed by open ended descriptions of the best and worst aspects of the role. The sample for this study was recruited from members of the ICU Research Coordinators Interest Group (IRCIG) with a response rate of 71% resulting in 49 participants. Of the participants 94% had a nursing background. This was a very limited and narrowly defined sample as it only included study coordinators who work in the specialty of intensive care in two countries. Four themes emerged from the free text data: the job is structured, the worth of the job, what the work involves and who I work with. When describing the worth of the role, responses such as making a difference,

getting respect and being part of the team were obtained. The best aspects of the study coordinator role included: autonomy, flexible hours, developing the role to what I wanted to be, and lack of work politics. The worst aspects of the role included the amount of on-call hours, pay and isolation. When describing the worth of the role from a negative perspective, responses such as feeling undervalued, no one knows what you do, no one knows how hard you worked to achieve things, lack of recognition and understanding from senior nursing management were described. This study also only focused on the role of study coordinator who coordinates a clinical trial which is only one aspect of drug research and development. It was also interesting to note in this study that CRNs perceived a lack of recognition from nursing colleagues.

In 2011 the above study was repeated to evaluate changes in the perceived positive and negative aspects of the ICU research study coordinator role in Australia and New Zealand using a multi-choice questionnaire modified from the previously used questionnaire (Roberts, Eastwood, Raunow, Howe and Rickard, 2011). Again no validity or reliability was reported for this questionnaire. Sample for this study were 56 of the 104 members of the IRCIG (54% response rate). The study did not identify the professional background of the participants. Results identified three themes: work condition, work environment and work role. Best aspects of the job identified were autonomy, variability, making a difference and intellectual stimulation. Lack of support for recognition in general, from doctors, and from fellow nurses accounted for the majority of the reported worst aspects related to the research coordinator role. One other negative aspect of the role was addressing requirements from the pharmaceutical industry that required tedious data collection.

Fisher (2006) conducted an ethnographic study to examine the everyday work lives of those working in the clinical trials industry focusing on the ethical conflicts embedded in clinical trials. Semi structured interviews were conducted with 57 participants at 20 investigative sites and included physicians, coordinators, administrators and patient subjects. Reported in this article is a subpart of that research which looked at the role of the study coordinator. The sample size for this portion of the study was 18 study coordinators and 3 recruiters who had previously been employed as study coordinators. Of these 21 participants, 10 were nurses, one was a physician assistant, and the background of the remaining 10 was not reported. The study found that job descriptions for study coordinators vary widely yet some of the common tasks include recruitment, screening, enrolling subjects into clinical trials. Another aspect of a coordinators role is study maintenance ensuring specific details of all studies are being completed according to the protocol and on schedule. Study coordinators emphasized the need for strong interpersonal skills as the establishment of trust with study participants is essential to the successful conduct of clinical trial. Nurse Coordinators expressed that their nursing expertise is often ignored as it is not seen as required for coordination of the study. Coordinators also felt they were vital in protecting patient's autonomy through the use of formal measures such as informed consent but also informally through talking as part of ongoing informed consent. The researchers noted that coordinators constructed professional identities with an altruistic mission. However, they often experience role conflict between research and patient care. Limitations of this study include the fact that it only investigates the role of the study coordinator and ethics in the drug development process.

In 2008, Instone, Mueller and Gilbert conducted a 17 month ethnographic field study at one large medical center to examine the process of informed consent in enrollment into pharmaceutical industry sponsored phase 1, 2, and 3 hepatitis C clinical trials. Data collection involved observation, interviews, and document review. The first phase of the study focused on observation of clinical trial activities and informed consent procedures. A more focused approach was then used to prospectively follow a cohort of 25 participants who enrolled in the hepatitis C clinical trials and cohort of 19 professional participants who were involved in overseeing the protocol related care. This study described the social organization of conducting clinical trials at this institution. Research nurses were responsible for the process of screening obtaining informed consent administering investigational drugs and managing researching clinical care throughout the course of the trials. The physicians oversaw the review of the research protocols and informed consent documents and were consulted if patients developed complications or if invasive procedures were required. Other research personnel serve to support staff of nurses and doctors. This study also identified therapeutic misconception among study participants where patients confused research with treatment. Research personnel also at times viewed clinical studies as offering treatment or treatment benefit which may have contributed to patients' therapeutic misconception. This study identifies role conflict in research coordinators as at times posing an ethical dilemma as they strive to define the boundaries between practice and research.

Quantitative Research on the Study Coordinator Role

In 1996, Isaacman and Reynolds completed a study testing the effects of the addition of a research nurse on study recruitment and the consent process for an ongoing

study of blood culture collection strategies. Successful enrollment of eligible study patients increase 36% in one year with the addition of the research nurse (year one enrollment 14% (40/281) and year two enrollment 50% (126/253)($p = 0.001$)). The study also demonstrated equivalent judgment regarding patient eligibility for the study between the research nurse and primary investigator with a 97.5 % inter-rater agreement. The authors of this study concluded that increased enrollment was due to an increase in the rate of identification of eligible patients by the nurse. The authors did not acknowledge increase in personnel alone may have accounted for the increase in enrollment.

Gwede. Johnson, Roberts and Cantor (2005) examined burnout in clinical research study coordinators in the United States. Participants were members of either the radiation therapy oncology group or society of clinical research professionals. A total of 252 participants were included in the analysis, 45% self-identified as nurses. The Maslach Burnout Inventory (MBI), a 22 item questionnaire which measures emotional exhaustion, depersonalization, and personal accomplishment was used to measure burnout. The Professional Satisfaction Questionnaire (PSQ) was adapted for this study to explore satisfaction with job responsibilities, relationships with patients, physicians, and other staff, control over and importance of job and emotional stress. Reported reliability and validity of these scales were acceptable. This study revealed 69% of study coordinators were satisfied with their jobs and 94% felt strongly that their jobs were important. This study also showed that study coordinators reported similar levels of burnout when compared with other healthcare workers with the exception of depersonalization which indicated lower levels of this aspect of burnout. Satisfaction with their job was strongly correlated with the level of emotional exhaustion burnout ($r = 0.60$,

$p < 0.0001$) and moderately with personal accomplishment burnout ($r = -0.36$, $p < 0.0001$). The authors conclude that job dissatisfaction and burnout in study coordinators needs to be studied further as these factors may impact the financial, data quality, and psychological aspects of clinical trial management. This study is limited in that it only looks at study coordinators who belong to one of two organizations conducting clinical trials. Additionally, not all participants were nurses thus limiting the relevance to the study of CRNs.

Eastwood, Roberts, Williams and Rickard (2013) completed a descriptive, exploratory study examining the self-reported role tasks, skills, job satisfaction, professional development and best and worst aspects of the research study coordinator role in the critical care settings in countries outside of Australia and New Zealand. An internet survey consisting of four parts with 27 questions was used. The literature did not clearly define survey development, validity, or reliability for this instrument. Snowball sampling methodology was used with participants responding to the distribution of the survey to the Regional Coordinators of critical care nursing organization affiliated with the World Federation of Critical Care Nursing. Results report 80 respondents from various undefined locations which were then grouped into North America, Europe and Latin America. Although the survey was distributed to other continents such as Asia and Africa there was no mention of the response rate from these places. The authors also identified that there was the possibility that nurses not working in critical care or whose role was not primarily research based completed the survey due to the snowball recruitment method used. Reported results indicate that the top three tasks performed by the research study coordinator were: data collection (92%), obtaining consent (90%) and

patient screening for study eligibility (64%). The top skills required were reported to be: clinical research knowledge (97%), creative problem solving (97%), ability to identify ethical questions, concerns or situations (94%) and objectivity (94%). Results indicated that there were many similarities but also differences in the role according to region. This study has limited use due to the sampling methodology that may have allowed for non-research nurses to complete the study.

Development of Measurement Tools for the Study Coordinator Role

As clinical research nursing moves forward with an agenda to further define this nursing specialty, tools and methods have been developed to provide quantitative evidence of the need for this specialty. In 2004, Ehrenberger and Lillington (2004) developed the Clinical Trial Nursing Questionnaire (CTNQ) to identify the significant dimensions of the clinical trials nursing role and to construct a reliable and valid survey instrument to reflect these dimensions. This tool was used to measure the frequency and importance of clinical trials nursing activities so as to better understand how CRNs contribute to oncology clinical research (Ehrenberger & Lillington, 2004).

Mori, Mullen and Hill (2007) used the 154-item CTNQ at 26 General Clinical Research Centers (GCRC) in the Western United States to describe the role of the CRN as a basis for developing a CRN professional organization and for the ANCC certification program. This tool assesses the activities, responsibilities, perceptions and experiences of the CRN including stress, job satisfaction, ability to communicate effectively with colleagues, perceived competency, level of education, professional associations, work setting, position title, and opportunities for advancement. Validity of this tool was established using a six-member expert panel and reliability was established with a test

retest reliability of 0.88 for the scale measuring frequency of activities and 0.92 for the scale measuring perceived importance of activities. Frequency responses ranged from “never” to “extremely frequent” on a five-point scale. A convenience sample was used for this study with 154 surveys distributed with 109 responses (71%). This sample size of 109 was too small to determine validity and reliability for this 154-item tool. The authors did not state if factor analysis was done in this study. Almost all tasks listed on the survey were considered important by study coordinators suggesting CRNs understand the components necessary for successful study conduct. The majority of respondents experienced acceptance/support by non-research nurses (66%), physicians (85%), and administrative staff (83%). Work-related stress was experienced by 67%, autonomy by 79%, and job satisfaction by 82%. This study is limited as the surveys were completed by coordinators working in a specific clinical research environment and may not be applicable to CRN’s working at other points along the continuum of pharmaceutical drug research and develop.

This tool has also been used to examine the role and responsibilities of CRNs working in clinical research in Italy (n= 30) (Catania et al., 2008) and CRN’s working in a pediatric cooperative clinical trials group (n=85) (Nagel, Gender, & Bonner, 2010). The researchers noted that the majority of CRNs worked in a hospital setting coordinating activities associated with clinical trials including both administrative and clinical duties. A key finding in these studies was that CRNs often act as patient advocates providing a vital link between clinical practice and clinical research. The vast majority of respondents in these studies reported autonomy and independence in their role as a CRN, but these studies were limited by their small sample sizes. The CTNQ was also used by Ziembra

(2012) in a doctoral study to better understand the relationship between the role and functions of the CRN and job burnout. He found that the role of the CRN included tasks such as obtaining informed consent, study implementation, management of investigational drug, subject recruitment and data management. Tasks less frequently performed included protocol assessment and protocol planning which were frequently performed by principal investigators at study sites. This study observed a relationship between job roles and burnout profiles, however, it was found to be not statistically significant. The results of this study are questionable due to the small sample size (n=40).

Scott, White, Johnson, and Roydhouse (2012) reported on the development and testing of a questionnaire which the researchers suggest is reliable and valid to measure the knowledge and skills of cancer clinical trials nurses (CTNs) in Australia. This tool was developed to collect data for the development of a postgraduate course in clinical trials. The questionnaire measures self-reported knowledge skills and perceived importance of knowledge and skills. The questionnaire was developed in a three-stage process. In the first stage, items were developed and a pilot test was performed. The second stage (n=61) involved a focus group evaluation and the third stage refined the questionnaire. The final tool was a 48-item questionnaire which was e-mailed to members of the Cancer Institute of NSW and the Cancer Nurses Society of Australia. There were 61 respondents to the survey. Internal consistency reliability was reported as high for all parts of the scale: self-reported knowledge scale (Cronbach's $\alpha = 0.98$), perception of importance of the knowledge scale (Cronbach's $\alpha = 0.93$), self-reported skills (Cronbach's $\alpha = 0.90$) and perception of importance of skills (Cronbach's $\alpha = 0.86$). Validity for all items was established using item convergent

(corrected item-scale correlation ≤ 0.3) and divergent validity (correlation of an item with an unrelated scale not exceeding the corrected item-scale correlation). Based on a literature search as of November, 2014 no other published studies have used this survey.

Matsumoto et al. (2012) developed the 23-item Stressor Scale for Clinical Research Coordinators to help identify the sources of stress for clinical research coordinators. The scale measures six factors: quantitative workload (Cronbach's alpha = 0.82, ICC= 0.84), conflict with investigators (Cronbach's alpha = 0.81, ICC= 0.78), ambiguity of work (Cronbach's alpha = 0.77, ICC= 0.76), conflict with other CRCs and with supervisors (Cronbach's alpha = 0.82, ICC= 0.82), demands from an affiliate other than the hospital (Cronbach's alpha = 0.76, ICC= 0.74), and difficulty in caring for trial participants (Cronbach's alpha = 0.73, ICC= 0.65). This scale was used to measure stressors in CRNs in work environments in 186 Japanese hospitals with 589 completed surveys. Of the respondents, 49.1% were nurses. This study may not be applicable to CRNs as the results include non-nurses and was limited to the country of Japan. To date no other published studies have used this survey.

In the Matsumoto et al. (2012) study the authors reported good test-retest reliability with a second questionnaire completed 3 weeks following the first survey. Internal consistency reliability was reported as high for the total scale (Cronbach's alpha = 0.88, Intra-class Correlation Coefficients [ICC]= 0.85).

Roles of CRNs Other Than Study Coordinator

In addition to working as study coordinator at investigative sites, CRNs may also work at many other jobs along the continuum of the pharmaceutical drug research and

development process. Nurses are employed by pharmaceutical companies in many varied positions supporting drug research and development yet the literature is sparse when looking at this work environment.

A doctoral dissertation by Shannon (2011) investigated how nurses perceive their professional practice within the pharmaceutical / biotech industry. Shannon interviewed 15 participants to explore the decision-making process surrounding their migration from traditional practice settings into the nontraditional practice setting of the pharmaceutical/biotech industry. Roles or job function of the interviewees included: regulatory affairs, pharmacovigilance, clinical research operations, and customer account representative. The process of “Immigrating in Nursing” emerged through grounded theory methodology (Shannon, 2011 p.60). This theory which emerged from the data involved a four phase process including: becoming disillusioned, acclimating into the corporate role, achieving belonging, and nursing specialty actualization. Through this process nurses were able to explain how they were able to restore, support, and foster their nursing practice in a non-traditional setting. A nurse’s previous expert status within a traditional practice setting did not transfer into the practice within the pharmaceutical / biotech setting where new skills and knowledge were needed. Nurses within the pharmaceutical / biotech setting frequently had to defend their professional practice against perceptions of negativity or invalidation from both the nursing profession and the public. Shannon noted that nurses within the pharmaceutical /biotech industry had experienced progressing through the four stages of this process as they became comfortable with their new non-traditional nursing roles. The sample was limited to English-speaking nurses in the mid-Atlantic region of the United States currently

working full time in a clinical role within the pharmaceutical/biotech industry. Data collection and analysis were conducted simultaneously using a constant comparative methodology as is consistent with grounded theory. This study laid the groundwork for future exploration of nurses working in the non-traditional work environment of the pharmaceutical/biotech industry.

A doctoral dissertation by Kavalam (2011) explored the lived experiences of nurses who transition from bedside staff nurse roles into pharmaceutical industry roles and the implications that this has for nursing recruitment and retention. Ten participants were interviewed. Three major themes emerged from her phenomenological research. The first theme, taking stock, included the sub themes of nurse identity, nursing environment, personal life, and motivation. The second theme, taking action, included subthemes of pivotal moments, fear, lifestyle, and lack of awareness. The third theme, adaptation, included the subthemes of feeling valued, perspective, new language, less job security, and new work model. A common thread that was found throughout all the interviews in this study was the nurse's quest to feel truly valued which was found in the pharmaceutical industry but not in the hospital setting (Kavalam, 2011). Roles or job function of the interviewees included: drug safety associate, pharmaceutical sales, director of marketing, brand specialist, quality assurance, manager of medical coding, data management coordinator, clinical research associate, protocol writer, business analyst, and medical science liaison. This study added to nursing knowledge by examining why nurses leave the hospital bedside, what they find in the pharmaceutical industry and what they made of that transition experience. This study focused on why nurses left traditional nursing role and moved into the pharmaceutical

industry. It did not address the experience of nurses' impact on the pharmaceutical drug research and development process. The author of this study stated data saturation was achieved overall with 10 subjects but did not specify if data saturation was achieved for all subthemes.

Definition of terms

For the purpose of this study, a clinical research nurse is a registered nurse who is working in a role other than study coordinator, in any environment along the pharmaceutical drug research and development continuum.

Conceptual Framework of Role Theory

Creswell (2013) states that when exploring a topic a theoretical framework serves as a lens through which to view the research. In this study exploring the role of the CRN, role theory is used to provide a contextual foundation and framework for the research. Role theory addresses the social concept of characteristic behavior patterns or roles. It explains roles by presuming that persons are members of a society, hold positions or roles within that society, and have role expectations for their own behaviors and those of other persons within that society (Biddle, 1986).

According to Peterson and Bredow (2009) nursing at times uses theories developed outside of nursing for research and to seek an explanation for why a phenomenon exists. The disciplines of anthropology, psychology, sociology, and philosophy have all contributed to the study of role and role behavior (Anderson, 1973). Role as a construct has been consistently difficult to define and analyze systematically because of its multidimensional nature (Hardy & Conway, 1988). Role is often described as having its roots in the theater and references the part one plays or is assigned in a

drama (Conway, 1988). Conway (1988, p.63) defined role theory as “a collection of concepts and a variety of hypothetical formulations that predict how actors will perform in a given role, or under what circumstances certain types of behaviors can be expected.” Role theory is an eclectic mix of psychological and sociological constructs and premises used to explain how individual behave in social circumstances and how these behaviors are perceived by others (Brookes, Davidson, Daly & Halcomb, 2007). Thus, role theory is an ideal foundation to explore the perceptions, feelings and viewpoints of nurses who work in the environment of pharmaceutical drug research and development as these CRNs work simultaneously in a nursing role and a clinical research role.

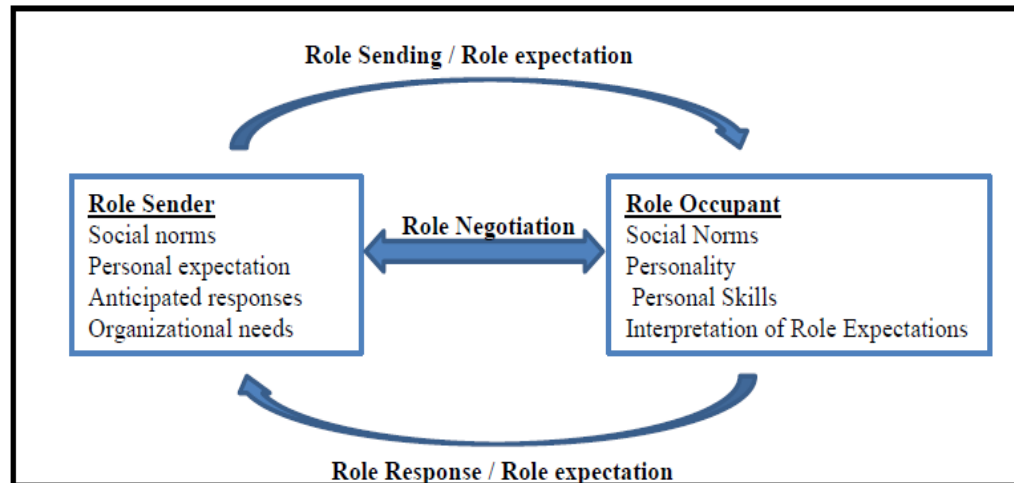
The three basic concepts of role theory are role, social position, and expectation (Biddle, 1986). Theorists have used the term role to describe characteristic behaviors, social parts to be played, or social conduct depending on the theorist definition. Biddle (1986) states role may be defined as: 1) a particular set of norms organized around a function, 2) a comprehensive pattern for behavior and attitude, or 3) behavior referring to normative expectations associated with a position in a social system. According to Hinshaw (1988), a role is formed by several components including: values, attitudes, and behaviors. Values are defined as ideas held in common by members of the social structure that guide the identification and prioritization of goals or objectives (Hinshaw, 1988). Attitude is defined as the tendency or readiness to respond to social events with a favorable or unfavorable evaluation. Attitudes guide role judgments and behaviors. Behavior is defined as observable social acts performed by an individual (Hinshaw, 1988). In role theory actual behavior is termed role enactment. Role demands or role prescriptions are expected behaviors which may or may not be an ideal behavior

(Hinshaw, 1988). Social position describes socially defined categories such as manager, teacher, or nurse (Hindin, 2007). The concept of expectation describes the characteristic behaviors or parts to be played by a person in a role. Role theorists differ on whether expectations about behavior associated with social positions are based on norms, beliefs, or preferences (Hindin, 2007). Not all individuals are exposed to the same expectation and not all individuals enact their role identically. Resultantly, roles may become personalized (Major, 2003). With many disciplines using role theory, there is a range of “types” of role theory based on the perspective of the theoretical tradition (Hindin, 2007).

In this study symbolic interactionist role theory, which is based on George Meads theory of the societal self, guides the research (Hindin, 2007). This role theory perspective states role behavior focuses on the meaning of symbols and actions to the individual (Conway, 1988). Symbolic interaction role theory suggests roles are learned and developed through social interaction (Hindin, 2007). Therefore, roles reflect norms, attitudes, contextual demands, negotiation, and the evolving definition of the situation as understood by the actors themselves (Biddle, 1986). With symbolic interactionism an individual gives meaning to objects and makes decisions based on his own judgment taking into account external and internal cues. Role identity is produced not only through self-conception but also through interaction with the attitude and perspectives of others around them. This perspective of role theory allows for the understanding of role as a relationship which takes place in informal interactions thereby providing insights regarding relationships among roles, role taking, emotions, stress, and self-concept (Biddle, 1986). As CRNs have both nursing and research roles, this theory will provide a framework to guide the research.

Interactions in role theory are comprised of role episodes (Figure 1) (Kelly, 1982). Role episodes occur when role expectations are sent by one person and received by the role occupant. This interaction is a continuous cycle. The person receiving the communicated expectations, the role occupant, is influenced by the relationship between themselves and the sender, the occupant's self-image, and the operating frame of reference. After a role occupant processes the sent communicated expectations, the resultant role expectation is enacted as a behavior. The behavior of the role occupant is then interpreted by the sender to see if expectations have been met. Role negotiation and collaboration takes place between the sender and the role occupant on a continual basis to reach a mutually satisfactory definition of the role (Brooks et al, 2007).

Figure 1: Representation of a Role Episode



Nursing has used role theory to explore the role of nurses in various practice settings. John Kelly (1982) used role theory as a model for human interaction and its implications for nursing education. He describes conflict situations in nursing relating them to the role conflict concept within role theory. He then goes on to describe how

nursing education can use the role theory to better understand nursing's role. He used the example of role theory increasing the nurse's understanding of the bureaucratic structure in large institutions which must place people in categories or social positions so that functions may continue efficiently. Nursing theorist Afaf Meleis examined the concepts of role and role transitions as she developed her conceptual framework of Role Insufficiency and Role Supplementation (Meleis, 1975). The development of Meleis' framework supported the claim that the concept of transitions was central to the discipline of nursing and led to her nursing theory of Experiencing Transitions (Meleis, 2010).

Role theory has been shown to be a useful framework to describe the concept of role and understand role perceptions. Appreciating the dynamics and interactions between individuals in a nursing specialty and the organizational / social structure of which they are a part is important in developing a scope of practice. Utilizing the conceptual elements of role theory focusing on the role perception of the role occupant (the CRN) will help to identify the role and perceived impact of that role encountered by nurses working within the pharmaceutical research and development environment and help to define the evolving nursing specialty of clinical research nursing. The theoretical framework of role theory will provide a lens through which to view the role perceptions and interactions of clinical research nurses as the aim of this study was to explore the role experiences and perceived impact of CRNs in roles other than study coordinator to the pharmaceutical drug research and development process.

Summary of Literature Review

The role of the CRN has been in evolution over the past 20 years and still remains relatively undefined (Raja-Jones, 2002; Hill & McArthur, 2006; Bell, 2009). Despite this lack of understanding of the CRN role, professional nursing is a member of the multidisciplinary research team conducting pharmaceutical drug research and development. Literature describing this nursing role and its perceived impact is limited. The CRN role has been described as diverse, multi-faceted, and complex being practiced in various ways and various settings throughout the continuum of pharmaceutical drug research and development (Eherenberger & Lillington, 2004). CRNs working in these roles bring unique skills and abilities to the role by virtue of their professional background (Fish, 1997).

The current literature describes the role of the CRN who works as a clinical trial study coordinator as part of pharmaceutical drug research and development. However, the current literature does not describe the role or the perceived impact that CRNs working in the pharmaceutical research and development environment but outside the study coordinator role have on the pharmaceutical drug research process. Doctoral dissertations by Shannon (2011) and Kavalam (2011) describe the transition of nurses from a clinical setting to the pharmaceutical environment but there is no current literature describing the role experiences or the perceived impact of the CRN in this environment.

Due to the lack of literature describing all aspects of the CRN role, there was a need for better understanding of this unique nursing specialty and its contribution to the pharmaceutical drug research and development process especially as the number and complexity of clinical trials increase along with mounting regulatory and economic

pressure to get drugs quickly to market (Eherenberger & Lillington, 2004). The researchers reported that as nurses with additional knowledge of the pharmaceutical research process, CRNs have the knowledge, ability and skills to be an integral part of the drug research and development process environment. However, there was a gap in the empirical evidence describing the CRNs' role and impact throughout all phases of the pharmaceutical drug research and development process not solely in the study coordinator role. Thus there was a need for further exploration of the CRN's role other than study coordinator and perceived impact within all aspects of the pharmaceutical drug research and development process.

Research Question

The question which guided this research study is: What are the role experiences and perceived impact of the CRN working in the pharmaceutical drug research and development environment in a role other than a research study coordinator?

Chapter 3: Methodology

Through this study, the researcher sought to explore and describe the role experiences and perceived impact of the CRN working in a role other than the study coordinator in the pharmaceutical research and development environment. As little was known about the role of the CRN other than the role of the study coordinator, a qualitative approach was used in this study to explore the CRN role. A constructivism philosophical worldview guided the study with focused ethnography the methodology appropriate for this research.

This chapter reviews the research method and key components of focused ethnography and provides a rationale for using this research method in this study. The characteristics of study participants, human subjects' protections, data collection procedures, procedure for data analysis, and the audit trail will also be discussed in this chapter.

Research Design

Qualitative methods are often used in research to expand a topic's knowledge base by understanding people's experiences and their subjective realities that cannot be measured quantitatively (Munhall, 2007; Parse, 2001). Other than the role of the study coordinator, there is a gap in the literature describing the role of the CRN who works in one of a variety of roles along the continuum of pharmaceutical drug research and development. A qualitative approach in this study allowed for an understanding of the CRN's role experience and perceived impact on the process of drug development.

One of the oldest forms of qualitative research methodology is ethnography, stemming back to ancient Greece (Clair, 2003). It is also known to be one of the oldest qualitative approaches used in nursing research (Olfiffe, 2005). Ethnography allows for learning about people from people, giving researchers an opportunity to explore and describe cultures, examining a group's observable and learned patterns of behavior, customs, and ways of life and understanding what the world and culture mean for a person living within that world. (Creswell, 2007; Roper & Shapira, 2000). Utilizing ethnography for this study allowed for examination of the CRNs' patterns of behavior, customs and ways of life as they live in both the nursing world and the pharmaceutical research world. Traditional ethnography demands prolonged engagement in the field and multiple sources of data collection, relying heavily on participant observation and informal discussions to assist in identification of key informant and potential participants for more formal, semi-structured interviews. A contemporary ethnographic approach being used by 'insiders', particularly nurses, is focused ethnography where researchers concentrate on a particular setting or culture looking at specific behaviors in specific settings (Olfiffe, 2005).

Focused ethnography is used to develop understanding about the cultural rules, norms, and values within a specific group and how those traits may influence and inform behaviors and complement rather than oppose conventional ethnography (Olfiffe, 2005). Focused ethnography is able to speak to specialized cultures because it presupposes the researcher possesses an intimate knowledge of the field to be studied allowing for focus on small elements or traits of the culture under study (Knoblauch, 2005). Researchers using this methodology are often members of that society performing the research within

a researcher's own working environment where participants are readily available (Higginbottom et al., 2013; Knoblauch, 2005). Focused ethnography method includes conducting short-term field visits with intense data collection and deep data analysis (Knoblauch, 2005).

Our present-day world is socially and culturally highly differentiated and fragmented and focused ethnography allows for exploration into the resultant highly specialized professional cultures revealing aspects of a culture that are sometimes known only to members of the culture or sub culture to be articulated to others (Fetterman, 2010; Knoblauch, 2005). With its focus on a particular aspect of a culture, focused ethnography may help in the development of future hypotheses that can be tested in future research. This method is the appropriate means for studying the role of the CRN as this atypical, highly specialized subspecialty of nursing lives in the multidisciplinary culture of pharmaceutical drug research and development. Focused ethnography allowed this study to explore aspects of the role that are known only to CRNs who work in this culture. Oliffe (2005) states that nurses are ideally suited to conduct this method of research due to their well-developed observation, documentation, and analytical skills.

Interviews are often the main form of data collection in focused ethnography. These in-depth interviews allow the researcher intimate access to the world of the participants including their ideas and thoughts to discover subjective meanings of the participants' experiences (Oliff, 2005). Due to this need to access in-depth knowledge possessed by participants, subjects are selected through purposeful sampling with no predetermined sample size; rather recruitment continues until data saturation and the topic has been fully investigated (Guest, Bunce, & Johnson, 2006). Intense data analysis

in focused ethnography demands iterative, cyclic, and self-reflective processes so that insights may be obtained from the collected data and to plan for further data collection (Higginbottom et al., 2013).

The purpose of this study was to explore and describe the role experience and perceived impact of the CRN other than the study coordinator working within the pharmaceutical drug research and development environment and articulate what it means to be a CRN working within this atypical nursing environment from the perspectives of the CRNs themselves.

Rationale for Methodology

A focused ethnography approach was employed as the methodology best suited to investigate the experience of being a CRN. With limited empirical research, the state of the knowledge surrounding the role of the CRN other than a study coordinator lends itself to an ethnographic approach which allows for expansion of a topic's knowledge base by further understanding people's experiences and their subjective realities that cannot be measured quantitatively (Munhall, 2007; Parse, 2001). This naturalistic approach of qualitative inquiry seeks to understand phenomena in context-specific settings such as the experience of CRNs working in the drug research and development environment, which are studied in this research (Creswell, 1998). Understanding this experience from CRNs' personal perspective opened a window into what it means to be a CRN. A focused ethnography research approach allowed for a better understanding of the role and perceived impact of the CRN from the subjective perspective of the CRN who works within this highly specialized field.

Sample

Sample Selection

The most common type of sampling in focused ethnography is purposive and criterion based (Creswell, 1998; Higginbottom et al, 2013). The participants must be individuals who have specific knowledge or experienced the phenomenon being explored and can articulate their experiences. This study employed purposeful sampling of information rich individuals who elucidated the research question. The sample for this study was registered nurses other than research study coordinators employed in the pharmaceutical drug research and development environment. Strategies for sampling originally included solicitation, identifying potential key informants through contacts within the industry, accessing nurses in the role through organizational listserve and snowballing. However, due to an overwhelmingly positive response, all subjects were recruited for this study by solicitation and word of mouth.

Because in-depth and lengthy interviews are required when using focused ethnography, it was convenient to recruit people who were easily accessible. The target population included participants who provided maximum variation within the pharmaceutical industry culture and yet still identify important common patterns (Higginbottom et al, 2013). Individuals were selected for participation so that the full range and extent of the role of the CRN along the continuum of the drug research and development process are represented. CRNs who work in various roles within the pharmaceutical industry within departments such as clinical trial operations, regulatory submissions, data dissemination, or pharmacovigilance were recruited for this study.

Sample size in qualitative research is guided by the principle of data saturation defined as when the collection of new data does not shed any further light on the issue under investigation and all data categories have been saturated (Holzemer, 2010). As with other methods of qualitative research, in focused ethnography the number of participants is usually not predetermined (Higginbottom et al, 2013). However, Creswell (1998) suggests five to twenty five participants may be needed for data saturation in qualitative research. This researcher interviewed 21 CRNs until the data was saturated for all the themes which emerged.

Inclusion and Exclusion

This study was limited to registered nurses (RN) 18 years of age up to 90 years of age currently working full time in the pharmaceutical drug research and development environment in a role other than a study coordinator role. Study participants needed to be able to understand and speak English and work in the United States of America. They had to be willing and able to sign informed consent as well as comply with study required interviews.

Pharmaceutical drug research and development environment included but was not limited to the pharmaceutical industry, biotech industry, medical center, private physician office, hospital, or a contract worker. Occupational titles could have included but were not limited to medical writer, clinical research associate, project manager, medical liaison, global study lead, study coordinator, sub-investigator, safety associate, or clinical trial manager.

Strategy for Obtaining Participants

After IRB approval, participants were recruited by reaching out to key informants using personal connections and word of mouth. An Invitation to Participate (Appendix D) was provided to key informants. The Invitation to Participate included a brief description of the study and contact information for the researcher. Interested participants were asked to contact the researcher via phone or e-mail and provide the preferred means of contacting them (e.g. email, phone, text). Upon receipt of such information the researcher contacted them, explained in more detail the study and if they agreed to participate in the study they were provided the IRB approved Informed Consent Form (ICF) (Appendix E) via e-mail or hard copy. Upon receipt of the signed ICF (electronic signature or hard copy), an interview meeting was scheduled at a mutually agreed upon time and location. Nine interviews took place in person and 12 interviews took place via teleconference at the convenience of the participant.

Human Subject Protections

Permission to conduct this research was obtained from Rutgers University Institutional Review Board prior to the performance of any study related activities. This study complied with all applicable Good Clinical Practice guidelines as defined by the International Conference on Harmonization. Participation in this research was voluntary and participants were free to withdraw at any time during the study. Each volunteer study participant was asked to sign a "Consent to Participate in a Research Study" document prior to study participation. The purpose, risks, and benefits of the study were explained to the participants. Participants were informed that there were no direct benefits of study participation however; additional information obtained in this research study may be

useful in improving the body of nursing knowledge. Participants were informed that possible risks associated with participation in this study included inadvertent loss of confidentiality or fatigue during the interview.

Data Collection

Ethnography generally uses three main sources of data: participant observation, interviews and examination of relevant documents to gain a better understanding of a culture (Cruz & Higginbottom, 2013). Focused ethnography may be practiced in one's own culture, focusing on specific aspects or nuances of the culture (Knoblauch, 2005). This role allows for reduced time in field participant observation (Higginbottom et al, 2013). As researchers are not immersing themselves in entirely foreign cultures but rather have prior experience in the culture, data collection may occur in short, intensive phases. The goal of data collection in focused ethnography is to understand and describe social practices and "insider perspectives" of those in the culture making it relevant to society as a whole.

In this focused ethnography study the key source of data was the in-depth interview which enabled this researcher to see the content and patterns of the participants' experience. This allowed access to the participants' ideas, thoughts, and meanings (Cruz & Higginbottom, 2013; Higginbottom et al, 2013; Oliffe, 2005). The interviews were semi-structured with a specific purpose and an informal approach using open-ended questions which allowed for flexibility and responsiveness to emerging thoughts for both the participant and the researcher. A topic guide which contained questions relevant to the research question along with accompanying probes was used during the interview (Appendix B1). These in-depth interviews lasted approximately 1 to

2 hours. The interview guide was modified based on early interviews to further investigate active nursing licensure and the participants' perception of still being a nurse (Appendix B2)

Demographic Data Sheets

Participants were asked to complete a demographic data collection form (Appendix A) at the time of the interview but prior to the audiotaping of the interview. This form was provided via e-mail or hard copy.

Interviews

Interviews took place at a time and location convenient to the participant and researcher in person or via teleconference. All interviews were audiotaped following collection of the demographic data collection form. Participants were numerically coded to prevent disclosure of identity. A semi-structured interview guide was used to provide consistency across interviews. (Appendix B1, B2). Participants were encouraged to respond in as much detail as possible until they have nothing further to add. This approach allowed for emergence of new ideas and thoughts and captured the meaning of the experience in participants own words. All interviews were transcribed verbatim by the researcher. In order to ensure credibility of the study findings all transcriptions were checked against audiotaped interviews for accuracy by the researcher.

The researcher collected observational and field notes during the interview to capture context of the interview and any additional data. The researcher's thoughts and reactions were included in these field notes.

Data Storage and Disposition

All electronic data from demographic data sheets, audio tapes and transcripts of interviews, informed consent documents and field notes are kept on a separate computer hard drive that is password protected and accessible only to the researcher or research team. All hard copy study information is kept in a locked file accessible only to the researcher or research team. In order to prevent disclosure of identity all subjects, each interview and demographic form was numerically coded. There is no link between the consents and the interviews or demographic form. Rutgers University will keep all study related data for six years. The data will be kept by the Rutgers University appointed data steward on a password protected Rutgers computer or stored in a locked cabinet located at Rutgers School of Nursing 180 University Ave. Newark, New Jersey. All study related data will be destroyed six years after study completion.

Data Analysis

Data analysis brings order, structure, and meaning to the collected data as researchers look to identify patterns in data and ideas that may help explain why those patterns are there in the first place (Bernard and Ryan, 2010). Higginbottom, et al (2013) state that data analysis in focused ethnography is an iterative, cyclic, and self-reflective process. Beginning with the first interview, the researcher read and re-read each transcript to generate insights into the data, explore possible additional questions/probes and to identify themes, categories and patterns (Pope, Ziebland, & Mays, 2000). This research used the data analytical steps outlined by Higginbottom et al (2013) including: coding for descriptive labels, sorting for patterns, identifying outlier or negative cases, identifying key themes or categories, and memoing for process, analytical insights and reflexivity.

This research used the computer data analysis software NVivo 10 to assist with the systematic analysis of data. This software was used to facilitate the sorting, classification, and arrangement of data which then assisted the researcher in identification of themes, subthemes and relationships in the data.

Validity / Audit Trail

In qualitative research it is important to clearly describe the research path. It is the responsibility of the researcher to provide a transparent description of all research steps taken in the course of the study from the start to reporting of the findings. All records must be maintained so that there is documentary evidence for neutral experts or peer reviewers with expertise in qualitative research to review and verify the path the investigator followed from raw textual data to results (Wolf, 2003). Lincoln and Guba (1985) state that the following are essential materials in the audit trail: raw data, data reduction and analysis products, data reconstruction and synthesis products, process notes, and materials relating to intentions and dispositions. In this study all the above materials will be kept by Rutgers for 6 years post completion of the study.

Validity ensures that the findings of a study are true and certain (Schwandt, 2007). It must be true that the findings represent the experience of the participants. In qualitative inquiry, validity rests in the richness of the discussions (Holzemer, 2010). Validity in qualitative research also means that the explanation adequately fits the description of the phenomenon (Denzin & Lincoln, 2008). Leininger (1998) states that validity can be judged by the extent to which understanding and knowledge are gained of the true phenomenon. This study used Creswell's (1998) process in order to ensure validity, credibility and trustworthiness in the study. This includes:

1. Peer review or debriefing: Dissertation chair was engaged to discuss the data and interpretation throughout the analytical process.
2. Clarifying researcher bias: In focused ethnography the concept of reflexivity or the recognition of the researcher as part of the world under study is crucial during interpretation of the data (Pellatt, 2003). This researcher maintained a reflexive journal and field notes during this study.
3. Member checks: Lincoln and Guba (1985) consider this to be the most critical technique for establishing credibility. Member checks ensure the researcher's interpretation of the individual experiences is faithful to the participants' actual experience. Member checks in this study included follow up with three key informants for clarification, review and feedback on the findings of this study.
4. Thick description: Data collection was rich with participants encouraged to share as much detail of their experience as possible including not only facts but commentary, meanings, interpretations, and interpretations of those meanings and interpretations (Geertz, 1998). With a rich description, readers will be able to determine if findings can be transferred to other settings.

Reflexivity

Focused ethnography is often conducted within a researcher's own environment where the researcher is intimately involved with the culture and "speaks the language." Focused ethnography allows the perspective of the participant (emic view) to be the center of the research while simultaneously being transparent about the perspective of the researcher (etic view) (Olliffe, 2005). As the researcher in focused ethnography is often

part of or intimately involved with the culture under study, they seek to understand human behaviors from an emic or “insiders” point of view. This insider point of view results in the intermingling of the researcher and the research (Byrne, 2001). Allowing the view of the researcher to be known, which is referred to as reflexivity, acknowledges the subjectivity inherent in ethnographic studies (Pellatt, 2003). With reflexivity, the researcher describes their background and integral connection with the culture under study and how this may affect the research process and the outcomes (Pellatt, 2001). With this disclosure, the researcher becomes a variable in the research process (DeSantis, 1994). This concept of reflexivity requires the researcher to continually conduct self-assessment and self-critique throughout the study and is crucial during interpretation of the data and when drawing conclusions (Higginbottom et al., 2013).

In order to allow for full transparency this researcher described her background and knowledge of the pharmaceutical drug research and development process in full in Appendix C. In this way there is clarity about the personal biases involved in this study from the beginning. Additionally, in order to maintain the rigor of this study, this researcher maintained a reflective journal and field notes to convey awareness of self-including beliefs, interests, and value judgments throughout the study.

Summary

The qualitative research methodology of focused ethnography has been discussed in this chapter as the appropriate methodology for exploring the role of the CRN other than the study coordinator working within the pharmaceutical drug research and development environment. This chapter discussed the research methods, characteristics

of study participants, human subjects protections, data collect procedures, data analysis, and the audit trail.

Chapter IV: Results

Medicine and health care in general have undergone a significant transformation in the last 50 plus years and the development of pharmaceuticals to cure, slow progression of chronic diseases or ameliorate symptoms have been at the center of this transformation. The purpose of this study was to explore and describe the role experiences and perceived impact of the clinical research nurse (CRN) working in a role other than the study coordinator in the pharmaceutical research and development environment. A focused ethnography methodology including in-depth interviews was used to elucidate the participants' perceptions of their role and the perceived impact of nursing on this role. The data from these interviews was analyzed using an iterative process to uncover themes and categories. This chapter introduces study participants through summaries of their demographic information and provides an insight into the contextual factors surrounding their employment. Four major themes which emerged from the data are described within.

Demographic data

The sample for this study consisted of 21 participants interviewed over a three month period. The participants all currently worked full time within the pharmaceutical industry but were not currently employed as study coordinators. All could read and speak English, and all completed a Demographic Questionnaire.

The average age of the participants was 49 years old, all were Caucasian, and 95% female and 90% maintained their nursing license. All participants were well educated as they all had a minimum of a bachelor's degree before becoming a clinical

researcher although not all had a bachelor's in nursing. Additionally 57% had advanced degrees, but only 19% of those were in nursing (see Table 1). Prior clinical nursing experience and experience within the pharmaceutical industry collected on the demographic form was significant; 95% of the sample had worked in hospitals, the mean years of clinical practice was 18.7 (13) and the mean years of working in the pharmaceutical industry was 14.9 (4.8), (see Table 1). Demographic data for subjects is presented in the table below.

Table 1. Demographic Data

| Demographic Data N = 21 subjects | | Educational background | N (%) | Previous nursing experience | N (%) |
|--|--------|-------------------------------|--------------|------------------------------------|--------------|
| Age | | Minimum of BA/BS | 21 (100) | Clinical setting | |
| Mean (SD) | 49 (9) | | | Hospital | 20 (95) |
| Range | 34- 65 | | | Public Health | 1 (5) |
| Active nursing license | | Highest degree in nursing | | Years as clinical nurse | |
| Yes | 90% | BS | 16 (76) | Mean (SD) | 18.7 (13) |
| | | MS | 4 (19) | Range | 2-40 |
| Gender | | Nursing as second degree | | ED/CC experience | 9 (43) |
| Female | 95% | | 2 (9.5) | | |
| Race/ethnicity | | Initial nursing education | | Years in Pharmaceutical industry | |
| Caucasian | 100% | BS | 12 (57) | Mean (SD) | 14.9 (4.8) |
| Non-Hispanic | 95% | Diploma | | | 10-26 |

| | | | | | |
|-----------------------|-----|------------------|------------------|-------|--|
| | | ASN | 7 (33) 2 (10) | Range | |
| Marital status | | Masters prepared | 12 (57) | | |
| Married | 67% | | | | |
| Divorced | 19% | | | | |
| Single | 14% | | | | |

Generalized categories of the roles of participants within the pharmaceutical industry included clinical trial operations, regulatory, pharmacovigilance, and medical liaisons. Roles varied, ranging from upper management with numerous people reporting to them, to independent roles such as medical writer. However all participants reported working within a matrix environment. Current role titles of participants are referenced in Table 2 below.

Table 2. Job Titles

| Job Title |
|---|
| Associate director in global safety licensing and contracts. |
| Associate director of early stage development operations |
| Associate for clinical safety and risk management (2) |
| Associate principal scientist |
| Associate principal scientist in clinical risk management and safety surveillance. |
| Clinical operations study team lead (2) |
| Clinical Project Leader |
| Clinical safety and risk management scientist |
| Department chair head for clinical operations for the early phase or phase 1 drug development |
| Director of clinical operations |

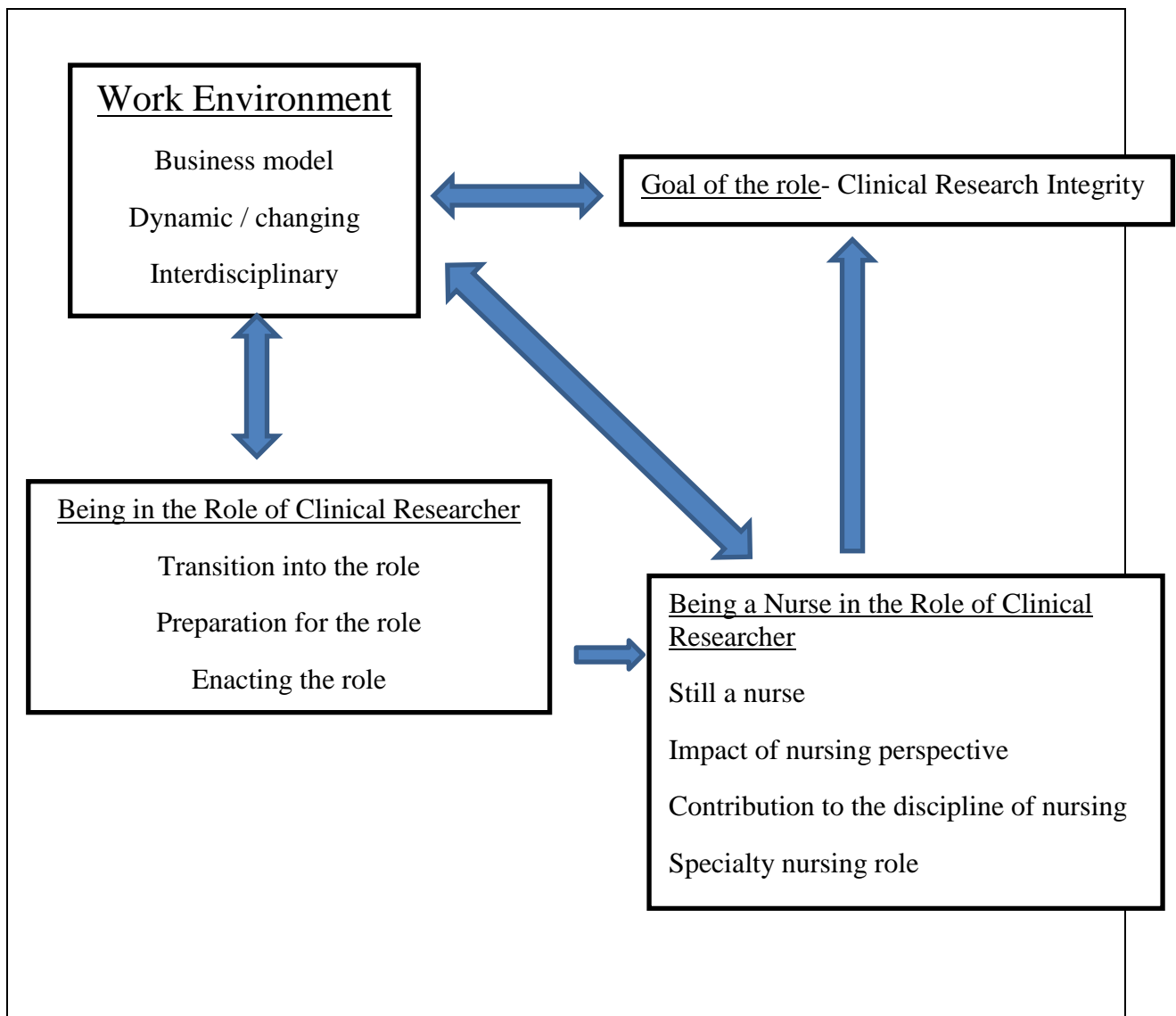
| |
|--|
| Director of human subjects protection |
| Medical writer |
| Senior clinical research associate (2) |
| Senior manager in third party vendor management. |
| Senior medical representative |
| Senior scientific specialist in the global medical information operations department |
| Study clinician (2) |

Participants in this study provided a sampling of the nurses employed throughout the pharmaceutical drug research and development process. The background demographic data, in addition to the in-depth interviews, provided a view into the role experiences of the participants.

Themes

From the data obtained during the 21 interviews, four major themes emerged. These themes included work environment, the goal of the role, being in the role of clinical researcher, and being a nurse in the role of clinical researcher. Each of these themes contained subthemes which help explicate the themes. Figure 2 is a visual representation of the themes and subthemes and their linkages.

Figure 2. Themes



Pharmaceutical Work Environment

All of the participants talked about the environment in which they worked and its

uniqueness as a site for nurses. The work environment was the first theme to emerge from the data. As participants spoke about their role in the pharmaceutical industry they shared stories about the tasks and goals of their everyday work. The pharmaceutical drug research and development environment was found to be different than the clinical setting that participants had previously experienced. Of the 21 Subjects, 19 were employed by a large pharmaceutical company, one was employed at a medical center and one is an independent contractor. Three subthemes articulate the work environment in which CRNs practice.

Business model

The pharmaceutical drug research and development process has as its ultimate goal to provide new or improved therapies to improve the standard of health care (Linberg, 1999). To accomplish this goal the pharmaceutical industry is a for profit business. According to the study subjects, the pharmaceutical industry environment is explicitly based on a business model and companies rise and fall depending on the outcomes of the research and development process. One participant clearly summed up this theme by stating “I think the industry of course is business.”

Participants indicated that their role was about the research process and providing outcomes in the drug research and development process. Subjects shared that the ultimate goal of the pharmaceutical industry is to get a product approved and marketed to the consumer. It is, therefore, a business model that underlies their work and not the clinical model that the nurses had experienced prior to entering the pharmaceutical industry environment.

According to one participant (#12), “the environment of a pharmaceutical company is very corporate.” She explained, “Our job is getting these products proven in trials that they work.” In order to accomplish that goal, “the day-to-day activities can be anything from budget management, study timeline issues, specific country issues, enrollment issues, IP inventory issues.... but you want to a good job and to keep things moving and to keep these compounds that we are working on approved.”

Another participant (#4) discovered shortly after coming to drug research and development industry that it was not:

...always very medical or clinically focused but rather, involved much more than just the medical clinical portion of running [a] research study. It involved, in some way, marketing. It definitely involved finance. It involved providing input to two-year rolling finance projections for accounting groups. It involves budgeting. It just involved a lot more than just the scientific portion of the study.

Subject #20 agreed stating, “The usual day involves a lot of business aspects of corporate America. “ and this focus was reflected by others when they described their day as, “a lot of meetings to talk about more meetings, “ or “full of teleconferences sometimes as early as 7 AM...some evening teleconferences.” Another participant articulated that she spends “the majority of my time on the phone, on teleconferences and in e-mail and have basically 4 to 5 face-to-face meetings.” Email is one of the primary means of interacting with others involved in the research projects and one nurse indicated that her day “Starts with looking at e-mail. Unfortunately e-mail correspondence is the primary activity of the day because it is how we communicate.”

However, some of the participants more clearly voiced the profit making aspect of the pharmaceutical industry in which they work, reflecting on their role in the drug research and development environment stating: “Moving into industry I sometimes get that feeling. I am just helping big Pharma make money.” Subject #6 shared the same sentiment stating the drug research and development process was all about making money for the company,

You want to get the drug out to market as quickly as possible so to help the patient and to make money. That is kind of, the cleaner document I create...the quicker we get the document out to the agencies and get the drug approved and get it to patients, the more money we make.

Dynamic / Changing / Unstable Employment

The pharmaceutical industry, being based on a business model, is subject to an ever-changing market, which includes company mergers, restructuring and layoffs. Additionally, clinical trials are finite with predetermined timelines for study completion. These are two factors that contribute to an unstable, changing employment situation for some participants. Subjects reported from one to six positions in their years in the pharmaceutical industry. Only four subjects reported having held one position in the industry on the demographic form. Subject #7 indicated that she worked for 13 years in clinical trials, subject #10 indicated that she worked in pharmacovigilance drug safety for 14 years, and subjects #11 and #15 worked in clinical research for 15 years but did not provide a breakdown of job titles. One participant has worked as an Institutional Review Board (IRB) manager for 12 years. The 16 remaining subjects had an average of 3.8 job titles during their time in industry. The range was two to six job titles. One participant's

description of how rapid changes in the pharmaceutical industry impacted her role and where she worked reflected the unstable environment:

[I was a] nurse practitioner who was involved in pharmaceuticals doing training ...to their sales reps. So, I was laid off from that position when the merger occurred and I did then get a job with the pharmaceutical company at the time and I was a nurse trainer which was the title And then from there I worked there for a few years and then we were bought by [another pharmaceutical company] eventually and under [this pharmaceutical company] my title was medical liaison for a little while.....They eliminated us into the sales division but we were a specialty representative who basically acted as the clinical lead on the sales team..... And then from there after that the company had a massive layoff and I was a casualty but then I was picked up by [a different pharmaceutical company] which at the time was [pharmaceutical company name] and now again is [pharmaceutical company name]. I worked for them again in their sales division and was a sales trainer and now I am a senior medical representative working with their device products.

Another participant articulated how the dynamic environment affected his own career trajectory within the industry explaining:

I started out as a CRA [Clinical Research Associate] in a CRO from there I moved over and became a lead CRA at a [pharmaceutical company A] And then from there, I joined [pharmaceutical company B] ... Started there as a lead CRA and worked my way from a CRA to a project leader, to eventually assistant

director for the cardio thrombosis department. Then following their announcement they were moving I was lucky enough to land a job here at [pharmaceutical company C] Started my career at [pharmaceutical company C]... as a clinical project manager for an HIV program and then within a couple months of joining [pharmaceutical company C] ...it was announced they were outsourcing all of their developmental operations activities. So I scrambled and found a job within [pharmaceutical company C] as a supply chain lead of all things. Did that for about a year... Then an opportunity arose... So I joined the team about two years ago as the study clinician

Study subjects also report that the change from project to project or job to job necessitates a need for flexibility and the ability to constantly learn new roles or acquire new knowledge. Subject #1 used the company's financial tuition assistance program "to get my Master's degree..." She indicated, "I feel [pharmaceutical companies] do not want you to stay stagnant or not learn things. That does not really help the company." There are many jobs along the continuum of drug research and development, all of which require specific knowledge and continual learning helps employees see the bigger picture. When Subject #5 had to move into a different role due to outsourcing of the current project, it necessitated learning a new role which was "a real eye-opening experience. Ignorance is bliss in terms of everything that goes on to actually get a drug to a trial."

Despite the need to take on unfamiliar roles requiring new learning, none of the participants talked about this aspect from a negative perspective. One participant (#1) simply stated: "There is something to be learned all the time. I think that right now that is

keeping me in this role...I think that this is a new area to me so it will be an area of growth and development.”

In keeping with the dynamic nature of the pharmaceutical environment, three subjects have changed positions since the time of their interview but remain in a drug research and development role.

Interdisciplinary Environment

Pharmaceutical drug research and development involves interdisciplinary coordination to ensure the safety and efficacy of a product with each team member contributing their expertise to the process. Multidisciplinary teams members each contribute within a matrix environment and must be able to work together to obtain the final product. Within the industry, interdisciplinary team work is not a goal, but a necessity.

Participant #1, who is a member of the clinical safety and risk management team, states she constantly interfaces and collaborates with the “regulatory team, clinical, epidemiology..., manufacturing and submission planning” teams to discuss safety related topics. These discussions may result in a change to a product’s label or safety information. She states that in contributing to the discussion she “may see things through a different lens than different professionals.”

One participant describes herself as the “hub in a wheel” of a multidisciplinary study team and another as a “coordinator of all that [supply and management teams], getting it all to work together. ” Another participant states that she works ”cross

functionally with the statisticians, pharmacokinetics, data management, safety people, and regulatory.”

Subject #15 stated that she works with a tremendous number of physicians at her company so “it helps to be able to know how to talk to physicians, to know how they think.” She feels nursing enabled her to “speak the language” of physicians. Subject #14 also works “hand in hand” with many physicians in her group as they review and discuss issues because “we understand the dialogue, the acronyms, and the usual day-to-day routine in a hospital.” On the other hand, one participant talked of working closely with people educated in journalism and philosophy who shared a “commonality in being analytical, intuitive and really bright” but who “understood the language of clinical research.”

Not only do CRNs work in an interdisciplinary environment, they also work in conjunction with health authorities in many countries, since pharmaceutical development is a global enterprise. Subject # 10 works in collaboration with professionals at the United States Center for Disease Control.

The Goal of the Role

The work environment just described frames the goal of the role of CRN, the second theme that emerged from the data. The pharmaceutical drug research and development industry strives to bring safe and effective new drug discoveries to market for the betterment of the public health. Within the industry, all clinical researchers regardless of discipline “share a common purpose in helping to develop safe and effective therapies supported by high integrity data and generated in environment where the rights, welfare, and safety of the clinical research subjects

have been protected with diligence” (Freunscht and Van Dermark, 2001, p. 17). What is clear in the data is that the overarching goal of the CRN role is to maintain the integrity of clinical research so that only safe and effective products come to the clinic or hospital bed. Two subthemes explicate the goal of the role: not direct patient care and integrity of the research.

Not Direct Patient Care

In talking about the goal of their work, participants described the goal, in part, by what it was not, direct patient care, but lay claim to influencing patient care in the long run. Participants in the study indicated that their role is no longer about taking care of the individual patient but rather working toward the betterment of the public’s health. One participant acknowledged that patients are not always seen in the industry setting. She shared her sentiment by saying, “In the vendor part I see very little of patients. I do take into account how this service affects them but usually if you are talking statistics, it doesn’t affect the patient per se on a personal-care basis.” Other participants indicated that “Although I am not holding a patient’s hand giving direct patient care, I am helping patients around the world” and that their influence on patient care is “just a little bit different. Not as hands on,” One subject clearly stated her position by acknowledging that that direct patient care is not included in her everyday job but the patient is still a part of the job. She states:

Remembering at the heart of all of this is the patient. While we don’t see them or have direct interaction with them, they are at home, they are in the hospital, they are in the offices, they are in outpatient healthcare centers and really they are the ones that are being ultimately impacted by the work that we do.

Integrity of Clinical Research

The subjects in this study conveyed an overwhelming sense of responsibility for ensuring the high quality of data supporting clinical research by maintaining the integrity of the clinical research. This quality research supports the true safety and efficacy profile of drugs while ensuring the rights and safety of the study volunteers.

Maintaining the integrity of the study means doing ones “best to try to ensure whatever studies ...are run ethically, that the science behind them is sound and that the subjects’ participation is not in vain.” This process requires “increased compliance for better evaluable data is for the best outcome of evaluation of the clinical trial.” One participant put it clearly:

I can contribute [to maintaining the integrity of the research] by making sure we are conducting safe, ethical clinical trials. Because of my understanding of patient research, what protections need to be in place, in looking at a protocol that makes sense and is safe for the patient but at the same time getting the scientific data we need, making sure we train our sites so they are currently conducting a trial and they are performing ethically.

Where the CRN works along the continuum from bench to product consumer determines, to a certain extent, how participants talked about the goal of the role. For those directly engaged in testing a potential therapy, “the whole goal of our current job is patient safety...keep them out of harm’s way” And this is done through creating ” a barrier to bad science, to people taking advantage of people who shouldn’t be taken advantage of, ” by “making sure the right subjects are being enrolled in the study...that

the data that is accumulated is valid.” For those who might be more on the marketing end one participant shared his perspective, “I feel ethically that when I am giving drug safety data it is as important for me to present the bad as well as the good. My job is to dig through the data, the beautiful and the ugly and if there is ugly, I am going to bring it forward.”

By ensuring the integrity of the research, i.e. that the data being used to decide if a new therapy is safe and for whom it is efficacious, participants felt that they were not just “helping one or two patients but thousands of patients.” The goal of the role situates both the experience of being in the role of a clinical researcher as well as what it means to be a nurse in that role.

Being in the Role of Clinical Researcher

Translational research requires a skilled multidisciplinary team of qualified persons to bring new discoveries to the public. As participants spoke about their role in the pharmaceutical industry they shared stories about how and why they obtained a job in the pharmaceutical industry, how they had prepared for that role, and how they enact their role in this environment. A third theme of Being in the Role of the Clinical Researcher emerged from the data. Within this theme three subthemes clarify the theme including: transition into the role (how they became a CRN), preparation for the role, and enacting the role.

Transition into the role (how they became)

The transition from a traditional nursing role to a role in the pharmaceutical industry did not happen in a planned manner for most of the participants; they “fell into

this role” by “chance.” Some of the participants were seeking a change, an alternative role from their experiences in bedside nursing, and were made aware of roles in the pharmaceutical industry by friends, colleagues, or random chance. Reasons for seeking alternative roles ranged from tiring of the traditional nursing role, to burning out, to seeking better hours and more money.

Subject #13 shared the story of how she came to the pharmaceutical industry by “accident” after a friend submitted her resume:

[It was] by accident. I actually had just accepted a job down in Florida ... a friend ...said give me your resume I will put it in... then [pharmaceutical company] called me about a week later and said we want you. So I fell into the clinical research field.

There was one participant, Subject #21, who was not looking to change roles but applied for a job in the pharmaceutical industry because of a referral from a former coworker.

...she ended up going to work at a pharmaceutical company in our area. It was in a CRA type position and she said ‘you know we are looking for people, would you be interested in interviewing?’ So, just on a whim I said sure with little or no understanding of what clinical trials nurses did at the time. So at the interview, it was a whole new culture for me. I interviewed and they offered me the position and that is how it started.

Some participants had clinical nursing jobs that were stressful and the opportunity to work in the pharmaceutical industry presented itself. Subject #1 shared that working

in the cardiac ICU in a children's hospital was, "a little bit emotionally stressful" and not a situation she was comfortable working in. As a result she was looking for a new opportunity, but not necessarily in the pharmaceutical industry. "I was swapping back and forth between days and nights 50\50. I think everything became tiresome after a while... I was looking for something different." As with many participants, a friend or relative who was working within the industry suggested this nontraditional role to the participant. Subject #1 went on to say, "So 10 years later I'm still at [the pharmaceutical company] and still working in clinical research."

One participant's story reflected another common reality, not knowing what the job entailed:

After 20 years being in the hospital I was ready for a change. I wanted to stay in healthcare but I knew I wanted to get out of the hospital and try something different. I just sent my resume out everywhere and I got an email from (a pharmaceutical company). I had applied for an adverse experience reporting coordinator. I had no idea what it was about.

Another participant, while searching for an alternative to hospital nursing in order to 'give my children a sense of normalcy' and not be " beholden to hospital hours and rotating schedules", responded to an ad in the paper which read "Nurses are you tired of the hospital?" She admitted, "It didn't even say what the job was. And to be honest I didn't have a clue." Money played a role in her decision to transition to the pharmaceutical industry. Based on the advertisement she too did not know what "the

heck they were going to have me do.” stating: I knew that I needed to provide for my family and the pay was better than I was making having patients’ lives in my hand.”

One subject (#7) with a Bachelor’s degree in biology was already working in clinical research in the pharmaceutical industry when she went back to school to obtain a degree in nursing. She explained her decision to obtain a nursing degree by stating, “I noted that I was struggling with medical terminology and it just seemed like the people who had a much easier time with it were people who had nursing backgrounds.”

Only subject # 6 had the career goal of obtaining a job in the pharmaceutical industry stating, “I knew I always wanted to get into pharmaceuticals.” This participant further explained that,

I lived right near [the pharmaceutical company]. It was something that was always present in my everyday life. Every day I thought it would be an awesome company to work for. So it was kind of something that even in nursing school in the back of my head I thought if nursing doesn’t work I can always go to this pharmaceutical company. I could always try to get a job at [the pharmaceutical company]. I also knew the pharmaceutical industry paid more and was more flexible and I saw more career advancement.

Although most of the participants came to the pharmaceutical clinical research role by chance, many stated they always had a strong interest in science, making statements such as “I liked science classes” and “I loved science in school.” Science and interest in the human body was also what pushed some of the participants into nursing “I was interested in science so I opted to choose nursing.”

Preparation for the Role

Because of the unplanned nature of moving into the new role, for most of the participants there was little if any formal educational preparation for the role. Only one participant, Subject #19 received formal clinical research education prior to entry into the pharmaceutical industry by obtaining a certificate in clinical research to facilitate her entry into the industry.

One participant, after exposure to research done by a pharmaceutical company in her specialty, stated her goal was to transition her career to the pharmaceutical industry. That participant, Subject #11, after hearing a presentation about the research done to discover a revolutionary new drug, focused on an educational and career path which would enable her to transition her role. She shared the following:

...when I was working in dialysis very early on in my career there I remember...it was the advent of Epogen® in the dialysis population. [Pharmaceutical company] was a new company and they would come and give us a talk, a presentation about the drug and the research and development behind it and this was going to revolutionize how, the quality of life for the dialysis patient.. A long story short is that it really piqued my interest especially the research and development during the presentation that I said that it sounds like something really interesting maybe I should consider pursuing, going into an area like that. It was at that point in time, I had already started going back to school knowing I would need a more advanced degree, not just an associate degree, to get into the industry. So I went back to school and once I finished my degree that is when I started to pursue

trying to get into the research arena. My first step was to be a research nurse, gaining more experience with that, and then moving over into [the] industry.

All subjects had a minimum of a Bachelor's degree prior to entry into the pharmaceutical industry. All but one subject had at minimum an Associate's degree in the discipline of nursing prior to working in the industry. This participant had a Bachelor's degree in biology when she started her career in the pharmaceutical industry and subsequently obtained both an Associate's and Master's degree in nursing.

The majority of participants indicated that their nursing education provided them a firm foundation for their pharmaceutical role with many participants indicating that the broad base of knowledge and the holistic view taught in their nursing program provided the 'foundation' that helps to "understand the science and understand the clinical implications." As such, nursing education well prepared them for their future roles in the industry.

One participant indicated that "nursing education is such a broad education and is very scientific which is helpful to what I've done over the years in the pharmaceutical company and I would have to say it has helped me for sure in understanding." Participants felt that they were "well educated" and that their nursing education prepared them "to be able to find what we need, to be resourceful...I think that overall we have a strong schooling and I think it is kind of a broad focus in school that helps to translate here." Subject #7 believes her nursing education enables her to be a reference for her pharmaceutical team stating that, "I feel like I am a medical reference person for my team sometimes."

One participant, who works in pharmacovigilance and patient safety, described her ability to use her broad knowledge base to reflect on alternative possibilities:

So shall we say, with my role, I think when you look at some things and think is that a signal? Are we concerned about the case? You use your medical judgment and nursing knowledge can help you see is there another reason that may be is another reason making that person have the adverse event versus the drug or vaccine. Like maybe that patient had a heart attack. Were they just a normal person or were they obese? Did they smoke? Did they not exercise? Were they on other products that could have done that? Did they have a stroke in the past? So you look at the whole picture. Your nursing background and medical knowledge help you with that.

Another participant explicitly connected up her educational background with her job requirements, articulating the value of assessing patients' history and writing up analyses:

I think that my nursing background is really important for actually writing the protocol, as well as understanding the science and the rationale behind the protocol because I have a broad view of the patients and all of their symptoms from my learning of anatomy and physiology. My scope is not limited to one therapeutic area because I understand the interconnectedness of all the bodies systems. Then once a trial is ongoing and throughout the life of the study we begin to look at data, particularly medical history, concomitant medication, adverse experiences, all of those pieces of data that we look at during a trial and of course

review and analyze at the end what we are writing up our results. I think my education is just invaluable in understanding that information.

Although for the most part participants did not receive formal education in clinical research, they all view their basic nursing education as good preparation for enacting the role of CRN within the pharmaceutical industry.

Enacting the Role

Drug development occurs along a continuum starting from identifying a molecule in the pre-clinical phase, progressing through the clinical stage, and ultimately into the post marketing phase. The roles of participants in this study spanned the continuum of research from phase I clinical trials through phase III trials, to dissemination of research results in the post marketing phase. Each participant's role performed a function within the bigger picture of drug research and development in the pharmaceutical industry. Two subthemes help to clarify this subtheme: what they do, and demands and proficiencies.

What they do.

Roles performed by subjects could be grouped into the following categories: drug safety and risk management, clinical trials, regulatory management, and data dissemination. The clinical trials role included clinical trial scientists, clinical trial operators, monitors of clinical trials, and medical writers. The regulatory management roles included regulatory compliance and human subject protections. The data dissemination role included medical information specialists and medical liaisons. The following gives you a sampling of the breadth of what participants in this study do in their role as CRNs.

Drug safety and risk management: All drugs and vaccines must continually be assessed for safety. This safety assessment includes investigational products during pharmaceutical development and marketed drug after regulatory approval. Four of the subjects, Subjects #1, #3, #6, and #10, work for a large pharmaceutical company and have roles involving drug safety and risk management. Although each is responsible for drug safety, there were variations in their roles. All of these subjects speak of looking at adverse events that have been reported for their assigned drugs and vaccines. They look at both individual adverse events and aggregate data in conjunction with other professionals to assess the benefit - risk ratio for a drug. Subject #1 encapsulates the basic responsibilities under this category, reporting that her job involves working with other professionals and teams to closely watch for any safety signals that may result in a label change for the drug:

We basically monitor the safety profile of the drugs and vaccines that the company makes both pre and post marketing... monitor for (safety) signals that may be new to the drug...do aggregate reviews of cases that are reported...discuss whether or not it is worth investigating further, either with clinical data or post marketing data....decide if it needs to move forward... to make a label change.

Participants in this role are expected to organize and run safety related meetings and work with other team members to “gather data and information and summarize it and analyze it and write it so that it can be utilized in...an ad hoc report... (to) a regulatory authority.”

Another participant works within the safety arena but her role is different. She works specifically with vaccine safety, monitoring the safety profile of vaccines. She is also responsible for the implementation and management of a viral identification program for vaccines that identifies if an adverse event was due to a vaccine virus or if it was due to a naturally circulating virus. This program was instituted as part of a risk management plan for two products. She also is responsible for establishing and running the company's pregnancy registry for vaccines. Both of these programs were mandated by the FDA. She is the company subject matter expert for the registries. In her words:

My job title is clinical safety and risk management scientist... my responsibilities include the...identification program...That is a program where we follow adverse events of interest after vaccination with one of the...[live virus] containing vaccines to determine if the adverse event of interest was [due to the vaccine or a naturally occurring]. So for epidemiological purposes it helps to monitor the safety profile of the vaccines.

Clinical trials: There were 12 study subjects whose role function was associated with clinical trials. Of the 12, five subjects' roles were associated with the scientific aspect of clinical trials and six subjects' roles were associated with the operationalization of the clinical trials, while one subject's role was as a medical writer.

The scientifically aligned roles involve jobs where the participants are involved with study design, protocol writing, protocol adherence, protocol deviation review, data review for safety and efficacy, and responsibility for the clinical study report. Two of the five scientifically aligned roles held by Subjects #5 and #21, have a job title of Study

Clinician, which reflects the involvement of a medically trained clinician in the clinical trial process. Subject #5 stated that he would not have gotten his job without his clinical experience stating, “if I didn’t have a nursing degree I wouldn’t be a study clinician. I had to have some kind of medical degree in order to be a study clinician whether it was an MD, nurse, PharmD.”

Subject #21 describes the role of a clinician as a multifaceted role with responsibilities from the inception of a protocol through the final clinical study report,

My role as a clinician is really focused around patient safety, protocol adherence, right from the beginning of the program. You write the protocol... we are the primarily accountable person for drafting the protocol and sending it through the approval process... We are responsible for...proposing a budget for our study... We develop the informed consent...we are accountable for making sure enrollment is occurring as targeted making sure quality is maintained. We have a significant role in reviewing clinical protocol violations and deviations looking at them for effects on patient safety. And then throughout the study it is monitoring patient safety...responsible for the drafting data review reports, clinical study reports... the study clinician is the central control.

Three of the five scientifically aligned roles held by Subjects #9, #11, and #15 were in the early development phase of clinical trials. In this area, the participants describe their roles as managers of clinical trials in phase I. Phase I studies have fewer subjects and a faster time to completion. With this constant turnover of studies, the workload level is high. Subject #15 states that her department does “about 100 clinical

trials a year to advance the early pipeline.” Subject #11 describes the position as a jack of all trades stating:

I work very closely with the clinical director and designing protocols, writing clinical study reports, writing annual safety update reports, working on the logistics for getting studies set up and implemented with the investigative sites, tracking all the regulatory documents that we need to get in house, reviewing all the data, working with data management to set up the database with for our data, cleaning all the data, doing medical review of the data, and working cross functionally with the statisticians, pharmacokinetics, data management, safety people, and regulatory.

Six of the participants engaged in clinical trials were associated with the operational aspect of running later stage larger clinical trials. Their jobs consist of managing these larger clinical trials on a day-to-day basis. This includes budget oversight, tracking enrollment, managing investigational product inventory, interaction with investigative sites, monitoring on-site data for accuracy, and overall implementation of the clinical trial protocol.

Two of the participants, (#16 and #19), are Clinical Research Associates (CRAs) commonly referred to as study monitors. In this role the participants interface on a routine basis with the investigational sites and review the source documentation, such as lab values in medical records, to verify that the data the sites are reporting is accurate. CRAs ensure study participant safety, regulatory compliance, and protocol adherence.

This role represents the pharmaceutical company to the investigative site personnel.

Subject #16 describes the role as follows:

As a CRA I am assigned at least 12 to 15 sites. I am the main contact person between the site and the company or the sponsor for any questions. I help to ensure the site is looking out for patient safety by looking at things remotely as well as on-site visits reviewing charts for unreported and reported adverse events. Making sure the right subjects are being enrolled in the study. I want to make sure that the data that is accumulated is valid data, that the right subjects are being recruited into the study and have met the right inclusion or exclusion criteria, monitor the investigational product, make sure it is being stored properly, administered properly, and that the site is taking accountability for it.

The four remaining subjects, Subjects #2, #4, #7, and #18, have roles operationalizing clinical trials, making sure all components of the study are running smoothly. They have various titles but are the project managers or operational lead for later phase studies. One describes her role as being the “oversight over everybody”, and another echoed the broad oversight piece by stating: “I am responsible for making sure the study starts and stops on time, budgets, just making sure all the little pieces come together.” Another participant talks about how she manages vendors who perform necessary tasks for the trials: “I do management of our vendors, oversight, communicating with the vendors on a daily basis in terms of study conduct, fielding questions from our contract research organization in terms of the processes.”

Subject #17's role is a bit more unique as she is a medical writer. She takes the raw data from a clinical research study and puts it in a format that enables the audience to understand the data. She describes herself by saying, "I am a medical writer and I consider myself a medical scientist." Her role includes writing a document that is related to medical research and it varies according to the assignment she has been given:

It will always be about a document. So what does a writer do? They write a document that is related to medical research... writing can be so many different things. It can be me digesting and interpreting data and writing about what are the results of the study... [or it could be] looking at a protocol, which is like a recipe for clinical trial...It is the use of analytical and intuitive skills.

Regulatory compliance: There are many regulations governing the conduct of clinical research. Three participants in this study had roles working to ensure that all regulations are followed in the drug research and development process. Each of the three had very different roles.

One participant (#8) works in an office of Human Subjects Protection. This position ensures the safety of study participants and that studies are conducted according to federal and state regulations. In this position, she ensures that the documents given to subjects fully provide all information about the study in language that subjects can understand. She describes her role in the drug research and development process as,

...fine-tuning paperwork that goes to the IRB to be reviewed to ensure that it is meeting the right regulatory guidelines and regulatory requirements for acceptability and improvability by the committee.

Another participant works with global safety licensing and contracts. She ensures safety information is collected and shared with all responsible for the safety profile of a drug. If a drug is developed by one company and marketed by another, both companies need to see the complete safety picture of the drug. Therefore, this participant ensures that all safety information is properly shared in compliance with all regulations. She describes her role as,

My focus, my primary responsibility, is to oversee the pharmacovigilance on safety data exchange agreements that are set up between [our pharmaceutical company] and other pharmaceutical companies. So we are making sure the framework is in place in order for that safety data to be exchanged between the companies when they share a product.

The final participant in this role works as a manager in third party vendor management. Many clinical trials are outsourced by pharmaceutical companies to vendors. Her job is to ensure that the vendor meets the company's standards for performing the assigned task.

Data Dissemination: At the end of the clinical trial process the results of the research must be disseminated to regulators, medical providers and ultimately the public to improve the public health. There were two subjects in the study whose role involved communication of clinical trial results.

Both participants train sales representatives, nurses, clinical staff, pharmacists, and physicians on a medical device or therapy, providing clinical information about the product and reviewing promotional materials. One participant described this role as:

I do training for specific vaccines to our national call center and for our sales representatives. I answer professional information requests for specific vaccines, which are questions healthcare providers have about our vaccines. I do research for them. I do literature searches and then provide standard answers for other questions they might have. The third part of the job is to review promotional materials for the specific vaccines for which I am responsible to make sure they are medically and scientifically accurate.

There are many diverse functional roles that nurses perform in the drug research and development process. Each role is unique but yet works within a matrix environment to bring a product to the clinical setting. However, despite the variation in the roles, participants highlighted some similar proficiencies and demands of their roles.

Proficiencies and Demands.

Study participants shared what a typical day would be for them. A consistence response was that the role was very challenging and demanding. The participants indicated that they needed more time to do their jobs, with one participant stating that she “I am responsible for making sure the study starts and stops on time, budgets, just making sure all the little pieces come together.” The busy roles they perform require one to “constantly assess what needs to be taken care of... at this moment and what can wait,” in effect “all day juggling whatever needs to be done” Additionally, the “metric focus of the job makes it difficult to look at other aspects of the trial” and as one succinctly put it “It is a tough role.”

The demands and role functions identified the needs to have certain proficiencies in order to adequately enact the role. Two of the key proficiencies needed for the role were writing skills and analytical skills. Participants spoke of the documents that they had to author. Examples include: protocols, investigator brochures, informed consents, monitoring plans, safety plans, clinical study reports, periodic safety update reports, developmental safety update reports, regulatory submission documents, and responses to regulatory requests. One participant shared that the writing she did in nursing school prepared her for her current role, which necessitates the writing of many documents:

I think a big part of my educational program, I feel like there is a lot of research that went into it all. A lot of writing papers and that kind of thing and I feel like it was a preparation for this role as well.

The medical writer explains that when she writes about an adverse event she is, “writing a narrative about a patient, you are writing in narrative as if you are a bedside nurse...we were trained in writing...I am stating exactly what happened, the good, the bad, the ugly.” Participants also shared that they have authored articles for publication as well as presented at meetings such as one participant who had recently presented a poster at a national meeting.

Another key skill utilized by participants in this study is the ability to analyze data. One participant describes how she must analyze data when she is “digesting and interpreting data and writing about what are the results of the study.” Others repeatedly spoke of how they must look at individual cases of adverse events but also must look at the data in aggregate for any potential safety signal which may emerge.

Being a Nurse in the Role of Clinical Researcher

The role of the CRN working in the pharmaceutical drug research and development environment is a non-traditional role for nurses. Participants in this study indicated that as nurses they brought unique skills and perspectives to the clinical researcher role. The fourth theme that emerged from the data was being a nurse in the role of clinical researcher. Four subthemes demonstrate what being a nurse in the role means: still a nurse, the impact of the nursing perspective on the role, contribution to the discipline of nursing, and the specialty nursing role.

Still a nurse (nurse working in the pharmaceutical environment versus doing nursing)

An overwhelming response from participants was that although they work in the pharmaceutical industry, they are “still a nurse.” Many participants voiced strong opinions about the matter. Most indicated that they used RN after their name on business correspondence or identified themselves as nurse in the work setting when meeting colleagues. When asked if they considered themselves a nurse, responses from most were an enthusiastic yes. One participant stated: “if somebody asked me what I do the first thing I say is I am a nurse. I’m a nurse who works in the pharmaceutical industry.” Others reflected on the notion that a nurse in any role is always a nurse: “I consider myself a nurse. I am a nurse. They always say once a nurse always a nurse. That’s just how I feel. It is part of my life

Seeing oneself as a nurse was connected to having a nursing license. All but two of the participants maintain their nursing license with one participant stating: “I will

never let go of my nursing license. Because I truly will hold on to it. I want to hold onto that I am a nurse in the pharmaceutical profession.”

However, in asserting their identity as a nurse, still a nurse, it appeared that, at least for some of the participants, they may not see themselves as practicing “nursing” in their pharmaceutical role. One participant stated that although she chose to get a nursing degree after working in the pharmaceutical environment “for the information, later on I ended up working *as a nurse* between doing clinical research jobs” Some participants expressed the sentiment that they may someday go back to *clinical nursing* such as Subject #19 when she stated, “I think there is a piece of me that always thinks I’m going to go back to it.” Another participant, who interestingly did not self-identify as a nurse, although she does use the initial BSN after her name on her business card, felt that while she continued to use her nursing skills but no longer felt a part of the nursing profession:

I feel like I am still using my nursing skills. I am still helping patients, just in a different way. But in nursing... I am so far removed from nursing and I don't keep up my license and I don't do the CEU's. I am not really in the nursing profession anymore...I say I was a previous nurse.

The vast majority of participants considered themselves “still a nurse” but some did not necessarily see themselves as doing nursing in their current role. In this study, participants were not specifically asked if they considered what they were doing as nursing so the pervasiveness of this perspective is not discernable.

Impact of nursing perspective on role in pharmaceutical drug research and development

Regardless of whether they see themselves as nursing in this role, participants were able to discuss what they felt was the impact of their nursing perspective on their CRN role.

Participants expressed the sentiment that being a nurse empowered them to put the patient in the forefront both as a study subject and as a patient who would ultimately be using the pharmaceutical product. The nursing perspective facilitated communication with other team members. Participants also shared that in their present role they utilized skills that they garnered from their nursing experience such as critical thinking, assessment skills, flexibility, time management, and prioritization. Three categories explain this subtheme: putting the patient in the forefront, expert communication, and transportable skills.

Putting the patient in the forefront.

Participants shared that due to their nursing perspective they put patients in the forefront of clinical research. They consistently spoke of being patient focused, patient centered and see themselves as patient advocates.

Participants indicated that their clinical nursing experience allowed them to connect with patients even in their present role in the pharmaceutical industry. This connectivity to patients engendered the nurses to always put patient safety first. One participant stated this very simply saying, “I think that patient safety and advocating for the patient is kind of in our, ingrained in us...nurses in general seem to be very compassionate.” Participants expressed that patient safety was their primary

responsibility: “the whole goal of our current job is patient safety first.” Another participant indicated that being a nurse guided her thinking for not only subjects in their studies but for patient who will be using the product saying, “I think when you’re a nurse, patient safety is the most important thing. While you are not actually taking care of patients here ultimately what you do impacts the patients who are taking the products.” Indeed, as one participant put it: “We own patient safety. So that is something in the back of your mind that you make sure that is at the heart of all you are doing. That is what matters.”

Participants also shared that as nurses they were able to look at clinical study patients with a holistic view seeing more than the disease under study: nurses “bring together the holistic view of a clinical setting, the patient perspective, the caring for a patient perspective, the science, understanding the health and the biology of the science.” The participants felt that their nursing background allowed them to pull together the patient, their environment and the research as one participant explained:

I think it is very important because we have, some more than others, we have a lot of background knowledge in therapeutic areas, disease processes as well as the patient care part of it. We put the two together. We might be thinking what is going on with the patient and the family sometimes as well as the disease process.

One participant indicated that the one thing nurses bring to the table that other disciplines do not is “reality,” with a focus on ‘real patients.’ As one participant stated: “You can’t help but realize these are real patients.” While another talked about the need to put yourself in the role of the patient, stating:

I think the way my nursing helps influence the job I do now is I can put myself in the role of the patient and because I have cared for them and when I read a protocol, ... in a 20 year career I have come across every diagnosis that could be out there, and I usually can put myself in the perspective of that patient that could either benefit from this type of trial or certainly from the medication if it would get approved. So I think always being able to recognize the impact that this would have on somebody's life and take it away from the lab perspective or just sitting and looking at looking at data listings. There is always that connection to the patient.

Participants shared how they were patient focused when they were looking at patients as study subjects, being able to understand the burden of the study on the patient: "I also understand that even though I don't see the patients involved in our clinical trials I understand who the patient is and what they are going through because I take care for patients." Another participant gave an example of how she put into practice that knowledge of the patient perspective:

You can read the protocol from a scientific level but you can tunnel and drill it down to the patient and we are able to make major impacts from just wording on informed consents or decision-making on the size of the product that they're going to take. Is it easy to swallow? Did anyone think about that upfront? Well, I have experience on placebo capsules made way too big and elderly patients couldn't swallow them on a previous study that I worked on.

Another participant described the importance of the patient's perspective in exploring subject burden:

Understanding what patients or even healthy subjects go through to get through a clinical trial to understand the procedures and some of the science behind what we do and developing the treatment plans and the flowcharts in the study and really knowing what is a reasonable, how many specimens can they have drawn, how much time does it take, what does it feel like to do those things.

Many study participants also spoke of understanding patient views and needs of the patient who would eventually take the drug in the clinical setting because of their nursing experience. One felt that she is able to "view things from the eyes of the patient." and another stated:

We are kind of advocating for those future patients who may receive the drug or vaccine...I think your mindset as a nurse is always to be a patient advocate. You know whether they can advocate for themselves or not...you are working with the team but I feel like the nurse does often assume the role of helping to advocate.

This advocacy includes: *treating the entire patient from not just awareness but to finances, how is his patient going to inject themselves when they have four small children around and the needle availability. Taking into view all these concepts, a nurse is a very unique piece that is essential making quality clinical research even better.*

Participants were able to have a holistic view by seeing more than a disease process that the product being tested addresses. They could understand the burden of the

study on the patient. They could understand clinic patient views and needs. Participants nursing experience allowed them to connect with study patients, prioritize patient safety and advocate for patients, both as research subjects and as product users.

Effective Communication.

Participants shared that due to their nursing perspective and their clinical nursing experience they, in their present pharmaceutical role, were able to provide enhanced communication in many situations across many disciplines and demonstrated a willingness to speak up. One participant stated that her nursing background gave her a “foundation” for effective communication and “*what makes our role easier is effective communication.*” Communicating across disciplines was critical skill in clinical research and one that nurses excel at:

There are a lot of doctors in clinical research and knowing how to work with doctors, knowing how to communicate with doctors is very valuable. That is sometimes you really need to work with them in a hospital or office type setting to really get it...being able to speak their language.

One participant spoke of being able to communicate with other members of the research team such as study coordinator because she is a nurse explaining, “I just think that nurses have a better relationship with study coordinators because lots of them are nurses. Even when I am speaking with the physician, I think it does go a long way when they realize I am a nurse.” Another spoke of a similarity between clinical nursing and working in the pharmaceutical company, stating:

[As a nurse] You have to be able to communicate with your colleagues, with patient's families, with the physicians, with social workers and so on and so forth and know how to work in a multidisciplinary team and that is what is also required in the pharmaceutical industry... You have to be able to communicate and all these characteristics apply directly to working in the pharmaceutical, in a group.

One participant shared that she is not afraid to speak or question physicians because of her nursing background stating:

As a nurse working in the research field I was never afraid to approach physicians and I find a lot of people are, even to question something... That is the kind of thing I think nurses bring to clinical research field.

Subject #8 sums up communication, the nursing perspective, and the impact of both on clinical research: "Communication that we are taught as nurses, how to communicate effectively without judgment, be supportive. Those are all things I have to do on a daily basis... If there is a research proposal or something that is being presented that is not appropriate, I have a voice and I use it. And that really does influence what we do."

Transportable skills.

Subjects spoke of the value of their clinical nursing experience telling of how the skills they utilized and sharpened in the clinical setting such as collaboration, critical thinking, analytical skills, assessment skills, quick thinking, being detail oriented,

flexibility, time management, and prioritization were now valuable assets in their present role.

A participant who had worked in critical care felt the most important skills she brought from her nursing experience to her present role was the ability to critically analyze and provide attention to detail. Another echoed this saying: “You have to be able to critically think without a lot of emotion. It is the assessment of what the situation is, the problem is, being able to critically think it from point A to point B rationally and logically. They are skills I use every day.”

Another participant indirectly addressed the skills embedded in the nursing process: “We have identified the efficiencies and then we are creating solutions and then we are implementing those solutions so it is kind of parallel to the [nursing] care plan.” One participant believes her ability to quickly assess a situation in her current role comes from her nursing experience stating, “I think you are constantly assessing situations. I think that definitely comes from nursing and being able to walk into the room and assess the conversation, the tone of the conversation. If what we are trying to discuss, if what we are trying to work out, if the conversation is going in the right way, constantly taking the temperature, assessing the tone of what is going on around you.”

Participants also discussed that their nursing experience enables them to more effectively prioritize the workload in their current role. One participant stated that “prioritization, leadership and communication” were nursing skills that prepared her for her current role and another indicated the need always to reprioritize, be able to juggle many things and reprioritize.”

It is evident from study participants’ expression of their feelings that being a

nurse and the skills they learned and utilized in providing patient care contribute greatly to their ability to perform their role in the pharmaceutical drug research and development industry. Indeed, these nurses value and rely on the knowledge and skills they gleaned from many years of practicing nursing.

Contribution to the Discipline of Nursing

In responding to the question on CRNs contribution to the discipline of nursing, few really addressed the contribution to the discipline per se. One participant felt that the discipline benefits from her being an ambassador for the discipline stating:

I believe my nursing profession benefits from me being in such a role being that I have expanded the role of nurse into industry that possibly was more scientists and again more business related whereas I bring a unique piece of nursing where we are taking care of the entire patient not just the disease.

The vast majority of participants indicated that the role of the CRN offered another career option for nurses stating, “it is another avenue that the nursing profession can feed into.” One participant took a very practical look at nurses in the pharmaceutical industry stating, “It gives you another well-paid development outlet. Also as nurses get older and can’t perform the physicality of bedside nursing, it gives a logical [next step], it allows you to take your experience and continue to function in some way in the sciences and get paid for that.” Additionally, for younger nurses it shows “that there are so many things you can do with your nursing degree. Not just direct patient care. That your knowledge base is a launching point for so many different avenues of use and this industry is one of them.” However, participants shared that it is a little known option for most nurses:

I think that one thing that is very nice about being a nurse is there are different opportunities. When you go to be the nurse you can be an ICU nurse, you can be a floor nurse, you can be a nurse educator, or you can be a school nurse, or you can work for insurance companies, or you can work for a pharmaceutical company. So I think that the opportunities here are just another avenue that a nurse can do.

When discussing the contribution of CRN to the discipline, study participants also talked about the reasons they stayed in the role. The most common reasons were: the “flexibility for work-life balance” and that “the hours are better. The pay is definitely better. As I am getting older it is definitely easier to work in an office than it is to work at the bedside.”

One participant shared what working in drug research and development has meant to her over her career providing her with many opportunities that she may not otherwise have had:

I have to say I've been in this position for 17 years and I am 56 years old and looking for that retirement phase. I think that is a very practical reason why I am staying right now. I have put a lot of energy into learning this role and I've had a lot of opportunity here that probably never would have gotten in a traditional nursing role in a hospital. Working with some incredibly brilliant academic people, the ability to travel around the world for this job. I go to places I never would've gone in another role. Just growing professionally. I have learned how to give presentations. I have been part of multiple publications. I have presented at a

major world conference. I was part of another program and an abstract was accepted for oral presentation at a Congress. Those types of experiences are very gratifying. I am very glad I had that. I don't think in my role as a critical care nurse I would have."

Participants also shared their broad perspective of how their role contributed to the overall drug research and development process. The study participants indicated that they played a small part in the huge process of pharmaceutical drug research and development. One participant summed it up by saying,

There is so much that goes into pharmaceutical development, there are so many pieces to the puzzle I think it is difficult to have a huge impact on the whole process, on the processes as a whole but I think that everybody has, everybody plays a role in it .

Participants also expressed pride and satisfaction in working on drugs that eventually help patients, and that it was a privilege to contribute work on drugs that are now available to the public. One participant shared this:

I worked on two compounds that ultimately went forward and were approved by the FDA so people are taking them right now and making their day-to-day life easier. That is a privilege that I don't know if most people have...helping people.

However, some participants indicated that although they feel at times that they have made a contribution, it may be hard to realize it on a daily basis. One participant explained:

There have been times when I feel like I have made a significant contribution. But there are so many players, so many different people on the team all making contributions and sometimes is difficult for me to see what my contribution has been. Every once in a while I feel like I make a real contribution. Most of the time, no.

Nevertheless, others presented a very positive view of their contributions health to the public through their roles in the pharmaceutical industry stating, “I feel very responsible for bringing quality products to the medical community in a proven way and in the safest way that patients will benefit from them.” One participant compared her contribution as a clinical nurse (direct patient care) with being a CRN saying,

I always believe in the adage that in nursing you are taking care of one patient or two but in the pharmaceutical industry you are have a part you are a part of that whole process to get one medicine out there to help hundreds to tens of thousands to millions of people so I feel that like being in the pharmaceutical industry I can help tens of thousands to millions of people instead of just those one or two people or five people that I effect on a daily basis like taking care of patients.

Specialty Nursing Role in Clinical Research

Although most participants identified themselves as nurses who work in clinical research, they did not necessarily see themselves under the specialty name Clinical Research Nurses. Indeed, many had never thought about it: “I guess I never really before thought about it as a specialty. I’m glad to know that it is.” Although most participants wanted to be part of a research nursing specialty there was not a consensus about the

appropriate title for nurses who work across the continuum of the drug research and development process. One participant thought the title Clinical Research Nurse was, “A good descriptor. I think other descriptors are nurse who works in pharmacovigilance, or drug safety. I don’t think there’s an appropriate bucket to do that. I think clinical research nurse is a better way to summarize what we do. We do research and I think that’s the best way to summarize it.” Another participant also feels part of the research nursing community but was unsure about the label CRN stating,

I guess more so as a clinical scientist. I don’t know if those terms are synonymous because I guess there are so many different areas a nurse can be in clinical research. You can be at an investigator site or a coordinator or you could be working over in safety getting the reports, dealing with med watch and FDA reports, or you could be in my role, or you could be a field monitor. So, if that were to become a formal title, then yes, I would consider myself to be a clinical research nurse.

One felt that the title CRN did not truly fit her job description stating, “I guess I would not call myself the title but I think I am part of the umbrella.” However, when asked to think about whether what they do should be a nursing specialty, one participant demonstrated her ambivalence when asked if she considered herself to be a CRN:

I don’t think so. No. I don’t think I ever thought about it that way just because to me...I should back up. To me I was never in the investigative side. I was more in the post marketing side but now that we are having this conversation, the words

are coming out of my mouth, now I think I should actually rethink. It is all research whether it is at the onset of the product or later in the product.

Participants considered themselves members of the discipline of nursing working in a specialty of clinical research. However, they could not clearly identify a title that would describe the specialty or encompass all nurses working within the nursing specialty.

Summary

This chapter described the four main themes which emerged from the data: Work environment; the goal of the role; being in the role of clinical researcher; and being a nurse in the role of clinical researcher. These were common themes among all 21 study participants. The work environment of nurses working in pharmaceutical drug research and development is a non-traditional setting for nurses and one that is business rather than care centered. It is also one that undergoes rapid and significant changes and requires interdisciplinary teamwork to achieve the common goal of getting a product to market. Employment in this setting means nurses do not provide direct patient care; rather the integrity of clinical research becomes the goal of their role.

Being in the role highlighted the many varied roles that nurses perform along the drug research and development continuum as well as the transition process from hospital/community nursing to working in the pharmaceutical industry.

All participants viewed themselves as nurses working in the pharmaceutical industry and highly valued the knowledge and skills gleaned through their nursing career. As nurses, they feel that they are patient advocates, 'putting the patient in the forefront.' However, the question of whether what they are doing is considered nursing still remains

unanswered.

Although few participants had considered, until asked, what they contributed to the discipline of nursing and whether their role should be a nursing specialty, all felt that: 1) this role is a good career path for nurses outside of traditional clinical practice and 2) it should be a nursing specialty but could not agree on an appropriate title for the specialty. One participant voiced the sentiment of many participants in her closing comments:

I think just that nurses play such a huge important role in everything that has to do with healthcare. We need to encourage that. We need to recognize that and encourage it. Whether that is in Pharma or device manufacturing or [a] mom and pop research idea from infancy to execution. I think that it is important. I think we all need to foster that.

Chapter V: Discussion

The purpose of this qualitative research study was to explore and give voice to the role experiences and perceived impact of the Clinical Research Nurse (CRN) (other than the study coordinator) who works within the pharmaceutical drug research and development environment. Using the theoretical framework of role theory, this researcher worked to elucidate the experiences and perception of nurses in these non-traditional roles. The interviews provided an in-depth view of how study participants described their current pharmaceutical industry roles, their role experiences and functions within the pharmaceutical company, and what it means to be a nurse in that role. The interviews also allowed subjects to speak of their nursing identity in a non-traditional specialty

nursing role and their perceived contribution to the drug research and development process.

Four themes emerged from the data in this study: pharmaceutical work environment, the goal of the role, being in the role of a clinical researcher, and being a nurse in the role of a clinical researcher. These findings will be discussed in this chapter.

Pharmaceutical Work Environment

The pharmaceutical drug research and development process brings many new treatments to the clinical setting to improve the standard of health care for the public. A multidisciplinary team works together in this industry to produce new drug therapies working along a continuum from discovery in the lab through clinical trials to a marketed product. This research and discovery process occurs explicitly within a business focused, market driven environment, which is quite different from hospital/clinic environments traditional to nursing practice. The pharmaceutical environment was the first theme to emerge from the data and it situated all of the other themes in this study. Previous research into both the role of study coordinators and non-study coordinator roles indicated that this was a non-traditional environment for nurses. For study coordinators this was not a major theme of participants' discussion (Mueller, 2001; Fisher, 2006). Transition from clinical nursing to this non-traditional role was a theme noted in Shannon's (2011) and Kavalam's (2010) dissertations.

Participants described the corporate environment and how different it is from the traditional clinical role of nurses in an acute care setting. The participants voiced that their work is strictly business oriented. Although many participants stated that they help

to bring products to market that will benefit the public health, they are also aware that they help the pharmaceutical companies make a profit. They found the work environment to be more than just the medical discoveries but also about the business and the marketing of pharmaceutical products. Within the development and marketing atmosphere of the pharmaceutical industry, business acumen is a key requisite for performing their role. The business skills needed in their current role were not necessarily those needed or utilized in the clinical setting. Participants shared that they quickly learned and adapted to the business model of the pharmaceutical companies.

Due to the business nature of pharmaceutical companies, the participants function in a dynamic, constantly changing environment. This environment leads to frequent changes in roles for many of the participants. The changes could be due to company mergers, restructuring, layoffs, or the end of a project which was planned or precipitated by unfavorable study results. These finite roles mean that job changes are common within the industry. CRNs had to switch projects, roles, or even companies to stay employed. This constant turnover mandated that participants in this study had to be flexible. They had to adapt to new situations, new team members, and new expectations of the role. With the constant change, study participants voiced that there was a constant need to learn. They had to learn new therapeutic areas and the new science behind a new drug, as well as new processes and procedures as they switched jobs. With the need to always be learning, this role attracts nurses who describe themselves as lifelong learners and who enjoy the constant challenge of mastering new knowledge. However, the unstable environment was also a point to be considered when working in the industry. Many subjects had numerous positions in the industry highlighting the unstable employment in

the role. This role requires CRNs to be able to adapt quickly to new environments and new projects. Nevertheless, most of the participants seemed to tolerate well the changing environment as they moved from one employment opportunity to the next.

This business focused work environment was not a focus in the literature describing the role of the study coordinator. The literature on the study coordinator role mostly describes nurses who work at investigative sites or at medical centers. The business setting appears to be unique to the CRN working in a role other than the study coordinator role.

Working in the pharmaceutical industry also entails working in a multidisciplinary environment. Nurses in the pharmaceutical drug research and development environment must work with physicians and pharmacists as they did in the traditional nursing settings but must also work with biologists, statisticians, epidemiologists, bioinformatics experts, and regulatory specialists in a matrix environment. In working with so many disciplines, there is a need for CRNs to be excellent communicators with the ability to listen, understand, and interface with many highly educated and highly skilled professionals in various disciplines. Nurses in this environment must not only communicate well but must appreciate the value each team member brings to the process. Current literature describes study coordinators practicing with autonomy in decision-making and problem solving, while simultaneously working within a team setting. This is consistent with the findings from participants in this study who work in the pharmaceutical industry.

As study participants shared their work environment, they also voiced why they did their job. They shared the belief that the goal of their role within this environment was to ensure the integrity of the clinical research.

Goal of the Role

The pharmaceutical drug research and development process' ultimate objective is to develop new or improved therapies that will aid in the prevention and treatment of illness (Linberg, 1999). Participants in this study repeatedly indicated that ensuring that the research was done correctly and supported by high integrity data while protecting research subjects was the goal of their role in the industry. They conveyed an overwhelming sense of responsibility for ensuring the high quality of data supporting clinical research. Their role was to help ensure that new drugs, which may eventually impact tens of thousands or more people, are safe and effective.

Although the nurses in this study worked in a business environment and not at the bedside, they still conveyed that they impacted patient care albeit in a different manner. The CRNs in the pharmaceutical industry do not directly care for patients; rather they work toward the betterment of the global public health by providing safe and effective new treatments. Study participants articulated their view that they care not only for a few patients but for millions of patients who may someday benefit by taking a product developed by the pharmaceutical industry. These participants noted that by ensuring the integrity of clinical trials all patients will benefit by receiving safe and effective medications. Therefore, the role of the CRN ultimately affects the public health through their contribution to the clinical research process.

The goal of the role as stated by participants in this study is consistent with the core values of the CRN role as stated in the Oncology Clinical Trials Nurse Competencies (2010). The Oncology Nursing Society (ONS) core values included: advocate for patient safety and trial integrity, advance evidence based oncology care through scientifically sound research and recognize the unique value that the professional nurse contributes to the successful conduct and outcome of clinical trials. Although these core values were written to describe the role of the study coordinator, they accurately describe the core values for CRNs who work in the pharmaceutical industry. Additionally, the nine functional competencies described by the ONS (2010) for study coordinators were tasks also performed by participants in this study. These included protocol compliance where pharmaceutical CRNs in writing protocols made sure that they were reasonable in terms of subject burden, informed consent process where participants made sure the informed consent form (ICF) was written at a level for patient understanding and patient recruitment where pharmaceutical CRNs provided the written materials allowing for eligible patient to know about the study. Other functional competencies were clinical trials related communication, management of clinical trial patients, documentation, ethical issues, financial implications, and professional development all of which were performed by study participants in either a direct or indirect manner.

Being in the Role of a Clinical Researcher

In talking about the environment and the goal of their work, participants spoke of how and why they moved into roles in the drug research and development environment,

how they were prepared for the role and how they enacted the role of clinical nurse researcher.

Most of the participants were led to the role by chance. They had not planned for this career but rather learned of it by chance from a colleague, relative, or an advertisement. All had practiced nursing in more traditional environments, hospitals and the community and they voiced frustration with these more traditional roles for nurses. Common concerns were long hours, off shift hours, money, and the lack of a flexible schedule. These concerns with their former nursing roles were push factors that helped them make the choice to move into the pharmaceutical industry. Participants shared that nurses in the pharmaceutical industry encouraged other nurses to make the move into industry but that they had not been aware of this career option while training to be a nurse.

Although they experienced a random method of career selection, most felt the career choice was a good fit for them. Although some spoke of someday returning to clinical nursing, none of the subjects were actively seeking to return to their former roles and all seemed happy with their decision to move to the pharmaceutical industry. Indeed, participants indicated that they wished they had known of the option at an earlier point in their career.

A common thread throughout the interviews was that subjects voiced an interest in science as well as an interest in caring for people. Subjects indicated that a role in the drug research and development environment allowed them to utilize their scientific knowledge while still caring for people. The notion of caring for patient moved from

caring for individual patients to caring for a larger community of patients by providing new treatment options.

The participants were all highly educated and worked with colleagues who were also highly educated. This was rewarding for many of the subjects as it allowed for intellectual stimulation in their roles. Intellectual stimulation was identified by study coordinators as one of the best aspects of the job (Roberts, Eastwood, Raunow, Howe and Rickard, 2011). Participants also felt that education was valued in the pharmaceutical environment as evidenced by role requirements and the willingness of companies to provide financial reimbursement for education.

Because most of the participants “fell into the role” few had any formal preparation for their roles in the pharmaceutical industry. However, all stated that their nursing education had well prepared them for their role in the pharmaceutical industry by providing them with a broad base of knowledge across many therapeutic areas. Although clinical research was not included in the nursing curriculum, for most, the knowledge learned about anatomy, physiology, pathophysiology, and the social sciences prepared them for their jobs. There were some participants who would have liked more classes on basic cellular biology and the clinical research process but they indicated that one would be able to gain this additional knowledge by furthering one’s education or by on the job training. The broad base of knowledge provided by nursing also enabled study participants to gain employment at numerous points along the drug development continuum from phase I to post marketing in the drug research and development process.

Kavalam (2011) in her study of nurses who transitioned from the traditional bedside staff nurse roles into pharmaceutical industry roles indicated that nurses ‘took stock of their current work situation’ and then “took action” to move into the pharmaceutical industry. Participants in this study did take stock of their current work situation but “fell into” the pharmaceutical industry role by chance. Consistent with Kavalam’s study, participants adapted to the new environment after leaving the more traditional nursing roles. Likewise, participants’ description of their transitional process substantiated the first two concepts of Shannon’s (2011) theory of Immigrating in Nursing, becoming disillusioned and acclimation into the corporate role.

Employment in the pharmaceutical industry was not a well-known option to many prior to obtaining their position. A few subjects voiced their opinion that this career option should be conveyed to nursing students. The flexibility to work from home, consistent standard working hours, increased pay, as well as optimal work life balance provided by these roles was an appealing benefit to most subjects.

The role functions for study subjects ranged across the continuum of drug research and development. There was a great diversity among roles, role titles, and role functions. This role diversity is consistent with the literature on the CRN role (Eherenberger & Lillington, 2004; National Council for the Professional Development of Nursing and Midwifery, 2008;). There were differences in roles among employers in the pharmaceutical industry with each job being slightly different. Not only was there variation in jobs but also variation based on the projects within the role function. Participants worked in many phases of pharmaceutical development and marketing

including drug safety and risk management, conducting and monitoring clinical trials, ensuring regulatory compliance and dissemination of data.

Participants conveyed that the roles in the drug research and development environment were about the research process and the outcomes. Participants employed in the drug safety and risk management role all appeared to have similar responsibilities addressing the safety of pharmaceutical products. Although each role varied slightly, all subjects conveyed a deep-rooted responsibility for monitoring the safety of the assigned products as this will affect each patient and every patient who will take the drug. These subjects appeared to have a great responsibility in detecting possible safety signals that could change the benefit: risk ratio of a drug. They were keenly aware of the implications the drug safety profile has for the patient and also the implications a change in safety profile has for the business.

The majority of participants were involved in clinical trials roles. For those who worked in clinical trials, this study's sampling of subjects exemplifies the diversity of roles in clinical trials as the nurses were employed throughout the continuum of clinical trials in the drug development process each contributing in a different way. Within the industry, nurses are perceived as scientists and work in collaboration with other scientifically oriented disciplines to design, implement, and conduct scientifically sound clinical trials. The nurses in a scientific role are key team members, adding their knowledge of disease processes and the health care system into protocols that operationalize the clinical trials and to ensure that the data collected was accurate and verifiable. They credited their nursing education and experience for fostering their ability to organize data, and to look at and assess data in a timely manner all of which was

needed in their present role. Participants indicated that as nurses they know how to get things done without compromising quality which is an important skill to have when conducting clinical trials.

Compliance with all health authority regulations was important to all participants as this is a critical factor to ensure the quality research - the goal of their role. In order for a drug to be approved, all studies from pre-clinical to phase III clinical trials must explicitly follow all health authority regulations. As nurses, CRNs are keenly aware of the need to follow all federal, state, and institutional regulations.

Data dissemination through reporting results of studies was a responsibility for participants involved in clinical trials. However, nurses who worked more towards the marketing end of the continuum had a more formal role in data dissemination through publications and presentations to the medical community.

Meeting the requirements of the varied roles was very demanding requiring long work days, travel, and business acumen. In these roles, CRNs must be able to constantly juggle all the demands and meet strict enrollment metrics and timelines. Participants conveyed that roles in the pharmaceutical industry are not easy and that to perform their roles there are two important proficiencies, the ability to write and the ability to analyze data. These skills were needed in order to author necessary documents, such as study protocols, and convey clinical trial results. Writing was essential to the majority of roles in the industry. The writing of documents or summaries was addressed by almost all participants in this study. Many also spoke of analyzing aggregate data to assess clinical trial results or to look at safety data for products. The need to be proficient in these areas

is very important to performing a role in the pharmaceutical industry. Participants repeatedly indicated that their role was just one of many functions necessary to bring a drug to the public. They were just a small part of the big picture but yet each was very proud of the part they played in helping improve the public health.

Being a Nurse in the Role of a Clinical Researcher

The role of the CRN working in the pharmaceutical drug research and development environment is a non-traditional role for nurses. Not all clinical researchers are nurses; however, participants in this study indicated that as nurses they brought unique skills and perspectives to the clinical researcher role.

Overwhelmingly, participants thought of themselves as “still a nurse.” Being a nurse was integral to their sense of self and a key part of how they define themselves. Pride in being a nurse was evident for all participants in this study. Never letting go of being a nurse was also evident throughout the study. However, there was a tension between ‘being a nurse’ and ‘nursing.’ Although I did not ask the participants if they were ‘nursing’ in their CRN role, it was clear that participants saw themselves as nurses who worked in the pharmaceutical industry but not necessarily “doing” nursing. This tension brings up a larger question of what is ‘nursing,’ especially among nurses who are not providing direct patient care. The American Nurses Association’s (ANA) broad definition of nursing and scope of practice encompasses those who may work in different roles, settings, and serve different populations (ANA, 2010). Therefore, is any job a nurse does ‘nursing?’ Conversely, if one does not practice in a ‘traditional’ setting, such as a hospital or clinic, but one in which the focus is on research, is this not ‘nursing? The Irish National Council for the Professional Development of Nursing and Midwifery (2008),

defined the CRN as “nurses or midwives involved in research for purposes other than nursing or midwifery.” Therefore “being a nurse” or doing “nursing” in the role of the CRN in the pharmaceutical drug research and development environment may be a question for future research and perhaps for other non-traditional roles for nurses. One of the key findings in Kavalam’s (2011) study was that nurses felt truly valued in the pharmaceutical industry but not in the traditional nursing role. Participants in this study shared how they felt supported in their present job but did not really indicate that they felt devalued in their traditional nursing roles. Indeed, they did not seem to even think about how they might be perceived in clinical settings. Regardless of whether they were ‘nursing’ or not, participants in this study discussed how they felt being a nurse impacted their role as a clinical researcher. Most felt that being a nurse allowed them to look at clinical research through a different lens, a nursing lens. They indicated that it was they, as nurses, who helped to put the human face on subjects in clinical trials and on the patients they were eventually helping with newly developed drugs. Study participants considered themselves to be patient focused and patient advocates which is consistent with current literature describing the role of the study coordinator (Nagel, Bender, & Bonner, 2010; Poston & Buescher, 2010). However, unlike other research, participants advocated for two different sets of patients, patients as research subjects and patients as ultimate consumers of the pharmaceutical product.

It was clear that participants’ roles were not about direct patient care but rather about the business of drug development. Participants conveyed this fact in their interviews but added the qualifier that the greater goal was to help many people not just a single patient. Participants in this study believed that they as nurses had a holistic view,

seeing more than the disease. They saw the entire patient as research subject, understanding his / her views and needs. They were able to understand the burden of participating in a clinical trial from the patient's perspective and convey that to the pharmaceutical research team. The overwhelming sentiment voiced by all participants in the study was that human subjects and patient protection was always forefront in their minds. However, being a nurse, participants also concerned themselves with the thousands of potential patient who could one day use this drug, considering issues of drug delivery, such as size of pill, frequency of testing needed to evaluate safety. They shared that nurses were the key team members who always thought of the patient first in the pharmaceutical industry. CRNs were the advocates for the study subjects and the patients.

Participants also credited nursing with enabling them to have good communication skills in many situations and across many disciplines, stating they were never afraid to speak up. Being able to listen, understand, and effectively communicate with many other disciplines as well as with patients was a key asset of CRNs, as it enhanced group dynamics enabling pharmaceutical projects to move forward. Communication skills also helped participants to connect with clinical study sites, as they could empathize with study coordinators and speak as a colleague with physicians.

As such, participants acknowledged the value of their clinical nursing experience telling of how the skills they utilized and sharpened in the clinical setting were applicable in the role of clinical researcher. These skills such as collaboration, critical thinking, analytical skills, assessment skills, quick thinking, being detail oriented, flexibility, time management, and prioritization were now valuable assets in their present role. Repeatedly, subjects referenced these skills which enabled them to have enhanced

performance in their current role. While, participants indicated that their nursing education provided them with the knowledge, it was their clinical experience that provided the added value of having a nurse in the pharmaceutical role.

Participants were asked about their contribution to the discipline of nursing and it was interesting to note that most never thought about how they contributed to the discipline. Some shared that it was nice to have an opportunity to give voice to the contribution of nurses in the industry as they believed this nursing role needs to be recognized by all in both the discipline of nursing and the pharmaceutical industry. However, participants in this study felt that in their non-traditional role they increased the awareness and respect for professional nurses in global industries and that this allowed for a greater visibility of what nurses can contribute to scientific research and medical knowledge.

In describing their present roles, participants in this study depicted roles that would fit into the five dimensions within the clinical research nursing domains of practice as identified by the National Institutes of Health Clinical Center (CRN, 2010²). Participants all spoke of how they directly contributed to the dimensions of study management, human subjects protection and contribution to the science, while their contribution to clinical practice and care coordination and continuity was indirect. Findings from this study indicate that CRNs working within the pharmaceutical drug research and development environment practice with the domain of clinical research nursing.

Participants in this study did not elucidate what they perceived their contribution was to the discipline of nursing nor their relationship with nurses in more traditional roles. The literature does describe how study coordinators perceived a lack of recognition from nursing colleagues (Roberts, Rickared, Foote, & McGrail, 2006). This perspective connected with the question of whether CRNs should be a specialty nursing role. According to Deininger (2008), nursing specialties involve education, knowledge, skills, abilities and competence developed through experience in a specialty area of practice. CRNs in this study describe how they met these criteria to be a nursing specialty. The specialty nursing role of clinical research is unknown to many in disciplines outside of nursing, to the discipline of nursing itself and unknown to even some nurses who enact the role including some study participants. Study participants also saw the need to expose nursing students to this nursing specialty as a possible career option and to inform them of the contribution of nurses to the drug development process.

Although most participants agreed, when asked, that there should be a nursing specialty for those who work in the drug research and development community, contrary to Shannon's (2011) theory they did not always think of themselves as working within a nursing specialty. Even though they all articulated that they were "still a nurse," none were actively working to actualize a nursing specialty role. Indeed, there was no consensus on a title for this role. Subjects did not want to confuse their current roles with the role of the study coordinator at the investigative site who also had direct patient contact. Yet, they saw a need for a nursing specialty that defines who they are and what they do.

Literature on the role of the study coordinator describes role boundaries and conflicts where nurses at times find it hard to deviate from standard of care and get in the “research mode” (Davis et al, 2002, p.414; Mueller, 2001). Participants in this study as CRNs in the pharmaceutical drug research and development environment did not seem to experience role conflict, perhaps because they are not involved with direct patient care. However, the literature on the study coordinator role does state that the critical roles of the study coordinator include: patient advocacy, study participant advocacy and study advocacy which is consistent with what participants of this study describe as advocacy roles of the CRN working in the pharmaceutical industry (Davis et al, 2002).

The Oncology Nursing Society (2010, p.5) defined the CRN as “specialty nursing role requiring a unique framework of knowledge for working with patients involved in clinical research trials.” Participants in this study considered themselves to be part of the nursing clinical research specialty but yet would not necessarily fit into the ONS’ definition for this specialty. Perhaps expanding the definition to state “working with or for patients” would allow for nurses working in the pharmaceutical industry to be included within this specialty.

The four themes which emerged from the data are somewhat similar to themes which emerged from Mueller’s (2001) study of 38 nurses working as study coordinators in clinical research. Although the setting and role are different, the themes of workplace assimilation of skills and knowledge by nurses, strategic interactional involvement of nurses with other on the clinical research team, and the need to formalize the nurse’s role through specialty training, were similar to the findings in the study of pharmaceutical CRNs. The theme of development of occupation processes with the creation of role

boundaries and definition was not found in this study as the pharmaceutical roles and processes are defined by the pharmaceutical companies. However, other similarities between the studies include: interaction with other professionals, seeing their role as a patient advocate, and utilizing their nursing training and experience. However, what was unique to this study was the clear articulation of the business environment/world of pharmaceutical drug development and marketing, which was different from the world of clinical practice. This environment underpinned all of what the participants experienced in this non-traditional role for nurses, and may be why themes identified in studies on the study coordinator role did not emerge. Nurses in the CRN roles explored in this study do not ‘touch’ patients, however they clearly put patients’ health and well-being ‘in the forefront’ of their work in the pharmaceutical industry.

Relationship of findings to Role Theory

Role theory was used in this study to provide a contextual foundation and framework. Role theory addresses the social concept of characteristic behavior patterns or roles. The role occupant and the role sender interact to establish the role expectations. The role occupant in this study is the CRN working within the drug research and development environment and the role sender is the pharmaceutical industry. In a role theory episode there is role negotiation between the role sender and the role occupant. In this study one did not see role negotiation per se in the study nor the concepts of role sender. However, one did see the concepts associated with the role occupant. Within the role occupant position CRNs bring the social norms of nursing, their individual personality, their nursing skills, and the interpretation of the role expectation to their current role within the industry. Study participants indicated they brought the social norm

of nursing such as being a patient advocate to their role in the pharmaceutical industry . They also brought their personality traits of flexibility, life-long learner and scientific mindedness to the pharmaceutical role. These traits in addition to the nursing knowledge and skills, which they brought to the role, framed nurses' role expectation and role response.

According to study participants, CRNs bring a unique perspective to the role of the clinical researcher in the pharmaceutical drug research and development environment. Focused ethnography was used in this study to examine the CRNs patterns of behavior, customs and ways of life in both the nursing world and the pharmaceutical research world. However, the data revealed the study participants see themselves as living in the pharmaceutical research world but not necessarily in the nursing world. Participants describe themselves as nurses who work /live in the pharmaceutical world.

Significance of the study

This study adds to the literature and the nursing body of knowledge by describing the CRNs' role experience and perceived impact throughout all phases of the pharmaceutical drug research and development process. This study offers a view into a nursing specialty which is not well known, acknowledged, or understood by the public or the discipline of nursing. As such, it increases awareness of the CRN role as an additional career option for nurses. The roles that study participants perform in the pharmaceutical industry add to the spectrum of roles available to nurses.

This study will increase awareness and visibility of the role that nurses play in the drug research and development process allowing for increased respect for the discipline

of nursing in a global environment. Awareness of the roles performed by study participants may encourage schools of nursing to include training on the drug research and development process in the nursing curriculum. This would allow nursing students to understand and appreciate the process involved with drug research and development. Training on this process would increase practitioners' awareness of their patient's option for clinical trial participation. This study raises awareness of the need for a specialty of clinical research nursing that includes nurses employed in this non-traditional nursing role. It also highlights the need for further research to more clearly articulate the different roles within an emerging specialty to better describe the domains of the role, its competencies and indeed a title that encompasses all of the nursing roles in pharmaceutical research and development.

This study raises awareness that there many additional non-traditional roles for nursing not only in the pharmaceutical industry but in other roles within the business environment. Traditional nursing roles are situated within a clinical model which is concerned with the direct observation and treatment of patients. Study participants worked and flourished within a business model which is designed to generate revenue. With the transformation of healthcare in the United States more nurses may seek opportunities within this business model. This research illustrates that nursing skills and knowledge are transferable into opportunities outside the traditional clinical model.

As non-traditional job opportunities in the business model increase for nurses, institutes of nursing education may be encouraged to include business training in their curriculum. This research study allows not only for the realization that there are many

opportunities for nurses to use their skills and knowledge in non-traditional roles but that nursing may be a springboard to other professions.

Limitations of the study

The qualitative design of this study presents the views of specific nurses' experience in the pharmaceutical industry and therefore the data is contextually situated and cannot be applied broadly. For example, all of the subjects were located in the Mid-Atlantic region of the US where there are a number of large and small pharmaceutical companies, perhaps facilitating their ability to change jobs compared to nurses in other parts of the US or world.

Another limitation to the study was a lack of diversity in the study subjects enrolled in this study. All subjects were Caucasian and all but one were females. Recruitment for this study was purposeful to provide for a wide selection of roles across the drug research and development continuum. However, a broader demographic base may have further informed the study. Additionally, recruiting participants from a broader geographical area may have further informed the study.

Participants in this study were recruited by word of mouth which resulted in subjects only representing a few large pharmaceutical companies and one medical center. Further research may seek to include more pharmaceutical companies ranging in size from small to large as well as biotech companies, clinical research organizations, and site management groups to provide an even broader scope of role functions.

Summary

This chapter discusses the study findings as the participants describe their role experiences and perceived contributions to the drug research and development process. It also described the meaning of these findings as they relate to the role theory and current literature. The significance and limitations of the study findings were discussed.

Participants in this study perceive themselves as working for the greater good of humanity through the contributions they make to the pharmaceutical clinical research process. They also consider themselves as nurses who utilize the knowledge and skills they learned as nurses in the clinical setting to advocate for patients in the research studies and as well as the ultimate patient consumers of the pharmaceutical product. They believe that nursing experience and knowledge positively impacts the role they are currently performing. This study contributes to the understanding of the unique experience of nurses working in this non-traditional setting.

Chapter VI: Conclusion

Study summary

In this time of great scientific discovery bringing a new drug to the clinical setting takes a highly skilled, multidisciplinary team of scientists and staff. Each member of this team must do their part to ensure only safe and effective therapies are brought to the public. Nursing is one of the disciplines involved in bringing these new drugs to the clinical setting. This study explored the role and perceived impact of clinical research nurses who work in pharmaceutical drug research and development in a role other than the study coordinator role using a focused ethnography methodology. Twenty-one nurses who work in pharmaceutical drug research and development at various time points along the drug development continuum were interviewed for this study.

There is limited empirical evidence on the role of nurses working in the pharmaceutical drug research and development process in a role other than a study coordinator. There are only two dissertations exploring this role for nurses. This research supports the findings of those two qualitative studies. Consistent among these three studies is the theme of transition from a bedside nurse to a role in the pharmaceutical industry. While participants in this study “fell into” the role by chance, in Kavalam’s (2011) study participants took action to find employment in the industry. All of the studies point out that participants did acclimate into the pharmaceutical environment. Nursing specialization actualization was achieved by nurses in the pharmaceutical industry in Shannon’s study while CRNs in this study considered themselves “still a nurse” but not necessarily working in a nursing specialty.

The literature on the role of the study coordinator is somewhat consistent with the findings in this study for the role of the CRN in the pharmaceutical industry. Putting the patient in the forefront, having a passion for patient advocacy, advocating for patient safety, and advocating for trial integrity are commonalities between the two roles. Additionally, working in a team environment, working independently, and role diversity are also experienced by both pharmaceutical CRNs and study coordinators. A notable difference between the two roles was that the study coordinator experienced role conflict between clinical practice and research. That was not experienced by CRNs in the pharmaceutical environment due, in part, to the lack of direct patient care performed by CRNs in industry settings.

Four major themes emerged from the data. These included: pharmaceutical work environment, the goal of the role, being in the role of a clinical researcher, and being a nurse in the role of a clinical researcher. The pharmaceutical work environment is a non-traditional setting for nursing. Study participants described the work environment of the pharmaceutical industry as business oriented with the goal of not only scientific discovery for the betterment of human health but also based on a business model whose purpose is to make a profit. The study participants adapted to this environment by being able to assimilate into this business environment. The pharmaceutical work-place was also an unstable work environment due to the time limits of clinical research, project timelines, business mergers, take overs, and business needs. Within this unstable environment, CRNs demonstrated the flexibility and the wherewithal to frequently change jobs, which meant constant learning and adapting to new situations. In this environment CRNs also worked in a matrix environment with many other disciplines

necessitating the need for cooperation, collaboration, and an appreciation for the value of all disciplines.

The second theme which emerged from the data was that the goal of the role for the study participants was to ensure the integrity of clinical research. Participants wanted to make sure that clinical research was producing a safe and efficacious product that will improve the health and well-being of thousands of people. They felt a strong obligation to guarantee that their clinical research was based on credible evidence obtained in an environment which ensured the rights of study subjects. Study participants shared that they had a broad perspective of their contribution to drug research and development, knowing they were one small part of the larger picture but that their contribution mattered. Participants also shared that the role of the CRN in the pharmaceutical drug research and development process was not about direct patient care but rather about caring for the larger population who would be using the drug, both study subjects and the post marketing public.

Being in the role of a clinical researcher was a third theme that came from the data. Participants transitioned into the role mostly by chance when looking for a new opportunity. Among the reasons for looking for a new job were work hours, increased monetary compensation, and non-optimal work-life balance in their clinical nursing role, all of which they found in the pharmaceutical industry. Participants shared that they were interested in not only the caring aspect of nursing but also loved scientific inquiry. Participants indicated that their nursing education and clinical experience had prepared them well for their current role in the pharmaceutical industry. Their education provided

them with a broad knowledge base and their clinical experience provided them with the skills to perform their current role proficiently.

Subjects shared their role experiences in the pharmaceutical industry which spanned the continuum of clinical research from phase I through phase III clinical trials to the dissemination of research results. Roles included: drug safety and risk management, clinical trials, regulatory management and data dissemination. Study participants indicated that the role is about the research process and research outcomes. Roles performed by CRNs were highly demanding requiring long hours, travel, constant meetings, and were metric focused. Proficiencies needed in these roles required keen medical writing and analytical skills as participants were required to analyze data and present it in writing in a way that would be understandable.

Being a nurse in the role of the clinical researcher was a fourth theme embedded in the data. There was strong sentiment that participants were “still a nurse.” Overwhelmingly, subjects indicated that nursing was a part of who they were and what they brought to the table. Their perspectives were nursing perspectives and they articulated this perspective in multi-disciplinary teams. However, participants did not indicate that what they did was nursing per se. This question remains for further research.

The impact of participants’ nursing perspective allowed CRNs to be patient focused, to put the patient in the forefront. They had a holistic view of the patient, not just seeing the disease or symptom, but because of their nursing background they understood the burden of clinical trial procedures on a patient and understood the clinical trial patient’s needs and viewpoint.

Subjects also stated that their nursing background provided them with the ability to effectively communicate in many situations, with many disciplines. They spoke up in team meetings as patient advocates, putting a human face on research subjects and putting patient safety first. Additionally, skills they learned in nursing school and honed in clinical practice such as critical thinking, analytical skills, and the ability to assess quickly, as well as their flexibility, time management, and prioritization skills, were transportable from the clinical setting to the pharmaceutical industry. Participants shared that these skills were added value that nurses brought to their pharmaceutical industry roles.

Working in the drug research and development environment was felt to augment other opportunities in the discipline of nursing. This was an additional career path that nurses could consider and a role that provided global recognition of what a nurse could offer to the industry. Their role provided additional value to the discipline of nursing. There was sentiment expressed that the role of the CRN should be presented to nursing students to offer a broader perspective of career opportunities for nurses. Current literature does not consistently define who is a clinical research nurse (CRN). The American Nurses Association's (ANA) definition of nursing includes those who work in different roles and settings (ANA, 2010). The Irish National Council definition of a CRN includes nurses who are involved in research but are not "nursing" (Irish National Council for the Professional Development of Nursing and Midwifery, 2008). The Oncology Nurses Society (ONS) (2010) defines the CRN as a specialty nursing role for nurses involved in clinical trials. The National Institutes of Health Clinical Center identified five dimensions within the domain of nursing practice for clinical research

nurses. The participants in this study, through the descriptions of their current roles, could fit into each of the definitions of the CRN. However, while the participants considered themselves nurses working in the pharmaceutical industry, they may not really see themselves as doing “nursing.” Participants considered themselves as a part of a nursing specialty but all had not self-identified as being part of a nursing specialty until asked. There was no consistency on a title or label that would be inclusive of all nurses who work within the pharmaceutical drug research and development environment.

Implications for nursing

This study adds to the body of nursing knowledge by providing an insight into the role experience and perceived impact of clinical research nurses in a role other than study coordinator on pharmaceutical drug research and development. Participants highlighted an area of nursing practice that needs further articulation, especially if it is to become a specialty practice for nursing. It acknowledges and validates an area of nursing practice in a non-traditional role which may expand the practice of nursing beyond known traditional and non-traditional roles and shine a light on additional career paths for nurses. The study also lays the groundwork for inclusion of nurses working in a drug research and development role in a nursing specialty of clinical research nursing. Finally, it provides support for nursing education to include the drug development process and business training in the nursing curriculum along providing awareness of potential career opportunities in non-traditional roles..

This research study illustrates that nurses have a unique role with the healthcare system. Nurses have roles within the traditional clinical model and within the non-traditional business model. This allows for increased career options for nurses. Nursing

roles are not limited to caring for individual patients but also may encompass non-traditional roles caring for the public health.

Future Research

Based on the findings of this study, further research is needed to more completely articulate the role of nurses working in the pharmaceutical drug research and development environment, thereby identifying competencies needed to formulate a nursing specialty role. An additional study may investigate if CRNs perceive they are nurses who work in the pharmaceutical industry or do they perceive they practicing nursing in a non-traditional way. This future study would add to the nursing body of knowledge about the role of the CRN who works in the pharmaceutical industry. Future studies that look at roles of nurses in the biotech industry, medical device industry, and smaller pharmaceutical companies may add further information to this study. Additionally, future research may include a broader demographic of subjects including minorities and those from a broader geographical area. Future studies may investigate roles of nurses in various business environments. As nurses continue to practice in non-traditional roles such as the pharmaceutical drug research and development environment, a question for future research may be “Is any job a nurse does ‘nursing’”?

As science is moving forward at a rapid rate, the multidisciplinary team needed to bring new pharmaceutical products to the clinical setting must be highly skilled with each member adding their expertise to the process. The research infrastructure includes nurses at many places along the continuum of pharmaceutical drug research and development. The roles that nurses enact in this environment integrate nursing skills, knowledge, training, and professional judgement to ensure the integrity of clinical research while

protecting research subjects. CRNs are part of the team that ensures only drugs that are safe and effective come to the clinical setting, thereby protecting the health of the public.

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Appendix A: Demographic Questions

1. Age _____
2. Gender Male ☐ Female ☐
3. Race _____
4. Ethnic Group Hispanic ☐ Non-Hispanic ☐
5. Marital Status Single ☐ Divorced ☐ Widowed ☐ Married ☐
6. Number of years in nursing _____
7. Number of years in clinical research _____
8. Educational background / Highest degree held in nursing

9. Certifications / professional designations _____
10. Work experience / setting / specialty

| Setting (hospital, medical office, industry) | Job Title | Length of employ | Comments |
|--|------------------|-----------------------------|-----------------|
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Thank You

Participant # _____

Appendix B₁: Interview Guide

1. Tell me the story of how you became a nurse?

- Tell me about your work history in nursing?

Tell me how you moved into the specialty of clinical research nursing?

- Tell me a little about your present role working with pharmaceutical drug research and development including your job title?
 - Tell me what it is you do in this role?
 - Give me an example of a usual day?
- Tell me what keeps you in this role?

2. What do you as a nurse bring to the pharmaceutical drug research and development process?

- Tell me how you as a nurse influence pharmaceutical drug research and development?
- Probes:
 - patient protection (safety)?
 - patient care?
 - clinical research protocols?
 - drug / clinical research budgets?
 - science of drug research and development?

3. What outcomes do you perceive as consequences of your role as a clinical research nurse on pharmaceutical drug research and development?

- Study management
- care coordination and continuity

- clinical practice
 - human subjects protection
 - contribution to science
 - financial implications
 - professional development
4. How do you perceive the impact of having a nurse as part of pharmaceutical drug research and development?
 5. What makes your role in the pharmaceutical drug research and development process easier?
 6. What are the barriers to performing your role?
 7. How does your work with pharmaceutical drug research and development make a difference to society and to nursing?
 8. Is there anything else you would like to share with me regarding your contribution to clinical research nursing?

Appendix B₂: Interview Guide

1. Tell me the story of how / why you became a nurse?

- Tell me about your work history in nursing?
- How many total years of clinical nursing experience do you have?
- Do you currently hold an active nursing license?

Tell me how you moved into the specialty of clinical research nursing?

- Tell me a little about your present role working with pharmaceutical drug research and development including your job title?
 - Tell me what it is you do in this role?
 - Give me an example of a usual day?
 - Was being a nurse necessary, helpful, or detrimental in obtaining this job?
- Tell me what keeps you in this role?

2. What do you as a nurse bring to the pharmaceutical drug research and development process?

- Tell me about any nursing skills you utilize in this role?
- Tell me how you as a nurse influence pharmaceutical drug research and development?
- Probes:
 - Patient protection (safety)?
 - Patient care?
 - Clinical research protocols?
 - Drug / clinical research budgets?
 - Science of drug research and development?

3. There is a movement to establish a specialty of clinical research nursing. Literature has reported nursing domains of practice for this new specialty. Would you tell me how you perceive working in your present role you do or do not contribute to or influence these domains:
 - Study management
 - care coordination and continuity
 - clinical practice
 - human subjects protection
 - contribution to science
 - financial implications
 - professional development
4. How do you perceive the impact of having a nurse as part of pharmaceutical drug research and development?
5. What makes your role in the pharmaceutical drug research and development process easier?
 - Does your nursing background make your role easier?
6. Has your nursing background in any way prepared you for your present role?
7. What are the barriers to performing your role? Is being a nurse a detriment to your role?
8. How does your work with pharmaceutical drug research and development make a difference to society and to nursing?
9. In your professional environment do you define yourself as a nurse?
10. Is there anything else you would like to share with me regarding your contribution to clinical research nursing?

Appendix C: Personal Reflection

As a nurse practitioner with over 40 years of nursing experience, I have broad experience working as a health care provider as well as working in many varied roles along the continuum of pharmaceutical industry sponsored drug research and development. I have had the opportunity as a clinician to see the improved quality of life and health outcomes for individual patients as well as the improved public health outcomes that are a result of pharmaceutical research and development.

As a nursing student in the 1970s, I was taught how to be a good bedside nurse in a hospital setting. I preformed tasks that were ordered by a physician. I dispensed medications to patients as prescribed by a physician. I learned the indications and possible side effects of medications and how to observe for those side effects in patients. Nurses at that time never questioned how drugs were developed or tested. We never were taught about the clinical research process. We innocently assumed drugs were safe and effective for patients if a physician prescribed them. I have worked in the hospital setting as a medical surgical nurse, an emergency room nurse, an intensive care unit nurse, a post anesthesia care nurse, and a cardiac care unit nurse. In the community setting I have worked as a school nurse from elementary school through high school and in special education schools. Never once during that time did I ever think to question the process used to establish the safety and efficacy profiles of medications I was giving patients. In the 1980s media coverage regarding clinical research for multiple dystrophy and HIV made me wonder who was doing this research to discover drugs for

these indications. Where was this research being done? How did they know these new drugs would be safe and effective?

In the late 1990s I took advanced pharmacology courses as part of the family nurse practitioner curriculum in my Masters in Nursing program. At that time I knew I would be the one prescribing drugs for patients. As a future healthcare provider I questioned how I could be assured that the medications I was giving to patients were safe, effective and the best choice for my patients. One of my wise professors told me to go back and read the published studies in the literature for the medications I would be prescribing. I found myself late at night scanning the literature for reports of clinical studies completed for particular drugs or classes of drugs. Based on that review at times I felt confident prescribing medications that were safe and effective based on published studies. However, at other times I was skeptical that the published literature truly reflected a positive benefit risk ratio for my patients. I then realized I needed to find out more about the clinical research process and becoming part of that process. After obtaining my nurse practitioner license, I began working at a veterans hospital as a primary care provider where I also became a member of the site's clinical research team conducting investigator initiated from pharmaceutical industry sponsored clinical trials. I worked as the study coordinator and sub investigator for many clinical trials in many therapeutic areas. I came to appreciate the hard work it took to operationalize a clinical study at an investigational site. I also came to truly appreciate the patients who volunteered to participate in clinical trials. As a clinician and a researcher, I owed them respect both as a patient, as a study

participant, and was obligated to conduct good, scientifically sound clinical research in an ethical manner. As I later took on the role of managing the investigational site I began to appreciate the managerial aspects of operationalizing a clinical trial such as finance and regulatory compliance requirements. In order to quench my thirst for more knowledge, I completed a post Masters certification in clinical research management at an academic university. This certification provided me with a broad overview of all the necessary aspects to bring a drug from the bench to the bedside. It was in this program that I realized the depth at which nurses were involved in all aspects of drug development. My next career move was to become a clinical research monitor for a pharmaceutical company. In this capacity I traveled to many investigative sites assuring clinical research was conducted according to the protocol and in compliance with good clinical practice. It was not long before I made the move to work for a large pharmaceutical company in the capacity of project manager for a global study. In this job I learned many more facets of the drug development process such as drug safety, pharmacovigilance, quality assurance, data management, medical affairs, marketing, finance, and regulatory compliance. After my next career move to a small biopharmaceutical company as associate director of clinical operations, I had the opportunity to work in a collaborative environment with bench scientists who discovered the molecules, physicians, finance personal, and management to move innovative products forward. It was in this small company environment that I truly came to appreciate that nursing knowledge and skills were extremely valuable at all points during the drug development process. For example it was nurses who

insisted that teaching materials be made available for investigators to explain experimental drugs and the clinical trial process to potential study participants and their families. It was also nurses who provided valuable input on how a study could best be operationalized in a hospital setting. My next career move was back to a medical center to become director of a new clinical research department. In this position I was able to utilize the knowledge and experience I had gained throughout the years to teach new investigators and new study coordinators how to run pharmaceutical industry sponsored clinical trials. In my present role as a contractor in a large pharmaceutical company I am responsible for the safety oversight of pharmaceutical drugs including investigational and post marketing products. In this role I often author safety assessment documents which are provided to regulatory authorities throughout the world.

Throughout my career I have worked with many nurses that are part of the intra-disciplinary team involved the pharmaceutical drug research and development process. I have witnessed their contributions to this process but yet observe the lack of published empirical evidence on the value of the CRN.

Through this study I hope to explore how CRN's who work in the pharmaceutical industries drug research and development environment describe their experience and value.

The following are entries to the researcher's reflective journal after study initiation.

February 22, 2015

As I embark on my dissertation data collection journey, it is an exciting time. To date I have interviewed four subjects. Obtaining subjects has not been difficult so far. Participants seem very willing to share their stories. However, finding a mutually agreeable time where we can interview and fit this extra assignment into our lives has been difficult. People seem excited about participating in a research study. None of the subjects has ever previously volunteered for any research study. They all understand research as this is the focus of their jobs. But they all seem a tad nervous about being a participant themselves and want to make sure that they are doing everything right. Many of the participants have asked are you sure you want to talk to me? It appeared to me that they did not feel they had anything to offer in a research study. I assured them I just wanted to hear their story.

During the interview most of the subjects were nervous in the beginning and then gradually opened up. It was amusing to see how in the beginning of the interviews it appeared that subjects tried to answer questions like they felt I wanted them to answer but as they became more comfortable during our conversation, they opened up and gave me more information. It was also interesting to me to see how some subjects did not see the value oversee nursing influence in their jobs when they first answered a question but when probed more deeply or later in the interview they provided information and insight on how their nursing background influence their present role.

One thing that struck me was how some participants were full of joy and a happy feeling when they talked about the role while other participants seemed a little angry about how they are treated in the industry.

One question I asked a subject and will again start asking other participants is: do you identify yourself or describe yourself as being a nurse? One theme I see as emerging is that nursing training is a valuable asset in performing their job for all participants. Every participant has paused when asked about the outcomes they influence. It appears that their influence or impact is not something they think about on a daily basis.

April 12, 2015

Fourteen subjects have been interviewed to date. Themes have emerged. One of the consistent themes that has emerged is that nurses “humanize” the clinical research process in a business environment.

It is encouraging to now see that nurses believe they have an influence on drug research and development. However, it is interesting that most question their contribution to the discipline of nursing.

April 25, 2015.

Twenty one subjects have been interviewed. I believe the data is saturated as no new themes have emerged. Not all nurses feel the same about the contribution of nurses to the clinical research process. However, all do feel that being a nurse is helpful. I feel great pride in that almost all participants stressed the importance of this research and wanted me to share the results with them.

May 12, 2015

In reviewing the data, I see how each participant feels their nursing education has provided a knowledge base for their present job. I look at my own career and feel the

same. Knowledge is often hidden in the back of your head but then you realize you can draw on that knowledge as needed. There is also the experience of working with patients that greatly influences the way you look at clinical research that involves any subject. I think most of the participants conveyed that they become protective of patients. I realize that is the way I often feel when being asked to help write a protocol or if asked to grant an inclusion exemption for a study. You want to make sure they are treated with the upmost of respect for their contribution to research. I feel very connected to the nurses participating in this study through our mutual respect for patients.

August 15, 2015

After taking a break from the data, I realize that some of the themes could be worded in a more appropriate way reflecting the experiences of the participants. I am also amazed when I again listen to the interviews how resolute the participants are that they are “still a nurse.” That hits close to home for me as I still feel I define myself as a nurse and feel very connected to fellow nurses working in the industry.

September 14, 2015

Again, I have reviewed the data and am struck at how almost all participants define themselves as nurses and feel camaraderie with other nurses. I also wonder if all nurses within the discipline welcome nurses who work within the pharmaceutical industry into their nursing world.

I believe that the data is saturated and that 4 themes consistently emerged. I related and share the feelings and views voiced by study participants. The dissertation will report the themes which have emerged.

November, 2015

I am honored to be a part of this nursing specialty of clinical research nursing. My colleagues are hardworking, intelligent individuals whom I have come to admire even more over the past few months as I have read and read the data. I also find that I miss the direct patient contact but know that the pharmaceutical industry is the right place for me at this point in my career. In again reviewing the data, the four themes which emerged have been slightly modified.

Appendix D: Invitation to Participate

Dear Clinical Research Nurse,

I am a doctoral candidate in the School of Nursing at Rutgers, The State University of New Jersey. There are many nurses who work in the untraditional nursing role of clinical research nurse (CRN) supporting the pharmaceutical drug research and development process. The role of these Clinical Research Nurses (CRNs) other than the role of the study coordinator is not addressed in the literature. Additional information is needed to better characterize and understand the experiences of these nurses. I believe that by learning more about the experience of CRNs who work in this non-traditional nursing role, I will be able to add to the body of nursing knowledge and contribute to the ongoing development of the nursing specialty of Clinical Research Nursing.

Your participation will include being interviewed by me at a time and location that is convenient for you, including meeting via telecommunication technology. This interview will last approximately one to two hours. You may be asked to participate in a follow up interview to confirm the study data. You will not receive any compensation for participation in this study.

I appreciate your consideration of my request to participate in this study. All information shared will be confidential. Your participation will help gain insight into the role of the CRN other than the study coordinator who works in the pharmaceutical drug research and development environment. This information may facilitate further definition of the nursing specialty of Clinical Research Nursing.

If you are interested in participating in this research study, please contact:
Rosemary Keller, RN, CRNP, Doctoral student, College of Nursing, Rutgers, The State
University of New Jersey, at rosemary.keller@rutgers.edu or xxx-xxx-xxxx and provide
the preferred time and means of contacting you (e-mail, phone, text). I will contact you
within one week to offer further explanation of the study, see if you have any questions
and see if you are willing to participate. Your participation in the study is strictly
voluntary and you may withdraw your consent at any time.

Thank you for your consideration of my request.

Kind regards,

Rosemary Keller RN, MSN

PhD candidate,

Rutgers, The State University of New Jersey

Appendix E: Informed Consent



School of Nursing
Rutgers, The State University of New Jersey
180 University Avenue
Newark, NJ 07102-1897

p: 973-353-3690
f: 973-353-1035
<https://nursing.rutgers.edu>

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Exploring the Role and Perceived Impact of Clinical Research Nurses on Pharmaceutical Drug Research and Development

Principal Investigator: Rosemary Keller CRNP MSN

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

The principal investigator of this study, Rosemary Keller or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Why is this study being done?

This study is being done to understand the experiences and perceived impact of clinical research nurses who work in the pharmaceutical drug research and development environment.

Why have you been asked to take part in this study?

You are being asked to take part in this study because you are a registered nurse working in the pharmaceutical drug research and development environment.

Who may take part in this study? And who may not?

Registered nurses at least 18 years of age but less than 90 years who speak English and work full time in the pharmaceutical drug research and development environment may take part in this study. Nurses who work in the role of study coordinator may not take part in this study.

How long will the study take and how many subjects will participate?

It is anticipated this study will take up to 18 months to be completed. Approximately 20 to 30 subjects will participate in this study. Your participation in the study will consist of an interview lasting approximately 1 to 2 hours. You may also be asked to take part in a short follow up interview to confirm the study results.

What will you be asked to do if you take part in this research study?

If you agree to take part in this study, you will be asked to complete a demographic information form and participate in an interview which will take place at a time and location convenient to you and the researcher. This interview may take place in person or by computer assisted technology. You may also be asked to take part in a short follow up interview to confirm the study results. All interviews will be audio taped following collection of the demographic data collection form.

What are the risks and/or discomforts you might experience if you take part in this study?

Possible risks associated with participation in this study include inadvertent loss of confidentiality or fatigue during the interview.

Are there any benefits for you if you choose to take part in this research study?

There are no direct personal benefits from taking part in this study. However, additional information obtained in this research study may be useful in improving the body of nursing knowledge.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?

There is no cost to you to take part in this study.

Will you be paid to take part in this study?

You will not be paid for your participation in this research study.

How will information about you be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. All electronic data from demographic data sheets, audio tapes and transcripts of interviews, informed consent documents and field notes will be kept on a separate computer hard drive that is password protected and accessible only to the researcher or research team until 6 years after study completion. All hard copy study information will be kept in a locked file accessible only to the researcher or research team until 6 years after study completion. Each interview recording, transcript, and demographic form will be numbered. There will be no link between the consents and the interviews or demographic form. All study related data will be destroyed 6 years after study completion.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?

Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Rosemary Keller 201 Horseshoe Lane Pottstown, PA 19465.

Who can you call if you have any questions?

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study investigator:

Rosemary Keller

201 Horseshoe Lane

Pottstown, PA 19465

(804) 357-6199

If you have any questions about your rights as a research subject, you can call:

IRB Director

(973)-972-3608 Newark

What are your rights if you decide to take part in this research study?

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY IRB

AUDIO/VIDEOTAPE ADDENDUM TO CONSENT FORM

You have already agreed to participate in a research study conducted by Rosemary Keller. We are asking for your permission to allow us to audiotape (sound) as part of that research study. You do not have to agree to be recorded in order to participate in the main part of the study.

The recording(s) will be used for analysis by the research team.

The recording(s) will include a subject identification number.

The recording(s) will be stored in a locked file cabinet or on a password protected computer and will be retained for 6 years after completion of the study and then destroyed.

Your signature on this form grants the investigator named above permission to record you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written permission.

AGREEMENT TO PARTICIPATE

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name: _____

Subject Signature: _____ Date: _____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent: _____

Signature: _____ Date: _____

Appendix F: Memo

Memo

March 14, 2015

After interviewing nine participants a few themes appear to be emerging from the data. I notice that nurses with more experience more readily make an association between the nursing skills learned in nursing school and practiced in the clinical setting and how those skills are utilized in their present role in pharmaceutical drug research and development. Nursing skills repeatedly mentioned by participants that were learned and utilized in clinical practice and are now essential in their current roles in the pharmaceutical industry include: critical thinking, effective communication, collaboration, prioritization, flexibility, quick thinking, assessment, analytical skills, patient education, professionalism, time management, and the ability to have a broad perspective. This feedback that nursing skills translate into useful skills in their pharmaceutical roles encouraged me to include a question on what nursing skills participants brought to their present role.

Frequently mentioned by participants is the holistic view that nurses bring to their present role. Repeatedly participants said they bring the “human side” to the pharmaceutical industry. They make sure the patient safety is a top priority and give a human touch to the business practices within the pharmaceutical industry. They articulated that they provide a different point of view than perhaps many other disciplines as they always keep the focus on the patient. Almost all participants indicated they were fierce patient advocates.

Another key point that participants need is that they were able to break down complex information so that all disciplines and even patients could understand the science. Some participants viewed themselves as scientists while others thought they did not contribute greatly to the science. This aspect will need to continue to be explored.

The value of nursing education is another theme that appears to be emerging from the data. Almost all participants stated they constantly use their knowledge of anatomy, physiology, and scientific method in their pharmaceutical industry roles. As I see this theme emerging I will probe participants to see if their nursing background and any further nursing education makes their present role any easier.

Many participants expressed surprised in their nonverbal communication that there was presently a developing specialty of clinical research nursing. Although almost all participants identify themselves as a nurse, they articulated that they never thought about clinical research being a nursing specialty. It appeared hard for some to identify what value their role brought to the discipline of nursing. I started asking participants if they thought of themselves or identified themselves as a nurse either professionally and/or personally. Going forward I will ask participants if they feel in their present role they would view themselves as clinical research nurses. It will be interesting to see the aggregate of their responses.

Another theme or thought proposed by some participants was that in their role as a professional in industry they raised the perception of nurses to a more professional status than was experienced in a clinical setting. This theme of increased societal respect for nurses through their roles in industry may be one I would like to explore further.

Additionally many participants indicated that this career path was unknown to them while in nursing school and believed an increased awareness of this career path within discipline of nursing was necessary.

Memo

11/3/15

After again sorting the data obtained from the interviews using the NVIVO 10, there are four major themes that have emerged. The data is saturated for these themes and subthemes.

1. Pharmaceutical Work Environment

- a. Business model
- b. Dynamic / changing / unstable employment (need for flexibility, lifelong learner)
- c. Interdisciplinary environment

2. Goal of the role

- a. Not direct patient care
- b. Ensuring integrity of clinical research
 - i. Population health outcome (ultimate goal)—ie producing a safe and efficacious product that will improve the health or well-being of thousands of people.

3. Being in the role of clinical researcher

- a. Transition into the role (how they became)
- b. Preparation for the role
- c. Enacting the role
 - i. What they do
 - ii. Demands

iii. Proficiencies

4. Being a nurse in the role of clinical researcher
 - a. Still a nurse (nurse working in pharmaceutical environment versus doing nursing)
 - b. Impact of nursing perspective on role in pharmaceutical drug research and development
 - i. Putting patient in the forefront
 - ii. Effective Communication
 - iii. Transportable skills
 - c. Contribution to the discipline of nursing
 - d. Specialty nursing role

Appendix G: IRB Approval

**Institutional
Review Board -
New Brunswick**

335 George Street
Suite 3100, 3rd
Floor
New Brunswick,
NJ 08901
Phone: 732-235-
9806

**Institutional
Review Board -
Newark**

65 Bergen Street
Suite 511, 5th
Floor
Newark, NJ 07107
Phone: 973-972-
3608

This is an auto-generated email. Please do not reply to this email message. The originating e-mail account is not monitored. If you have questions, please contact your local IRB Office above.

DHHS Federal Wide Assurance Identifier: FWA00003913

IRB Chair Person: Robert Fechtner

IRB Director: Carlotta Rodriguez

Effective Date: 1/8/2015

7. eIRB Notice of Approval

8. _____

9.

10. STUDY PROFILE

11. _____

Study

[Pro20140000910](#)

ID:

Title: Exploring the Role and Perceived Impact of Clinical Research Nurses on
Pharmaceutical Drug Research and Development

| | | | |
|--------------------------------|-------------------|----------------------------|-----------------|
| Principal Investigator: | Rosemary Keller | Study Coordinator: | Rosemary Keller |
| Co-Investigator(s): | Teri Lindgren | | |
| Sponsor: | Department Funded | Approval Cycle: | Twelve Months |
| Risk Determination: | Minimal Risk | | |
| Review Type: | Expedited | Expedited Category: | 6 7 |
| Subjects: | 60 | | |

14.

15. **CURRENT SUBMISSION STATUS**16.

| | | | |
|-------------------------|----------------------------|---------------------------|-----------------------------|
| Submission Type: | Research Protocol/Study | Submission Status: | Approved |
| Approval Date: | 1/8/2015 | Expiration Date: | 1/7/2016 |
| Pregnancy Code: | 45CFR46.204 | Pediatric Code: | No Children As Subjects |
| | | Prisoner Code: | No Prisoners As Subjects |

18.

| | | | | | |
|------------------|---|-----------------|---|-------------------------|--|
| Protocol: | Keller_Clinical Research Nurse_7Jan2015.doc | Consent: | Keller_ consent form_02Jan2015.doc. pdf | Other Materials: | Keller_Appendix A_Demographic form 02Jan2015.docx.pdf Keller_Appendix B _Interview questions_02Jan2015.docx. pdf Keller_Appendix C_Reflexivity.pdf Keller_Appendix D_Invitation to Participate_02Jan2015.docx .pdf |
|------------------|---|-----------------|---|-------------------------|--|

19.

20.

21.

* Study Performance Sites:

Rutgers University School of Nursing, 180 University Ave, Newark, N. J.

22.

ALL APPROVED INVESTIGATOR(S) MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.
2. **Continuing Review:** Approval is valid until the protocol expiration date shown above. To avoid lapses in approval, submit a continuation application at least eight weeks before the study expiration date.
3. **Expiration of IRB Approval:** If IRB approval expires, effective the date of expiration and until the continuing review approval is issued: **All research activities must stop unless the IRB finds that it is in the best interest of individual subjects to continue. (This determination shall be based on a separate written request from the PI to the IRB.) No new subjects may be enrolled and no samples/charts/surveys may be collected, reviewed, and/or analyzed.**
4. **Amendments/Modifications/Revisions :** If you wish to change any aspect of this study, including but not limited to, study procedures, consent form(s), investigators, advertisements, the protocol document, investigator drug brochure, or accrual goals, you are required to obtain IRB review and approval prior to implementation of these changes unless necessary to eliminate apparent immediate hazards to subjects.
5. **Unanticipated Problems:** Unanticipated problems involving risk to subjects or others must be reported to the IRB Office (45 CFR 46, 21 CFR 312, 812) as required, in the appropriate time as specified in the attachment online at: <http://rbhs.rutgers.edu/hsweb>
6. **Protocol Deviations and Violations :** Deviations from/violations of the approved study protocol must be reported to the IRB Office (45 CFR 46, 21 CFR 312, 812) as required, in the appropriate time as specified in the attachment online at: <http://rbhs.rutgers.edu/hsweb>
7. **Consent/Assent:** The IRB has reviewed and approved the consent and/or assent process, waiver and/or alteration described in this protocol as required by 45 CFR 46 and 21 CFR 50, 56, (if FDA regulated research). Only the versions of the documents included in the approved process may be used to document informed consent and/or assent of study subjects; each subject must receive a copy of the approved form(s); and a copy of each signed form must be filed in a secure place in the subject's medical/patient/research record.
8. **Completion of Study:** Notify the IRB when your study has been stopped for any reason. Neither study

closure by the sponsor or the investigator removes the obligation for submission of timely continuing review application or final report.

9. The Investigator(s) did not participate in the review, discussion, or vote of this protocol.