From Direct Patient Care to Clinical Research: Transitioning to an Emerging Nursing Specialty

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Dedication

This dissertation is dedicated to my father, John Edwin Watson, whose faith in and love for me was exceeded only by his abiding devotion to God and family.

Acknowledgments

It's a joyous adventure to go back to school in the 5th decade of your life and discover that by taking this step you have opened a door to a whole new way to pay it forward. Through the inspirational and dedicated support of the staff and faculty of the GWU Executive Leadership Program (ELP) I have now adventured further than I would have thought possible, and along the way found my voice as an advocate and champion for nurses who've built their careers in the world of biomedical clinical research. Thank you Dr. Ellen Goldman, my dissertation chair, for your patience and persistence in shepherding me through my travels, and for my committee members Dr. Christine Pintz and Dr. Elizabeth Mahler for bringing new perspectives and a keen eye to my work. It was a joy to work with you. I am also so very grateful for the support of colleagues and friends from Cohort 20, especially Drs. Paige McDonald and Guy Lotrecchiano for keeping me in the game through various moves and career changes, and being my friend, coach, and sounding board. Thank you also to 10 wonderful nurses who gave me their time and shared their remarkable stories. You inspired me just as I hope the work we did together will inspire others to see nursing as the broad and versatile career that it is.

As I reflect on the past few years and all the missed outings, parties, date nights, and birthdays that working on a doctorate required, I am especially grateful to my wonderful family. To my daughters Kailey, Jordan & Regan, and my husband Rob, who now knows my thesis almost as well as I do as he patiently listened, read, and re-listened to every word for almost two years, I love you all so much and could not have made this amazing journey without you.

Abstract of the Dissertation

From Direct Patient Care to Clinical Research:
Transitioning to an Emerging Nursing Specialty

The role of the professional nurse has evolved in numerous and unexpected ways since the founding of Nightingale's first school of nursing in 1860. One contemporary sphere in which nurses work is the biopharmaceutical and medical device industry, but little research exists regarding how the nurse engages with and experiences this role.

This qualitative, phenomenological study was undertaken to address the research question: What is the nature and process of the transition experience from a direct patient care role to a clinical research specialist role for the professional nurse? Two subquestions were also explored: What barriers and supports are encountered during the transition process? What facilitates successful work role transition from direct patient care to clinical research?

Ten professional nurses who had transitioned to industry based careers at least two years prior to this study were identified and selected via referral sources. Each nurse participated in a series of three in-depth recorded interviews. Through an iterative process of transcript review, coding, and thematic analysis, and utilization of Ashforth's (2001) ABCs of Role Identification and Nicholson's (1984, 2013) Work Role Transition Theory as lenses for interpretation, seven key themes emerged. These themes include: 1) I am alone: transition can be an isolating experience, 2) I am unprepared: transition requires mastery of unfamiliar skills and knowledge, 3) I am scared and sometimes overwhelmed: transition is associated with a lack of security, structure and balance, 4) I can do it: self-reliance and resourcefulness facilitate successful work-role transition, 5) I need to build new bridges: transition requires networking and support from others, 6) I am becoming:

the transition experience can be empowering and offers opportunity for growth, and 7) I am still a nurse: nursing identity and values endure through transition.

This study offers several recommendations for further research to more deeply explore identified themes and ways to facilitate success in this work-role transition. In addition, using feedback from study participants, recommendations and suggestions are offered for nurse educators, professional nursing credentialing organizations, and to other nurses considering a career in the clinical research arena.

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CHAPTER 1:

INTRODUCTION

Overview

The role of the professional nurse has slowly been expanding and shifting for several decades (Apker, Ford, & Fox, 2003; Bullough, 1976). To this point, the American Board of Nursing Specialties, the primary accrediting board for specialty nurse certification, now lists over fifty different nursing specialties for which certification is offered (American Board of Nursing Specialties, 2015). Additionally, the American Nurse Credentialing Center (2010) recognizes certification programs in over forty different nursing and advance practice nursing specialties, spanning a variety of traditional clinical areas such as cardiology and oncology, but also including less traditional roles such as nurse executives and forensic nursing. While many of these specialty areas are readily recognized as nursing roles associated with direct patient care, increasing global need for expertise in clinical trial design, management, and execution over the last two decades has driven a demand for a new type of nursing specialty that is not necessarily patient care focused. This is the role of the clinical research nurse specialist (Castro et al., 2011; Hastings, Fisher, & McCabe, 2012; Spilsbury et al., 2007), a key role in medical, pharmaceutical, and medical device research that does not appear on the nursing specialty list.

Within the biomedical research industry, there is no clear definition of clinical research nursing, nor are there consistent role titles or job descriptions (Castro et al., 2011; Hastings et al., 2012). It is clear, however, that there are at least two distinct roles to which nurses gravitate. The first is that of the Clinical Research Coordinator or

Research Nurse. This is a role typically enacted in a health care or medical school setting by either staff nurses or nurses hired specifically to support a clinical research project or program (Chadwick, 1992; Hastings et al., 2012; Mueller, 2001; Mueller & Mamo, 2002; Pelke & Easa, 1997; Sadler, Lantz, Fullerton, & Dault, 1999). The second, far less researched or discussed role filled by many professional nurses is that of the Clinical Research Associate (CRA). In fact, extensive review of the nursing literature resulted in only the most cursory mention of this function. The CRA is an industry-based professional who "supervises, monitors, and supports the administration and progress of a clinical trial" on behalf of a biopharmaceutical or medical device sponsor (ACRP, n.d.-b) (See Appendix E for a sample job description). While this role does not require a nursing background, there is ample evidence that nurses are often hired to work in this capacity. The National Sample Survey of Registered Nurses (NSSRN) (U.S. Department of Health and Human Services, 2010) surveys the registered nurse population with current licenses in the United States every four years. The survey provides data on the number of licensed RNs in the country, their educational background, positions and types of work settings, salaries, geographic distribution, and basic demographic characteristics. In 2004, under the category of "Other," pharmaceutical/medical device/medical software was added as a distinct selection option for employment environment. The number of nurses responding to the 2008 survey as "Other" has more than doubled since 2000, from 4.1% to 9%, and the surveyors estimate that almost 10,000 currently licensed registered nurses are working in the biopharmaceutical and medical device industry. It is important to note, however, that "Other" is specifically typified as a non-nursing occupation, and that these

RNs in the biotech industry are classified in the same category as elementary school teachers and individuals working in retail sales.

As noted, nursing literature related to understanding the research nurse role is limited. In reviewing the literature, most articles accessed discussed *nursing research*, or research conducted by nurses to examine nursing practice (Polit & Beck, 2004). However, literature largely outside of nursing that discusses *clinical research* and *clinical trials* repeatedly makes mention of a member of the research team referred to as the research nurse, the clinical research associate, the clinical research coordinator, or the research nurse specialist (Davis, Hull, Grady, Wilfond, & Henderson, 2002; Rico-Villademoros et al., 2004; Showstack et al., 1999). Thus, in spite of the lack of focus on the research nurse role by the scholars in the nursing profession, it is clear that research nursing is not rare, and that fairly large numbers of registered nurses view themselves and function as professional research nurses (Davis et al., 2002; Ocker & Pawlik-Plank, 2000; Raybuck, 1997; Spilsbury et al., 2007). These nurses are not only poorly recognized by their profession, but those in industry are outside of the normal nursing education and social support framework (Mueller & Mamo, 2002). It is rare, for example, for nurses choosing to move from direct patient care to clinical research to have received the necessary education, training, and support during their basic nursing preparation or employment setting to successfully make this transition (Mueller, 2001; Raja-Jones, 2002; Redman, Templin, & Merz, 2006). A study of 597 nurses at Tokushima University Hospital revealed that while most nurses (≥ 90%) had a basic awareness that clinical trials were conducted at their institution in support of pharmaceutical and medical device development, less than 10% had received any training in Good Clinical Practices, the

industry and regulatory standards and practices required to conduct biomedical research in human populations (Yanagawa et al., 2014). Given the lack of support and specialty training nurses in research receive, one has to wonder how, why, and under what circumstances do professional nurses make the transition to this role.

Research on nursing role transitions goes back to the mid-seventies (Kramer, 1974). The transitional period of focus, however, has generally been that which occurs between graduation from college and entry into nursing practice (Casey, Fink, Krugman, & Propst, 2004; Ellerton & Gregor, 2003; Kramer, 1974; Oermann & Garvin, 2002). Given the magnitude and expected continuance of the current nursing shortage (AMN Healthcare, 2010; Buerhaus, Donelan, Ulrich, Norman, & Dittus, 2006; Goodin, 2003; Mittelman, 2010), the focus on initial career transition is understandable, and finding ways to attract and retain new graduate nurses is essential (Lavoie-Tremblay et al., 2006; Roberts, Jones, & Lynn, 2004). With the rise of advanced practice nursing (APN) specialties, a good amount of data also exists on APN role development and transition (Bamford & Gibson, 1999; Jones, 2005; Sechrist & Berlin, 1998), but research on understanding what attracts and how a nurse experiences a mid-career transition to a non-traditional field like clinical research, is essentially non-existent. In spite of using dozens of different key word phrases and terms over a period of more than three years, not a single research article could be located that explored the role of the nurse as a CRA in industry, or in any way addressed the nature of the transition experience or process from traditional direct patient care nursing to clinical research.

Support for the clinical researcher may not exist within the nursing profession, or be recognized by nursing credentialing boards, but several associations, professional

organizations, and universities have stepped in to fill that void. The Association of Clinical Research Professionals (ACRP), for example, offers certification programs for both Clinical Research Associates (CRA) and Clinical Research Coordinators (CRC), and in 2010 noted that of their 30,000 members, 7,600 had earned certification as CRAs and 14,200 had earned certification as CRCs (ACRP, n.d.-a). Similarly, the Society of Clinical Research Associates (SoCRA) offers a Clinical Research Professional certification, specifically recognizing that many of their certificants are nurses (SoCRA, 2010), and the newly founded International Association of Clinical Research Nurses has a mission 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 across all clinical specialties" (http://iacrn.memberlodge.org/aboutus). In the university setting, there has been a proliferation of masters level clinical research programs and certifications as well. Drexel University in Philadelphia, for example, offers an MS in Clinical Research Organization and Management, an MS in Clinical Research for Health Professionals, a Certificate of Study in Clinical Research, and within the School of Nursing, is one of a pioneering group of universities now offering a Master of Science in Nursing in Clinical Trials Research (Drexel University, 2014).

So, while it is clear that nurses are among the ranks of clinical researchers, how and why nurses entered the career field of clinical research remains significantly understudied, resulting in a lack of a consistent definition of this role or a roadmap for role transition (Davis et al., 2002; Raja-Jones, 2002). Research has demonstrated that as nurses begin to move into innovative roles, it is not uncommon for them to encounter a

variety of barriers to effective practice (Jones, 2005). Barriers to effective transition and practice specifically defined for clinical research nursing are conflict between level of responsibility and authority, a lack of supervision, and significant educational deficits (Redman et al., 2006). Two key problems related to responsibility and authority conflicts are "overdelegation of responsibility and authority [to research nurses] . . . particularly without independent quality control systems . . . , and delegation of responsibility without authority to resolve issues essential to the trial operation" (pp. 483-484). Redman et al. (2006) further noted that because the nurse's educational background focuses on clinical practice, they may not understand that the primary duty in the role of researcher is to maintain study integrity, a commitment that may or may not lead to better health outcomes for the patient.

Because the research nurse role may result in significant role ambiguity and conflict (Spilsbury et al., 2007) and be poorly recognized by the nursing profession (Raja-Jones, 2002), the research nurse's ability to develop a secure professional identity may also be a barrier to effective transition and practice. Erikson (1985) maintains that genuine professional identity will not mature without the growth and development of trust and understanding between the individual and the profession with which they identify. The nurse's professional identity is a reflection of the values, knowledge, skills, and culture of the nursing profession, and is, therefore, developed through interaction with other nurses (Ohlen & Segesten, 1998). The nurse working in clinical research, however, is often the only nurse on the clinical research team, and in industry, may be the only nurse in her/his department. This results in a common complaint among research nurses that they feel isolated and under-supported by their employers (Mueller & Mamo,

2002). Research nursing also requires the acquisition of education and skills beyond most nursing programs, and in attempting to access this, the nurse may have little interaction with other nursing professionals (Davis et al. 2002; Raja-Jones, 2002; Spilsbury et al., 2007). Finally, Raja-Jones (2002) proposes that while the requirements and autonomy of research nursing mirror that of currently recognized advanced practice nursing roles, other nurses with advance practice certifications rarely acknowledge this. In fact, she maintains that much of the resistance to the recognition and support for development of new advanced practice roles comes from within the nursing profession.

The impact of this and other suggested barriers has been characterized as high levels of work stress and inefficiency, and may even result in research misconduct (Bramstedt, 2004; Jones, 2005; Redman et al., 2006; Reynolds, 2004). The potential impact on human subject protection, patient safety, research integrity, and the overall trustworthiness of the research endeavor, however, can be far reaching and unrecoverable. Understanding the nature and process of the nursing role transition from direct patient care to clinical research may help to illuminate both barriers as well as methods to achieve success, and will be the focus of this study.

Statement of the Problem

The nature and process of the transition experience for the professional nurse to the expanded specialty role of clinical researcher is poorly understood and largely unsupported by the nursing profession (Davis et al., 2002; Raybuck, 1997). As a result, research nurse specialists suffer from a lack of practice and educational standards and a fundamental lack of the support and protections that professional recognition offers,

leaving the nurse, the clinical research participant, and the trustworthiness of the clinical research enterprise vulnerable.

Over the last half century, clinical trials have become widely accepted as the 'gold standard' for evaluating new pharmaceuticals, medical devices, and therapeutic interventions (Marks, 2006), leading to current annual expenditures for biomedical research in the United States in excess of $100 million (Dorsey et al., 2010). With demand for research at an all-time high, the physicians who generally lead the research team have attempted to balance their role demands as doctor and researcher through delegation of research activities to other health care providers, principally nurses (Mueller, 2001). This systematic delegation and devolution of professional activities and responsibilities from one group to another has been described as a key feature of the social dynamics of expert labor, and results in new occupational roles and boundaries (Abbott, 1988). Specialty training and education are key steps to the formalization of an occupational role as a means for occupational leaders to equip new members with "the full protections of professionalism" through credentialing and other specialty symbols that distinguish them from other workers who perform similar tasks (Abbott, 1998, p. 106).

Mueller (2001), examining the experience of evolving occupational boundaries in a population of clinical research nurses, noted that while the nursing profession appears to be aware that many nurses function in this role, virtually all of what limited specialty education the nurses in her study received was obtained through either on the job or commercially offered training, leading to a substantially high level of clinical, technical, and ethical uncertainty. Similarly, a meta-analysis examining role development and

effective practice in emerging nursing specialties concluded that poorly defined boundaries between key professionals, poor role definition, and related ambiguous role expectations were significant hindrances to effectiveness (Jones, 2005). Likewise, the transition from a traditional nursing role to a newly recognized clinical nursing specialty has been characterized as stressful and frustrating due to poor role clarity and lack of support and appropriate supervision (Glen & Waddington, 1998). As a role in clinical research has been demonstrated to receive essentially no support from the profession (Raja-Jones, 2002), and does not necessarily require a nursing degree (ACRP, n.d.-b), the nurse in transition may experience similar frustrations. Failure to effectively transition to and engage in clinical research, however, may have serious consequences ranging from the loss of institutional research privileges and destruction of professional reputation, to the placement of research subjects and the trustworthiness of the clinical research enterprise at risk (Redman et al., 2006; Reynolds, 2004).

Purpose and Research Question

The purpose of this study was to gain a better understanding of how the transition process is experienced by nurses who make a decision to leave direct patient care for a career in clinical research.

Research Question

The following research question guided this study: What is the nature and process of the transition experience from a direct patient care role to a clinical research specialist role for the professional nurse? Two subquestions are also explored: What barriers and

supports are encountered during the transition process? What facilitates successful work role transition from direct patient care to clinical research?

Significance of the Study

Several contributions to theory in the field of transition research are made by this study. For example, while findings agree with theories proposing that transition is both a psychologically and socially mediated experience, in this population, the predicted sources, level, and timing of social support during transition varied in a number of significant ways from predicted patterns. Additionally, the cognitive and affective adaptations required, and the impact of transition on the work-role identification process appear to have been somewhat unique to this study population. Transition was also demonstrated to be a process, as predicted by both Ashforth (2001) and Nicholson (1984, 2013), but the process followed varied in several significant ways from patterns predicted in existing theory.

This study also holds important significance to understanding the impact of study findings on practice and social/professional attitudes and behaviors toward professional nurses working in the biopharmaceutical and medical device industry. First, given the rapid growth in demand for clinical trials and the need for qualified professionals to manage them, this research highlighted key opportunities to improve the preparation, education and training, and ongoing support of professional nurses in the CRA role, and thereby improve the overall quality and trustworthiness of the research process (Mueller & Mamo, 2002; Redman et al., 2006). Second, this research afforded a better understanding of the cognitive and affective dimensions to the nature of the transition experience and behavioral adaptations required of nurses to achieve transition success

(Ashforth, 2001; Ashforth & Kreiner, 1999; Clore & Ortony, 2000; Lazarus, 1998), thereby providing potential educators and employers of research nurse specialists with needed information to help facilitate and support role transition (Lavoie-Tremblay et al., 2002). Third, it is hoped that this study will bring the nurse as a clinical research professional, specifically those working outside of traditional hospital settings, to the attention of the nursing profession, and to nursing specialty and certification boards. This is important because specialty boards establish and enforce standards, educational requirements, and related credentialing mandates that strengthen the profession and lend much needed support to the development of a strong professional identity and to the effective practice of the nurse specialist (American Board of Nursing Specialties, 2010; Jacobs, DiMattio, Bishop, & Fields, 1998). Finally, this research provides nursing educators with insight that may allow them to better prepare the baccalaureate nurse for the challenges and opportunities of a changing work landscape and the emergence of the Clinical Research Nurse Specialists as a new nursing role (Cohen, 1981; Corwin, 1961; DeFillippi & Arthur, 1994; Duffield & Franks, 2002; MacIntosh, 2003).

Conceptual Framework

The conceptual framework guiding this study utilized two major compatible lenses for considering the nature and the process of work role transitions (Ashforth, 2001, for ABCs of role identification; Nicholson, 1984, 2013, for theory of work role transitions).

Nursing is, by definition, an interdisciplinary career choice based on an educational model described by the American Association of Colleges of Nursing as including “a variety of disciplines from health and other fields of study that collaborate

through joint planning, decision-making, and goal setting" (American Association of Critical Care Nurses, 2014). As a result, most nursing theories are an amalgamation of a variety of different constructs pulled from both psychosocial and hard science bodies of knowledge and practice. This has created many challenges for the nursing profession as it has struggled over the years to define its professional identity. Nevertheless, Findlow (2014) describes nursing as "territorially stronger than many disciplines . . . enjoy[ing] continuity, a shared distinctive language and artifacts" (p. 121). To achieve this level of saliency, the nursing identity is constructed through a repetitive course of education and socialization in relation to others (Currie et al., 2010). Willitts and Clarke (2014) acknowledge that becoming a nurse is a "complicated social activity" (p. 164) and suggest that the study of the professional nurse is, therefore, best understood by applying a social identity theoretical framework, like that used in Ashforth's (2001), "role transitions and the self" (p. 54).

While there are many transition theories to choose from, Ashforth's (2001) general role transition framework is particularly salient to a conversation around transition in nursing due to its strong theoretical base in social identity theory, and its conceptualization of transitions as socially and psychologically mediated processes that are both defined by and transformative of personal and professional identity. Ashforth's underlying premise that role boundaries (physical, temporal, cognitive, emotional, and relational) have a significant interplay with identity, and his assertion that transition is experienced at different magnitudes (micro versus macro) depending upon how much it stresses those boundaries provides an instructive framework through which to examine a

transition to an emerging specialty within a tradition-honoring and identity-centric profession such as nursing (Maggs, 2006).

Ashforth's (2001) ABCs (affect, behavior and cognition) of role identification (Figure 1.1) provide the lens through which the *nature* of the role transition, including how the nurse's personal and professional identity is experienced, was examined. While Ashforth recognizes that both a person-based and a role-based (collective) identity co-exist, it is assumed that the collective identity is central to role transition. Identification in this model is defined as "the sense of oneness with a group or role, entailing the perception (cognition) and valuing (affect) of that oneness" (p. 210). Affect, behavior, and cognition are defined as fairly tightly coupled psychological forces, each with the potential to influence the other. In turn, the social context in which identity is formed functions as a validation mechanism that may reinforce (or fail to reinforce) the newly formed identity through mechanisms such as direct feedback, praise, recognition (or lack thereof), or some sort of rite of passage or incorporation.

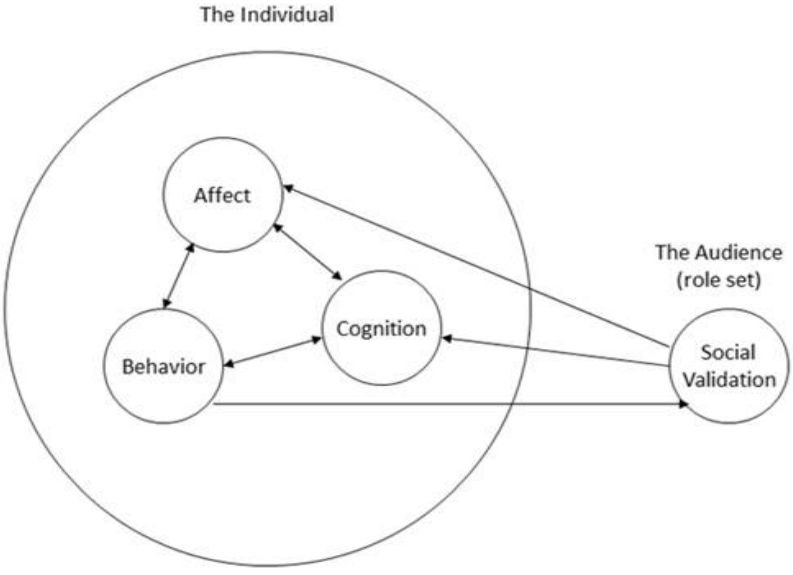

Figure 1.1. The ABCs of role entry (Ashforth, 2001, p. 209).

To better examine the *process* of role transition, Nicholson's (1984, 2013) theory of work role transitions was employed. Nicholson defines work role transition as "any change in employment status and any major change in job content" (1984, p. 173). Nicholson poses that transitions are normal, regularly occurring, and recursive, and as such, Nicholson makes three basic assumptions about the transition process. First, transition is a process requiring adjustments of the self and of the environment, and is cyclical and continuous in nature (Nicholson, 1984, 1987). Second, work role transition is experienced as four psychosocial stages, including preparation, encounter, adjustment, and stabilization. Nicholson (1984) maintains the transition stages and their outcome are independent of one another, and thus, have an independent impact on how the individual experiences the transition affectively or cognitively, and on how one experiences their identity.

In a recent publication on leadership, Nicholson (2013) adds dimension to the affective and cognitive aspect of transitions by exploring the concepts of destiny, drama and deliberation within the conversation around transition's nature. Destiny, in this conceptualization, notes that for some individuals, destiny rules, and may actually be preferred. Transition and change are normal processes to be endured, and follow a predictable course. Drama captures the unknown, everything in life transitions that is *off-schedule* or unpredictable. Depending upon the affective and cognitive nature of the individual in transition, this may be seen as fun, or as threatening as "you [may] end up somewhere you didn't intend" (Nicholson, 2013, p. 196). It is in the process of deliberation, however, defined as a time "of reflection and choice" (p. 197) that the individual is able to take best advantage of the opportunities that change and transition

have to offer, allowing destiny to be found, rather than endured, and empowering the individual to expect and navigate the unexpected that transition inevitably brings.

The relationships between the key concepts under investigation are presented in figure 2. Professional Nursing is the collective environment in which the transition is occurring, and the identity of the professional nurse, conceptualized in terms of it emotional valence, salience, and level of social validation (Ashforth, 2001), is an antecedent condition that both impacts and may be impacted by (through identification experiences) the nature and process of work role transition. Transition itself is depicted as a dynamic, cyclical experience, progressing through stages from preparation to stabilization, and both impacting and mediated by the affective and cognitive nature of the individual moving through them (Nicholson, 1984, 2013).

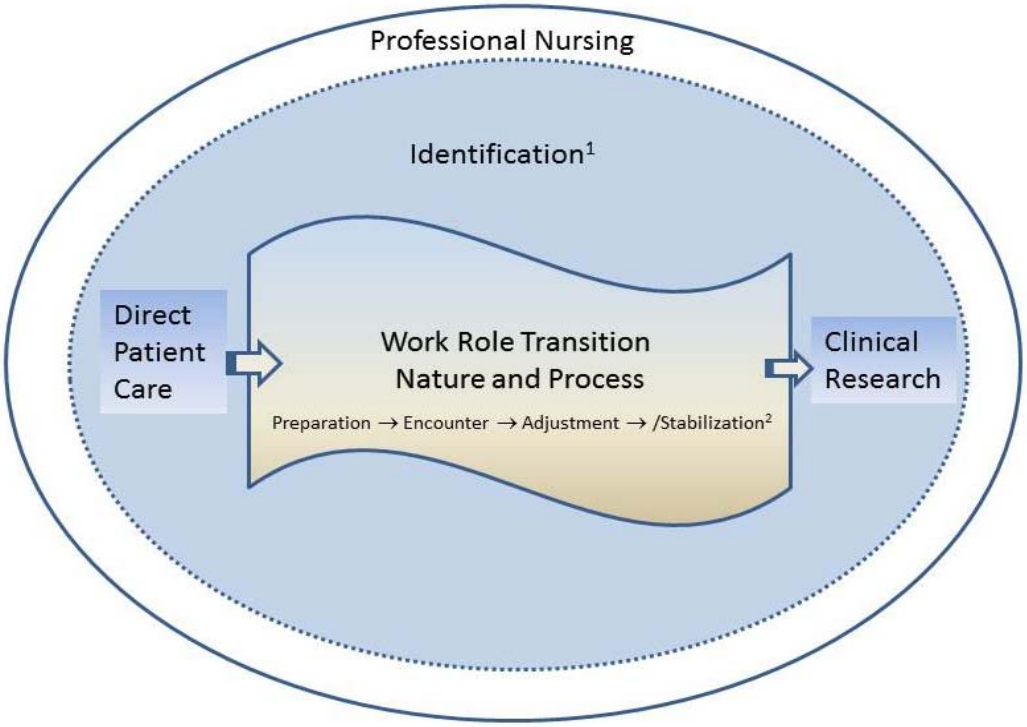

Figure 1.2. Conceptual framework (Ashforth, 2001[1]; Nicholson, 1984, 2013[2]).

Summary of the Methodology

This study was designed to examine the nature and process of the individual experience of the professional nurse's transition from direct patient care to the clinical research nurse specialist role. To examine the transition process, the qualitative inquiry paradigm, specifically phenomenology, was employed (Creswell, 2006). Creswell suggests that phenomenology is especially well-suited to gaining an understanding of the nature of an experience, and, as Moustakas (1994) notes, is useful in exploring both the research participant's intentionality as well as the nature of their inner consciousness of an experience. Because the framework selected for this study is grounded in social identity theory, and the psychological aspect of self-called *meaning* is defined in terms of the way a person makes sense of their role (Ashforth, 2001), an interpretive ontology and social constructionist epistemology guided the inquiry (Berger & Luckmann, 1966; Sandburg, 2005).

Participants for this study were professional nurses who had attained a baccalaureate or higher level of education, transitioned at least two years ago from direct patient care roles to the role in industry such as Clinical Research Associate (CRA), and had experience working in the biopharmaceutical or medical device industry in a full time capacity. This specific type of clinical research nursing role was chosen due to its lack of previous investigation, the assumed higher magnitude of the transition (as it entails leaving traditional patient care to work for a biopharmaceutical or medical device employer or client), and to reduce the potential confounding effect that nurses working full time inside a health care setting who may still engage in some level of direct patient care could introduce. The actual title and scope of practice of the nurse in this role varied

so role function was assessed according to the focus and nature of the job and type of employer. Two years was selected because organizations such as the Association of Clinical Research Professionals require that the CRA be in this professional work role full time for two years before they are considered competent enough to apply for and take the CRA certification exam (ACRP, n.d.-b). The level of education was considered as there is some evidence that nurses with higher levels of education are more likely to view their work as a profession (Jones, 2005; Lillibridge & Fox, 2005). A purposive sampling technique relying upon snowball referrals was used (Patton, 1990), and all participants were consented under an IRB-approved protocol.

Data were collected over a series of three interviews of approximately sixty to ninety minutes each (Seidman, 2006). Conducting multiple interviews allowed both the researcher and the participant to consider the transition experience on multiple occasions. Interviews were be semi-structured, but kept flexible with the goals of developing rapport and affording opportunity for ongoing and iterative reflection. After obtaining permission from each participant, all interviews were recorded, transcribed, and shared with the research participant to ensure they were complete and accurately reflected the meaning that they intended to communicate. It was expected that saturation would be reached after interviewing 10-12 participants (Lincoln & Guba, 1985; Strauss & Corbin, 1990). Actual saturation occurred at interview 3 of participant 8. Because participants 9 and 10 were already consented to participate in the study, they too were interviewed to add to the robustness of data collected.

Each transcript was read a number of times throughout the research process to ensure a robust interpretive process, followed by identification, review, and coding of

phrases or terms most relevant to the research questions (Moustakas, 1994). The goal of coding was to deconstruct or "fracture" (Strauss, 1987, p. 29) the data generated to identify key patterns or themes, as well as to identify any discrepancies requiring further examination (Hill, Thompson, Williams, Hess, & Ladany, 2005; Maxwell, 1996). When all patterns and themes had been explored and no new information was revealed with subsequent readings, saturation was considered to have been achieved (Corbin & Strauss, 2008), and a list and description of key concepts and phenomena was generated. Individual participant profiles were created, including participant specific exemplars (verbatim descriptions drawn from transcripts) of each key concept or phenomenon, and all data were examined both individually and as a group. Moustakas' (1994) analytic reduction technique including horizonalizing (preliminary grouping of relevant expressions), reduction (testing each expression or description to see if it can be abstracted and labeled), elimination (removing expressions or descriptions that are insufficient in detail or cannot be labeled), clustering remaining invariant constituents, thematic labeling, checking individual themes against the complete record of each study participant for compatibility, constructing individual textual and structural descriptions, and finally developing composite descriptions of meanings and essences of the transition experience for the group as a whole was employed.

Trustworthiness was ensured according to Lincoln and Guba's (1985) four criteria of credibility, transferability, dependability, and confirmability. Credibility was managed through repeated engagement over time (multiple interviews) with each study participant, checking for accuracy of interview transcription (member checks), and ongoing self-reflection on the part of the researcher to identify and bracket potential researcher bias

(Moustakas, 1994; Yardley, 2000). Transferability was ensured through the creation and use of thick description. Dependability was ensured through iterative listening and review of interview transcripts, and use of a peer and faculty advisor to review the first few transcripts for bias and/or leading questions, and to check data coding. Confirmability was ensured through rigorous archival of all research materials and maintenance of transparency in detail for all aspects of data collection and analysis (Lincoln & Guba, 1985; Yardley, 2000).

Limitations

This study is subject to several limitations:

1. Participants were limited to Clinical Research Associates (or related roles) working in the biopharmaceutical or medical device industry to support new product development and safety, and thus, are not fully representative of the complete spectrum of nurses working in clinical research roles outside of industry. This may limit the transferability of conclusions drawn.
2. This study was conducted under the assumption that educated professional nurses, when appropriately guided through an interview process, can effectively communicate their transition experience and identify key challenges and success factors. While this appears to be the case, it should also be noted that this ability was not of a uniform level across all participants, resulting in the potential for more articulate participants to contribute disproportionately to the findings.
3. The study population reflects a purposive sample, leaving recruitment dependent upon referrals, and all individuals agreeing to participate live in the Southern and

Eastern United States. As a result, actual participants enrolled may not represent the full spectrum of the target population, thereby limiting transferability.

4. Examining the nature and process of the transition experience requires that the transition has been completed. As a result, the study generated very little direct information about nurses who are unsuccessful in making this transition.

Definitions of Key Terms

Clinical research: Patient-oriented research: research involving a specific person or group of individuals, or the use of materials from humans. This research can include:

- Studies of mechanisms of human disease
- Studies of therapies or interventions for disease
- Clinical trials
- Studies to develop new technology related to disease
- Epidemiological and behavioral studies to examine the distribution of disease, the factors that affect health, and how people make health-related decisions
- Outcomes and health services research (National Institutes of Health, 2010).

Clinical research specialist: A professional nurse working in the field of clinical research in the role of a Clinical Research Associate (CRA): a research professional who irrespective of job title, supervises, monitors, and supports the administration and progress of a clinical trial on behalf of a sponsor (ACRP, n.d.-b).

Direct patient care (in nursing): "Care of a patient provided personally by a staff member. Direct patient care may involve any aspect of the health care of a patient,

including treatments, counseling, self-care, patient education, and administration of medication" (Mosby, 2009).

Identification: An expression of identity in social identity theory, identification is "the sense of oneness with a group or role, entailing the perception (cognition) and valuing (affect) of that oneness" (Ashforth, 2001, p. 210).

Identity: "A persistent sameness within oneself (selfsameness) and a persistent sharing of some kind of essential character with others" (Erikson, 1968, p. 57).

Macro-role transitions: "The psychological and (if relevant) physical movement between *sequentially* held roles" (Ashforth, 2001, p. 7).

Nature of transition: The interplay between the difficulty (magnitude, social desirability, voluntariness, predictability, collectivity, duration, and reversibility), the emotional/cognitive valence of the transition experience, and the social validation received (Ashforth, 2001).

Process of transition: A series of 4 independent psychological stages (preparation, encounter, adjustment, and stabilization) that may impact how an individual experiences the transition and their identity throughout the transition process (Nicholson, 1984).

Professional nursing: a nurse possessing at least a baccalaureate degree whose work role meets the definition of a professional:

- Provides a service to society that is considered important
- Practices based upon a distinct body of knowledge
- Has the ability to be self-regulating
- Maintains a commitment to life-long learning

- Is a member of a specific professional subculture (Zerwekh & Claborn, 1997).

Transition: "The psychological and (if relevant) physical movement between sequentially held roles" (Ashforth, 2001, p. 7).

Work role transition: "Any change in employment status and any major change in job content" (Nicholson, 1984, p. 173).

Summary

The study undertaken here was a qualitative, phenomenological exploration of the nature and process of the work role transition a professional nurse undertakes to move from direct patient care to clinical research. The lack of available literature or published research on this topic, in spite of evidence that many nurses have made this transition, indicated a need to better understand the nature of the experience, the barriers and supports impacting the process, and what types of measures may be taken to facilitate success. The following chapter provides the necessary background and examination of relevant literature that support and inform this study.

CHAPTER 2:

LITERATURE REVIEW

Introduction and Background

Shifts in technology, a broad liberal education, and the transferability of skills and knowledge to non-patient care roles have helped to transform the once linear career model of professional nursing into one with a myriad of roles that reach beyond patient care (Duffield, Aiken, O'Brien-Passas, & Wise, 2004; Duffield & Franks, 2002). The most common career venues outside of direct patient care that professional nurses seek are management, administration, education, health, research, and sales (Duffield et al., 2004).

Professional nursing is, in essence, becoming a 'boundaryless career' (DeFillippi & Arthur, 1994). Boundaryless careers defy traditional organizational assumptions regarding order, hierarchy, and pre-programmed progression patterns in favor of recognition that certain skills, traits and capabilities may be transferable, and adapted to career pathways that are outside of traditional or expected professional norms (Arthur & Rousseau, 1996). Rigid hierarchies commonly found in the U.S. healthcare delivery system that constrain creativity (Ewens, 2003) are being traded for the opportunity to engage in further educational and professional development, improved opportunities for reward and recognition, and jobs perceived to be of higher status (Duffield & Franks, 2002; Mueller, 2001). According to Ewens (2003), the constraints that nurses experience in most health care environments often illuminate a gap between what the professional nurse has come to believe his/her role should be and their experience in reality, prompting them to seek a better integrated self through role change.

There is no clear pathway from direct patient care to clinical research, so the decision to engage in this work role change is an especially intriguing one. While literature on research nursing is extremely limited, much of what does exists points to the challenges and difficulties research nurses experience (Chadwick, 1992; Mueller, 2001; Raybuck, 1997), and the scientific, social and personal consequences of the inability to meet the demands of this role (Redman et al., 2006). When examining the role of the professional nurse managing and conducting research to support the development of new pharmaceuticals and medical devices, the lack of data and literature is somewhat surprising. This is reflected in a recent dissertation published by Shannon (2011) noting that, in spite of an exhaustive literature search, "no studies were found of nurse professional practice in the pharmaceutical and biotech industry" (p. 13).

This literature review focuses on the nature and process of work role transition from the traditional direct patient care nursing role to that of the nurse engaged in clinical research for the biopharmaceutical or medical device industry. A historical and current perspective on modern nursing and the development of nursing specialties is presented, defining and charactering the role of the clinical research nurse and its impact on the clinical research enterprise. The concepts of nursing identity and identity development are explored, and literature on work role transitions and the impact of transition on professional work role identity are presented as relevant to the topic of this study.

Research Databases and Search Strategies

To obtain the necessary literature for this review, numerous data sources were accessed. Access to literature on the nursing profession, nursing educational models, the clinical research nurse, nursing specialization and certification practices, and statistics

regarding the nursing workforce was obtained through Google Scholar, JSTOR, Journals at OVID Nursing Collection, Science Direct, ProQuest Research Library, and a variety of relevant professional association and governmental web sites. Key search terms and phrases included “clinical research nurse,” “clinical research associate,” “nursing specialization,” “masters programs in clinical research,” “baccalaureate nursing education,” and “professional nursing.”

Literature on transitions and work role transitions was drawn from numerous published texts, EBSCOhost Business Source Premiere, ERIC, JSTOR, ProQuest ABI/Inform, Google Scholar, and Dissertations and Theses Online. Keywords used included “transition,” “work role transition,” and “transition theory.”

To explore the relationships between work role transitions, identity, and nursing identity, additional literature reviews were conducted combining these terms as keywords. Sources accessed included Google Scholar, Journals at OVID Nursing Collection, published texts, Wiley-Blackwell Medicine and Nursing Backfiles, CINAHL Plus, Journals at OVID, ProQuest Research Library, and Science Direct Elsevier. In addition to exploring the data sources listed here, references for most relevant publications were also reviewed to identify key publications that had otherwise been missed.

The literature search was initiated in 2009, and continuously updated. To reflect the period of time over which nursing specialization has developed, particular attention was paid to literature published since the middle of the 20th century. Because the study is focused on professional nurses, the exploration of identity and work role identification, as

a core component of Ashforth's (2001) role transitions theory, was bounded primarily to nursing identity versus the broader identity conversation.

Literature on Professional Nursing

Since the 1990s, nursing has been one of the fastest growing fields of employment in the United States. The Department for Professional Employees of the AFL-CIO reports that "between 2003 and 2011, the number of employed registered nurses (RNs) increased from 2,449,000 to 2,724,570. This represents an increase of 10.1% (AFL-CIO, 2012, p. 1). Nevertheless, nurses continue to experience low wages for their level of skill and education, exposure to significant environmental danger and injuries, missed work due to overexertion and stress, and burnout at alarmingly high rates (AFL-CIO, 2012). While the overall employment numbers look good, it is important to recognize that there are also an estimated 500,000 RNs in the United States are not practicing nursing (Herbst, 2007).

Public perceptions of the status of the nursing profession may be somewhat different than those of the individual practicing nurse. While on the one hand, when Gallop (2013) requested that Americans "please tell me how you would rate the honesty and ethical standards of people in these different fields," of the 22 fields listed, nurses received the highest rating (very high/high) 82% of the time. This was 13% higher than medical doctors, 37% higher than judges, and 60% higher than business executives. Nevertheless, due to a number of factors, including perceived subservience to physicians and relatively low wages, nurses continue to suffer from a rather poor social image that has been noted to be a major concern in the research (Findlow, 2014; Takase, Maude, & Manias, 2006; Yetter, 2010). A study conducted on a population of 943 registered nurses

working in a variety of different clinical settings, for example, noted that nurses' self-image was consistently higher than that of what they perceived as their public image, and this image gap was consistently tied to high turn-over rates, stress, and difficulty in maintaining performance (Takase et al., 2006). Why this disconnect between personal and social image continues to exist today is debatable, but to frame this conversation, it is helpful to look at the development of nursing as a profession.

Development of the Nursing Profession

During the Victorian era, in the character of Sarah Gamp, Charles Dickens depicted a nurse as a sloppy, drunkenly, incompetent, lower class woman who had no education and no manners (Dickens, 1843–1844/1994). Hospitals of his time were unsanitary, had poor working conditions, and many of the women who worked in them were indeed poor and uneducated (Joel, 2006). Early modern nursing as a profession, however, was emerging during the same period with the foundation of Florence Nightingale's first school of nursing at St. Thomas's hospital in London in May of 1860 (Dingwall, Rafferty, & Webster, 1988). Nursing during these early years is commonly described as a calling, by Nightingale as a skilled calling, and the development of the profession is described more as a triumph of spirit than as the emergence of an identifiable scientific body of knowledge and expertise (Dingwall et al., 1988; Dock & Stewart, 1920; Maggs, 2006; Sweet, 2007). By 1918 there were 1,580 accredited schools for nursing in Europe and the United States, and by 1920, nursing was described as consisting of three primary specialty areas, hospital nursing, visiting nursing, and private duty nursing (Dock & Stewart, 1920).

Today nursing has diversified into many different recognized specialties, characterized as clinical nurse specialists in advanced nursing practice (Davies & Hughes, 2002; Hamrick, 1996). The title *Clinical Nurse Specialist* was first used in 1938 and has been linked to several social trends including developments in science, advancements in knowledge base (Cotton, 1997; Peplau, 2003), and changes in public need and health care delivery structures (Aiken & Sloane, 1997; Peplau, 2003). Peplau (2003) broadly defines specialization within a profession as "a division of the generic field or some recombination of aspects of different fields, which occurs along some logical lines" (p. 3). The key characteristics of a nurse specialist, according to Peplau, include the possession of a broad undergraduate education, a strong theoretical base and analytical skills, a thorough knowledge of the specialty area of focus, the ability to collect and communicate data, and the discipline to function as an independent practitioner. To be more specific, Cotton (1997) defines nursing specialization as "a level of knowledge and skill in a particular aspect of nursing which is greater than that acquired during the course of basic nursing education" (p. 26). Over the past several decades, nurse leaders have engaged in and encouraged specialization, beginning with the American Nurses Association's (ANA) promotion of baccalaureate education for entry into practice, and encouragement of the development of advanced practice roles through masters and doctoral level preparation (Malone & Marullo, 1997).

The rapid development of new nursing specialties for advanced practice has been attributed to shifting current societal needs, changes in governmental policy or regulations, workforce supply and demand shifts, the development of new educational opportunities for women, and support and recognition by the nursing profession itself

(Styles, 1996). Tracing the progress and development of the clinical nurse specialist role from the late 1930s to today, however, reveals a bumpy road, meeting barriers of control and accusations of illegitimacy (Cotton, 1997). For example, it is not uncommon to hear a complaint that the nurse practitioner, a specialty originally born due to a shortage of physicians, is not actually a nursing role at all, and Raja-Jones (2002) maintains that a significant amount of resistance to the recognition and support for development of new advanced practice roles comes from within the nursing profession itself. In short, the scope and definition of the advanced practice role remains somewhat unclear, and is often poorly distinguished both within nursing and between nursing and the practice of medicine (Davies & Hughes, 2002). This is further evidenced by the fact that advanced practice nursing and advanced nursing practice are often confused (Bryant-Lukosius, DiCenso, Browne, & Pinelli, 2004). Whereas advanced clinical nursing practice refers to a direct patient care nursing role (Brown, 1998), advanced practice nursing may or may not be characterized in this manner (Brown, 1998; Bryant-Lukosius et al., 2004; Ketefian et al., 2001; Styles & Lewis, 2000). For example, the Advanced Forensic Nurse, an advanced practice nursing specialty recognized and certified through the American Nurses Credentialing Center (2015), does not engage in direct patient care and is thus considered to be engaged in advanced practice nursing, but not advanced *nursing* practice.

Hanson and Hamrick (2003) describe the evolution of the development of a new nursing specialty in three stages: specialty emergence in practice settings, the introduction of organized training for the new specialty, and finally, as the knowledge base grows, the standardization of curricula for graduate level education. Building on

this, Bryant-Lukosius et al. (2004) and Ketefian et al. (2001) both describe the development of an advanced nursing specialty as a process through which an identified practice need becomes apparent, and higher level or unique clinical skills and knowledge are obtained through the initial pursuit of additional education, standardization, certification, and specialty licensure. As a reflection of this process, Cotton (1997) notes that as specialization evolves, evidence of positive patient outcomes emerge, new nursing specialty journals and educational curricula are developed, and a demand for credentialing as a way to create and maintain practice standards results. Standards for specialization, however, remain a topic of debate, for while there is growing agreement that nursing specialties should require graduate level education (Bryant-Lukosius et al., 2004; Canadian Nurses Association, 2000), this has by no means been a universally accepted or enforced requirement (Pearson, 1996; Woods, 1997).

While nursing roles such as anesthesia, oncology, and primary care have developed along a traditional trajectory and ascended to the level that the nursing profession recognizes them as nursing specialties, there are other practice functions that traditionally began as part of the nursing role that have not. Nutrition, physical therapy, and occupational therapy, for example, diverged from nursing to develop as independent specialties with governing boards and professional associations of their own (Cotton, 1997; Hanson & Hamric, 2003). Thus, the fact that a new area of needed competency within the nursing profession is identified, and educational and training programs are developed to address this need does not necessarily mean that the nursing profession will take up the mantle of recognizing, accepting, and supporting this new role as a nursing specialty.

The clinical research nurse is a modern example, a role often filled by professional nurses, for which dozens of advanced degree programs have arisen over the past three decades (Association of American Medical Colleges, 2008), but which the nursing profession has yet to either recognize, or take an active role in establishing standards, offering certification, or managing practice quality of the nurses working in this field (Chadwick, 1992; Spilsbury et al., 2007). The lack of consistent nomenclature of title, role definition, educational and training requirements, and support from the nursing profession has broad implications in terms of the quality and integrity of the research process, the protection of human subjects participating in clinical trials, and the overall validity and reputation of the clinical research enterprise (Redman et al., 2006; Reynolds, 2004).

Clinical Research Nursing

The clinical research nurse may be broadly defined as a "registered nurse . . . employed . . . to help facilitate and conduct any phase of a clinical trial" (Spilsbury et al., 2007, p. 550). Clinical research nurses may assist the research subject to navigate their responsibilities and the activities required in a given research protocol; manage research subject recruitment; administer and verify informed consent; collect, record, and verify critical research data; monitor the research team for protocol and regulatory compliance; perform data quality audits and data management; function as a patient advocate and protocol or study manager (Ocker & Pawlik-Plank, 2000; Raja-Jones, 2002; Raybuck, 1997; Spilsbury et al., 2007). Within the world of research nursing, there are two primary groups of professionals, clinical research nurses or coordinators (CRC) who are largely employed by the physicians or the medical and academic institutions that conduct clinical

trials, and study managers or clinical research associates (CRA) who monitor study conduct and control research integrity and quality for the pharmaceutical and medical device manufacturers that sponsor the research (Mueller, 2001; Stonier, 2003).

A literature review conducted to better understand the research nurse role proved difficult. Searches conducted on the terms *research nurse* and *research nursing* resulted almost exclusively in articles describing *nursing research*, an activity within traditional nursing roles that is focused on nurse-initiated studies and interventions. On the other hand, a search on the terms *research nurse specialist, research coordinator, or clinical research associate* (often identified as a nurse), resulted in numerous articles on clinical trials and clinical research noting this individual to be a key and critical member of the research team (Davis et al., 2002; Rico-Villademoros et al., 2004; Showstack et al., 1999; Wright, Crooks, Ellis, Mings, & Whelan, 2002). The contrast between a frequently mentioned role in the clinical research literature and almost complete lack of publications focusing on the research nurse in the nursing literature appears to indicate that the role is poorly understood within the nursing profession (Raja-Jones, 2002; Raybuck, 1997), and that little or no data have been collected regarding the nature and prevalence of this nursing role or the process by which nurses transition from traditional patient care roles and environments to the specialized world of clinical research.

Noting this research gap, a grounded theory study was conducted to examine how nurses working in the biopharmaceutical industry perceive and process their professional practice (Shannon, 2001). The experience of practicing nursing in this new corporate environment was described as evolving in four phases beginning with disillusionment, moving through acclimatization and achieving a new sense of belonging, and culminating

in a period during which the nursing specialty is actualized in the new environment. One finding of particular interest to this study was that in spite of the lack of support, and even open resistance by the nursing profession and peers to this non-traditional role, during the process of acclimatization individuals working in this new industry still identified themselves as nurses, affording them an ability to redefine their new work as nursing practice. Research participants reported that industry valued their nursing background, and this gave them a great sense of pride in the unique contribution this allowed them to make.

In January of 2007, The National Institutes of Health Clinical Center for Nursing officially recognized the role of the clinical research nurse by launching an international effort to define this specialty practice. The National Institutes of Health, however, recognized only staff nurses who deliver direct patient care to research patients, referred to as Clinical Research Nurses and Clinical Research Coordinators (Hastings, 2010), making no mention of the industry-based Clinical Research Associate (CRA) in the initiative. As noted in Chapter 1, professional associations and higher education, on the other hand, not only appear to recognize the role of the CRA, but are embracing it through the creation of CRA specialty certifications and offering a variety of advanced degree programs that target, among others, the CRA population (ACRP, n.d.-a; Drexel University, 2014; SoCRA, 2010). A brief internet search on the keyword phrase “masters programs in clinical research,” resulted in a number of hits from some of the most prestigious universities in the country, including, among many others, The University of Maryland, Universities of California at San Diego and San Francisco, University of Virginia, Johns Hopkins, and The George Washington University. The certifications

offered through professional associations are also well credentialed. The Association of Clinical Research Professionals CRA certification program, for example, maintains NCCA (National Commission for Certifying Agencies) accreditation (ACRP, n.d.-a), and SoCRA (The Society of Clinical Research Associates) educational programming is accredited through the Accreditation Council for Clinical Research Education (http://accre-accredit.org/), a global accreditation body established in 1965.

The mechanism through which a nurse might choose a research coordinator focus over a research associate focus is unclear (Mueller, 2001), and even less is known about the motivation that drives nurses to seek these specialty roles. While professional nurses may enter clinical research immediately following their basic nursing education, this is unusual, as most make this transition after practicing in traditional patient care roles for some period of time. This may be attributed to the fact that few schools of nursing encourage or prepare baccalaureate nurses to participate in clinical research (Sung et al., 2003). As a result, the types of preparation and education that most nurses engage in prior to entering this field remains unclear, and the nature of how transition to this career is experienced is apparently unexamined.

The Clinical Research Nurse in Practice

The world of clinical research differs significantly from that of direct patient care (Mueller, 2001), and the nurse engaged in making this transition is often educationally unprepared, may lack key skills and competencies that are unique to research, and often lacks adequate support from others and the nursing profession (Raja-Jones, 2002; Redman et al., 2006). Research teams from the Department of Medical Ethics at the University of Pennsylvania and Wayne State University demonstrated that insufficient

education and training of research personnel, poor oversight and supervision, workload and role conflicts, and a lack of consistent role expectations and standards create an environment at risk for scientific research misconduct (Redman et al., 2006). The consequences of misconduct may include loss of institutional research privileges, reliance upon fraudulent data in seeking new drug or medical device approval, official sanction or prosecution by the Food and Drug Administration, public perception that the clinical research enterprise is untrustworthy, and ultimately, the endangerment of the clinical research subject. Although research coordinators report an impression that the overall incidence rate of research misconduct is fairly low (Pryor, Habberman, & Broome, 2007), Gardner, Lidz, and Hartwig (2004) reported that of 549 published clinical trial authors surveyed, seventeen percent admitted to having personal knowledge of research fraud or misconduct.

While much of the research on scientific misconduct is appropriately focused upon the physician investigator, as s/he is legally regarded as the individual holding primary responsibility, the majority of activities related to clinical trial management and implementation are actually performed by more junior research personnel, especially the clinical research coordinator and monitor (CRA) (Mueller & Mamo, 2002; Pryor et al., 2007). The United States Office of Research Integrity, evaluating clinical trial scientific misconduct over ten years of publically funded research, concludes that the vast majority of sanctioned incidents of misconduct occur during activities associated with trial coordination, data recording and management, and research subject recruitment and communication (Reynolds, 2004), all activities more likely to be conducted by the research nurse or coordinator (Ocker & Pawlick-Plank, 2000; Raybuck, 1997).

Failure to perform research activities to required practice standards reflects a common gap in the education and training of professional nurses (Redman et al, 2006; Reynolds, 2004). To better understand the sociocultural and professional underpinnings of this gap, it is helpful to examine how the nursing profession crafts and develops the identity of its members, and how that identity is experienced by the nurse in practice.

Literature on Identity, Identification, and the Nursing Identity

There is no clear conceptual agreement on what constitutes an individual's identity, but there is fairly good consensus that one's identity is imbedded in certain norms, self-conceptions, expected behaviors, values, and beliefs (Scott, Corman, & Cheney, 1998). The literature suggests that nursing identity is developed socially and iteratively through interaction with other nurses and engagement in a rather unique educational process (Currie et al., 2010; Ohlen & Segesten, 1998). For this reason, to best understand the development and experience of the nursing identity, while it is useful to spend some time examining the more general tenants of identity theory, the underlying basis for what it means to be a nurse lies in theories that emphasize the development of socially constructed identity

Both social identity and identity theory maintain the self is reflexive by nature, an entity that is experienced in relation to socially constructed categories or classifications in the environment (Turner, Hogg, Oaks, Reicher, & Wetherell, 1987). Social Identity theorists refer to this as *self-categorization*, whereas, in identity theory, it is called *identification* (Tajfel & Turner, 1986), and it is through this process that the individual's motive for identity is formed (Ashforth, 2001). According to Tajfel (1974), social identity reflects the individual's awareness that they are a member of an identifiable group, and

membership in this group is in some way significant or emotionally valuable to them. The group, in this definition, is described as a collection of individuals who share an identity derived through consensus, and prescribe norms for both individual and group behavior. Erikson (1974) similarly suggested that one's social identity could be described as the integration of group norms, characteristics, values, and ideals into the self.

According to social identity and identity theory, the individual self, as well as the professional or role-based self, are both viewed as socially constructed and socially defined, and the product of a social learning process (Ashforth, 2001; Ashforth & Mael, 1989; Bandura, 1986; Robinson, 1996; Stryker, 1987; Tajfel & Turner, 2004), reflecting Mead's (1934) concept of self as something that exists in a reflexive relationship with the world. Social identity theory draws a conclusion supported through work in the fields of neuroscience and psychology (LaBar & LeDoux, 2003; Lazarus, 1998; LeDoux, 2000), that to reach a state of identification, both a cognitive sense of awareness as well as an affective affinity for a particular identity are required (Tajfel, 1982). The relationship between how one is socialized to experience the self and the nature of the identity experience is highlighted in the work of Markus and Kitayama (1991) who propose that individuals develop a socially constructed self-system that represents one's core conceptions or self-schemata, and its nature determines how a person experiences their world both cognitively and emotionally. The self-system, therefore, is a reflection of the culture with which an individual most identifies, and cultures generate socially constructed meanings for experiences through the development of interpretive frameworks (Durkheim, 1961; Geertz, 1973). Nursing is a profession associated with a culture described as highly socialized, complex, and distinctive, with a highly specialized

and common set of rules and rituals, and a deeply embedded set of values and social/professional expectations (Suominen, Kovasin, & Ketola, 1996; Tutton, Seets, & Langstaff, 2007). For the professional nurse considering a career that falls outside of the core role to which nurses are socialized and educated (Redman et al, 2006; Reynolds, 2004), and for which, as a result, no rules, rituals, or clear professional expectations exist (Schouten, 1991), maintaining a clear perspective on identity may be challenging and have a negative impact on the transition experience (Ashforth, 2001; Barton, 2007).

For reasons that are somewhat unclear, research is extremely limited on what being a professional means to the individual nurse (Secrest, Norwood, & Keatley, 2003), and as such, it is difficult to locate a succinct definition of the professional nursing identity. For the professional nurse, role identity development and socialization begins during nursing school, an environment keenly focused on transforming nursing values, norms and ethical standards into the behaviors and personal self-concept of the nursing student (Cohen, 1981; Fagermoen, 1997). A key professional identity precursor for the baccalaureate nurse includes a broad liberal education that emphasizes coursework across multiple disciplines including science, mathematics, social studies, psychology, foreign language, ethics and law, research and theory, core nursing skills development, and exposure to various nursing roles (Duffield et al., 2004; Duffield & Franks, 2002). This creates a professional identity for the new graduate that tends to be quite broad (Corwin, 1961). Modern healthcare practice models, on the other hand, tend to narrow the scope of nursing practice (Duchscher & Cowin, 2006). Ewens (2003) argues that the resulting reality gap experienced by many nurses may cause them to separate their self-concept from their work role, and this is echoed in the findings of a study of 943 registered nurses

that a nurse's personal image may be significantly different, and in many cases better than what they perceive as their public image (Takase et al., 2006).

Sluss and Ashforth (2007) note that an individual experiences identity on three different levels (personal, interpersonal, and collective) allowing them to maintain more than one identity in dynamic equilibrium. In circumstances where an individual must *wear* several identities simultaneously, some more salient than others, it is the personal identity that tends to be the most tenacious and resistant to disconfirmation. Ashforth (2001) observes that role identities have different degrees of salience, allowing an individual to occupy and enact a work role without experiencing it as self-defining. Conversely, where self and professional identities are tightly intertwined, as is the case for many nurses (Ohlen & Segesten, 1998), even role identities viewed with ambivalence may remain central to the core self identity of the individual (Ashforth & Kreiner, 1999).

One key to understanding the gap that emerges between the broad identity developed during baccalaureate nursing education and the narrower experienced identity of the professional nurse may be to consider the impact of technology on practice. Technological change today is rapid, and as a profession that frequently interfaces with new technology, the role and function of the nurse in practice must also undergo constant modification and change (Johnson, Cowin, Wilson, & Young, 2012).

Rapid developments in technology are changing the ways nurses interact with their patients and other healthcare providers, how they access education and knowledge support, and how they feel about themselves (Horton, Tschudin, & Forget, 2007). Johnson et al. (2012) notes, "from the macro level of cultural change to the micro level of individual expectations and experiences," the nurse's professional identity is constantly

assailed (p. 566). To illustrate this, MacIntosh (2003) discovered that nurses' identities were in a constant state of change, and reported that due to ongoing dissonance between their expectations and the experiences they were having at work, nurses tended to constantly rework their professional identities. MacIntosh's study is based upon the assumption that identity development is a socially enacted process, and she concluded that to rework identity, the nurse had to move through three stages: 1) assuming adequacy (concentration on the task at hand with little to no reflection on interpersonal consequences, 2) realizing practice (developing awareness of new work contexts to identify discrepancies and balance differences), and 3) developing a reputation (reintegration and demonstration of competence and proficiency). Currie et al.'s (2010) research also acknowledges that identity results from a socialization process, but concludes while collective level identity is central to the prospects for successful role transition, person-based or self-identity has the potential to transcend the more collective role-based identity.

Ashforth (2001) distinguishes between how identity is experienced at a collective versus personal level. Referring to the collective identity as a *global* identity, he proposes that the global identity of an individual answers the question of 'who am I?', while the meaning of that identity to a person is reflected in the question 'why am I?' Meaning, as Ashforth envisions it, is an expression of "the power of ideas, values, hopes and ideals to confer purpose and significance" to one's life (p. 65). To understand what an identity means to an individual and how that identity is experienced, it is necessary to understand how each person makes sense of the nature of their role. This sensemaking exercise is defined as "an interpretive process where one organizes stimuli into some kind of

intelligible framework" (Karl Weick as paraphrased in Ashforth, 2001, p. 66). Ashforth maintains that the strong desire for identity and meaningfulness triggers individual sensemaking. While this process may help to validate the merger that an individual seeks between their various roles and the person they believe themselves to be, it may also, in contrast, expose the differences and contradictions between what an individual sees as their ideal self and the reality of the work role they play. The cognitive dissonance that results can create a strongly conflicted identity (Festinger & Carlsmith, 1959), and individuals may seek to reduce the conflicted state they are experiencing through either distancing themselves from the role or through embracing creative alternatives (Dukerich, Kramer, & McLean-Parks, 1998). Ashforth (2001) refers to this process as role dis-identification, noting that individuals caught up in this dynamic may engage with their work role in a negative manner, may seek to change jobs or careers, or may form or engage with an outgroup with either the power to enact the role changes they desire, or the ability to motivate them to seek a new role while feeling less conflicted about leaving.

Distinguishing role or professional identity from personal identity and depicting both professional and personal identity development as social learning processes is a common theme in identity research and theory (Ashforth, 2001; Ashforth & Mael, 1989; Robinson, 1996; Stryker, 1987; Tajfel & Turner, 1986). Ashforth (2001) notes that the personal identity provides the template for the role identity that people experience, and conversely, the more the individual values their role identity, the more influence it has over their personal identity. Professional identity development viewed in context of Social Identity Theory (SIT), begins with a sense of one's' own uniqueness, and while both social role and individual identities are socially constructed, the desire to experience

some distinctiveness of self through work role tends to emerge within the social collective (Brewer, 1991). Role Theory (Biddle, 1979) suggests that a role is a function of the expected behaviors and status of its occupant, and the assignment or allocation of a given role depends upon norms regarding what is permitted or sanctioned in society. The dynamics of role entry, therefore, involve a combination of a desire to distinguish self, the ability to access the necessary role skills, and opportunity to engage in the necessary role socialization process (Biddle, 1979; George, 1993). Ashforth's (2001) model of role identification, with foundations in social identity theory, identity theory, and role theory provides an excellent lens to examine the experience and meaning of *professional* identity for the nurse in transition. This model will be discussed in the next section.

The Literature on Work Role Transitions

Transition has been described in a variety of different ways in both theory and research. For the purposes of this literature review, clarifying the distinction between role transition and work role transition is useful. Ashforth, Kreiner, and Fugate (2000) describe role transitions as "boundary-crossing activities, where one exits and enters roles (p. 472), and note that individuals may hold and transition between many roles that function as building blocks for larger social systems. Work role transition, on the other hand, pertains specifically to roles enacted as part of one's work or career activity, and is broadly defined as "any change in job status and any major change in job content" (Nicholson, 1984, p. 173). Differentiating role transition from work role transition from a nursing perspective, Anderson (2009, p. 203) defines work role transition as "the human experience associated with entering a new community of practice . . . a dynamic, developmental process with associated emotional work, critical tasks and diffusion

through role boundaries to assume the new identity, values, and knowledge base of the new role."

Work role transition has been conceptualized as being associated with 'rites of passage' marked by certain socio-cultural rituals, such as ceremonies, customary practices, and taboos (Sheehy, 1977; Turner, 1969). Rites of passage are explored through the work of van Gennep (1960), in which he identifies three phases in the process from disengagement to engagement with a given role or status. These include: (1) separation, the initial process of disengagement, (2) transition, the period of adaptation and change to fit a new role, and (3) incorporation, a process through which an individual integrates the self with the new role. Rites of passage, according to van Gennep, are often composed of culturally prescribed rituals, including symbols and activities of kindred groups. The transition through the rites of passage has been described as a praxis in which people try on their provisional self as they attempt to pass the test of experience (Athens, 1995).

Rites of passage within the nursing profession have been studied in student nurses transitioning into new roles with preceptorships (Weiland, Altmiller, Door, & Wolf, 2007), in the transition from graduate to registered nurse in the hospital setting (Godinez, Schweiger, Gruver, & Ryan, 1999; Holland, 1999; Tradewell, 1996), in nurses undertaking a transition to advanced practice roles (Barton, 2007), and from nurse to nurse educator (MacNeil, 1997). In each case, it was concluded that rites of passage play an important role in the transition experience for the professional nurse. Transition experiences for which there are no clear rites of passage, or through which an individual

must travel without a clear and available set of supports and resources, however, are generally considered to be difficult (Ashforth, 2001; Barton, 2007).

The importance of the psychological or psychosocial resources or attributes the individual in transition possesses is a common theme as a key factor in role or work role transitions (Heppner, Multon, & Johnston, 1994; O'Neil & Fishman, 1986; Schlossberg, 1981). Heppner et al. (1994), for example, identified six key psychosocial constructs, including self-efficacy (belief in one's ability to transition), self-versus-relational focus (the ability to make career decisions without considering the needs or desires of others), sufficient career motivation, rational beliefs (a realistic view of oneself), willingness to take risks, and a basic belief that career transition is in one's control, that are instrumental in successful career transition. An understanding that many transition theorists appear to share is that both role transitions and work role transitions consist of a process and are in some way socially enacted and enabled (Ashforth, 2001; Carlson, 1983; Erikson, 1980; Heppner et al., 1994; Nicholson, 1984; Oliva & Kallenberg, 2003; Schlossberg, 1981; Sheehy, 1977).

For the purposes of this study, one transition model, and one work-role transition theory will be applied as lenses for examining work role transition. Ashforth's (2001) ABCs (affect, behavior, cognition) of Role Identification will be applied to examination of the nature of work role transition, and Nicholson's (1984) work role transition model, including newly added affective and cognitive dimensions of destiny, drama and deliberation (Nicholson, 2013) will be applied in examination of the transition process. Both the Ashforth model and Nicholson's theory have a basis in social identity theory, and were selected due to the frequent mention in recent publications of the pivotal role

professional socialization plays in the development of the nurse and nursing identity (Currie et al., 2010; Shannon, 2011; Willitts & Clarke, 2014). In addition, both Ashforth's and Nicholson's work address attributes of macro-role transitions, "defined as the psychological and (if relevant) physical movement between *sequentially* held roles" (Ashforth, 2001, p. 7). This definition will be used in this study to differentiate from smaller and less disruptive within-role transitions (such as a movement from supervisor to director in the same or similar department) so as better to reflect the level of magnitude a transition from direct patient care to a career as a Clinical Research Nurse represents.

Ashforth's ABCs of Role Identification

Ashforth (2001) contends that the motives for role transition involve four psychological aspects of self, including identity, meaning, belonging and control. Identity in this model is tied to the act of identification, whereby an individual generates their sense of oneness with a group through perceiving, understanding, and valuing the oneness experience. The idea of meaning in Ashforth's model is comprised of both meaningfulness, addressing the salience and significance of role, and meaning making, a concept drawn from Weick's (1995) sensemaking ideas. Belonging, defined by Baumeister and Leary (1995), as "a pervasive drive to form and maintain at least a minimum quantity of lasting, positive, and significant interpersonal interactions" (p. 497), refers to the need for social connectedness and control, loosely defined as a construct of "spanning ability (e.g., competence, expertise), discretion (autonomy, self-determination), and power (e.g. impact, influence" (Ashforth, 2001, p. 67). Ashforth (2001) emphasizes that transition is an identity-related process that pivots on the need for self-knowledge, desires for self-expression, and the needs for self-continuity,

directiveness, and enhancement. This complex set of affective and cognitive needs and desires functions as a group of triggering forces to enact behaviors that are aimed at securing affirmation of role identity throughout the transition process.

Identity in this context is a socially constructed phenomenon wherein the individual's sense of self is "largely grounded in the perceptions of other" (p. 215). In achieving role identification, individuals receive social validation when they are recognized as an exemplar of the role and manifest values group members hold. When an individual strays from expected role enactment or engages in behaviors that send a message they are not playing their part, this threatens to break the socially constructed identity frame, with the potential to create a significant amount of affective and cognitive dissonance for the person in transition.

The need for social validation in work role transitions is so strong that when it is not clearly available, individuals will seek to create or find it wherever they can (Ashforth, 2001). Rothbaum, Weisz, and Snyder (1982) maintain that identity, as a sense of oneness, is often enacted through redefinition of an experience in the most positive terms possible. In her study of nurses working in the pharmaceutical industry, for example, Shannon (2011) found that her participants experienced themselves by interpreting new learnings through a nursing lens, perpetually defending this interpretation, recognizing and celebrating the value of nursing in industry, and by reframing their new work role as "unique combinations of nursing professional practice skill-sets and industry expertise" (p. 106).

The strength of role identification and subjective importance of role identity in Ashforth's (2001) model are directly impacted by how well the four psychological

motives are met, and inversely, serve to reinforce those motives. Ashforth characterizes identity as becoming one with the role, noting that in some instances an individual may actually assume a “transitional identity” (p. 74) in order to enable the transformation process. This was highlighted in a qualitative study of how identity was constructed in junior level professionals transitioning from technical to managerial work, noting that individuals in transition experiment with possible or provisional selves as a way to acquire identities consistent with socially constructed role models (Ibarra, 1999). Research undertaken to understand how identity is reconstructed after plastic surgery similarly noted that individuals in transition tend to formulate a possible self, and that this process often precedes actual separation, acting in some cases as the change initiator (Schouten, 1991).

Since development of his original model of the ABCs of Role Identification, Ashforth and his colleagues have published a number of papers that test individual components of the ABCs model, and contribute to ongoing identification model and theory development (Tables 2.1 and 2.2). For example, to expand upon understanding about the relationships between the affective and cognitive components of identification, Kreiner and Ashforth (2004) conducted a study of experienced adults across multiple industries, concluding that the level of identification the individual experiences with their career and organization can be undermined by breaches in psychological contract and large amounts of intrarole conflict. Supporting this, Sluss, Ployhart, Cobb and Ashforth (2012), drawing conclusions from 2 rather large field studies (N = 186 and N = 1,101), noted that positive symbolic interaction and personalized relationships between the employee and their organization fostered loyalty and inspired behavior, and that

negatively valent symbolic interaction had the inverse effect. Expanding the focus of this research from just the employing organization to include a simultaneously held relationship with a profession may be useful in this study in examination of the nature of transition as Ashforth's ABCs of Role Identification are applied.

Table 2.1
Ashforth's Identity and Identification Research Addressing Individual Level of Analysis

Participants	Type of study	Purpose / goal	Findings
231 graduating undergraduate business majors entering 1st job (Saks & Ashforth, 2000)	Longitudinal field study utilizing questionnaires administered prior to job entry, at 4 months, and at 10 months	Test behavioral plasticity theory in predicting work adjustment through the examination of role dispositional factors, situation variables, and interactions	Weak support for dispositions and behavioral plasticity theory in predicting adjustment to work over time; concluded that newcomers' adjustment to work role resulted largely from the situation and support systems encountered. Also noted a strong relationship between unmet expectations and work adjustment.
330 experienced employed adults across industries with a mean organizational tenure of 8.8 years (Kreiner & Ashforth, 2004)	Controlled, non-randomized, exploratory survey-based correlational analysis utilizing multiple previously developed scales	Explore and operationalized dimensions of an expanded identification model. Relevant variables examined were positive and negative affectivity, and cynicism.	Results demonstrated the utility and viability of the expanded identification model designed to understand how individuals derive their identity vis-à-vis the organizations within which they work. Researchers conclude that identification, disidentification, ambivalent identification and neutral identification are related yet discrete concepts, and that at the individual level, psychological contract breaches foster disidentification and intrarole conflict fosters ambivalence.
Two field studies: • Population 1: 186 newcomers in	*Study 1*: temporally lagged survey-based correlational analysis utilizing scales developed for	Testing of theoretical proposal "that relational identification generalizes to	Researchers conclude that identity and transformation, rather than exchange and transaction build and determine role relationships

Participants	Type of study	Purpose / goal	Findings
12 telemarketing companies • Population 2: 1,101 newcomers to U.S. Army (Sluss, Ployhart, Cobb, & Ashforth, 2012)	this study to test 4 hypotheses *Study 2*: similar to study 1- a 5th hypothesis added to focus on supervisor prototypicality	organizational identification through affective, cognitive, and behavioral mediating mechanisms" (p. 949).	in organizations. Personalized relationships "can inspire and influence organizational attachment via affective, cognitive, and behavioral conduits" (p. 965). Empirical evidence supports the role of symbolic interaction in the social identification process, and demonstrates that relational identification promotes organizational identification when a supervisor is perceived as prototypical of organizational values.
251 customer service reps from an Indian call center (Ashforth, Joshi, Anand, & O'Leary-Kelly, 2013)	A combination of survey and interview data collected to examine the nature of worklife. Exploratory factor analysis was employed to examine 4 identification variants across 10 hypotheses	Research the expanded model of organizational identification generated in Kreiner & Ashforth (2004) to self as experienced in occupations.	Occupational identification, disidentification, ambivalent identification, and neutral identification can be differentiated, and have different distinguishing patterns of antecedents and outcomes. Researchers conclude that each form of identification may be a unique experience and recommend future interpretive research on exemplars to gain a deeper sense of the phenomenology of each form.

Table 2.2
Ashforth's Identity and Identification Model and Theory Development

Premise	Goal and concepts under development	Key propositions and ideas	Key recommendations for research and study
Current theory does not adequately address "how one's definition of self might be influenced by interpersonal relationships and the consequent interplay of three 'levels' of identity: individual (or personal), interpersonal, and collective (or group, social)." (Sluss & Ashforth, 2007, p. 9)	Explore the interplay between self-definition and levels of identity. Define relational identity and relational identification (model development).	Key propositions proposed (examples): • "The greater the number of particularized relational identities . . . the more stable and resistant to disconfirmation the generalized relational identity will tend to be" (p. 14). • The more salient the role-relationship, "the more likely the individual will develop a particularized relational identity" (p. 15). • Multiple personally identified relationships make the individual resistant to identity disconfirmation. • Greater relational identification creates more empathy, loyalty, and better in-role performance • Valence is self-fulfilling. • High role salience and strong valence differences yield ambivalence, and may impair the role-relationship.	• Use data collection methods designed to generate thick description. • Explore identification ambivalence factors more thoroughly. • Examine the cognitive hierarchy of relational identities / identifications • Explore the extent to which relational identities are transferable and if there are limits to how many different relational identities an individual can maintain.
Identification "roots the individual in the organization" (p. 359). To fully explore identification, it is important to extend the concept of an "organization" to	Model development to address the following issues: • What is identification, why does it matter, and how does it occur?	• Individual identity within an organization emerges from the "essence of the collectives and roles in which he or she is a member" (p. 328). • Identification can be represented by a nested	• Focus on research topics where "the highly identified person views the collective or role as tantamount to self" (p. 359). • Study the dynamics that may

Premise	Goal and concepts under development	Key propositions and ideas	Key recommendations for research and study
include other types of collectives (teams, networks, & occupations) (Ashforth, Harrison, & Corley, 2008)	• Enacting identity and sensemaking • Constructing identity narratives • Occupational and career identification • Conflict & convergence	set of concentric circles with the core self at the center, content such as "I care about" or "I can do" around this, and with behaviors ("I do") as the outside ring (p. 330). • Identification is a process engaging both the collective and individual identity, and iteratively enacted through sensemaking and sensegiving.	tip functional into dysfunctional identification. • Concentrate on understanding identification as a dynamic process. • "Develop more parsimonious models of identification with multiple loci.
Current theory & research does not adequately address the phenomenon of cross-level identity. (Ashforth, Rogers, & Corley, 2011)	Explore how identities at one level of analysis enable or constrain those at other levels?	• Individual identity shapes collective identity and vice versa. This relationship is mediated by social processes and shared understanding results from interaction. • Complexity may impede identity isomorphism across levels	• Examine the way structuration impacts the degree of isomorphism. • Explore the relationship between cross-level identity and image and the impact on self.

Ashforth (2001) embraces a rather commonly held belief that individuals have many possible selves, and that these selves are extremely instrumental in mitigating adaptation to career change precisely because that are changeable, thereby liberating the individual from ordinary restraints and limitations (Markus & Nurius, 1986; Plimmer & Schmidt, 2007). Ibarra (2003), on the other hand, suggests that achieving a successful career change, may be difficult precisely because we are many selves, stating that this makes it "nearly impossible to think out how to reinvent ourselves, and therefore, it is equally hard to execute in a planned and orderly way (p. 2). The reification of imagined

selves prior to transition, including a career transition, however, may function to enhance self-efficacy beliefs and facilitate the role transition process (Bandura, 1997; Heppner et al., 1994). To assess the *nature* of role transition, Ashforth (2001) maintains that there seven key attributes that should be examined in terms of difficulty and emotional valence.

- Magnitude, defined as "the degree of role contrast . . . the number of core and peripheral features of the role identity that changes and the extent of the changes (p. 89), is experienced on a continuum from low to high, and may be assessed by examining the degree of roll contrast between the individual's current work role and the role to which they are transitioning.
- Social Desirability, defined as the "social or collective analog of an individual's assessment of valence" (p. 94), is a reflection of occupational prestige, and is assessed in terms of the relative value the new role is perceived to bring to the collective. Social desirability can also be, however, an internally constructed, self-edifying perspective used to create more positive valence when transitions are difficult or unconventional (Ashforth, 2001; Crocker & Major, 2003).
- Voluntariness, defined as a continuous attribute of the transition process that is associated with the degree of control over the exercise of choice that the individual experiences, may be examined in terms of the how much effort a collective or organization is willing to exert to convince or force an individual to choose a particular path. Expressed on a continuum from highly voluntary to highly involuntary, the more involuntary a transition is, the more threatening it becomes to the individual's sense of control and their valued identity (Ashforth, 2001).

- Predictability, defined as the ability to "anticipate the date of role exit, the onset and duration of the role entry period, and the nature of the events surrounding the exit and entry" (p. 99), can be examined in terms of how much effort the individual in transition must exert to spontaneously adapt to unplanned for or poorly characterized circumstances.
- Collective versus Individual refers to the level of involvement that peers play in the socialization process in role exit or entry, and may be examined in terms of the level of support and facilitation the individual receives from their peer group as they engage in the transition process.
- Duration is defined as "the length of time between when a person seriously entertains thoughts of exiting a role (or in the case of an involuntary exit, when he or she learns of the exit) and when he or she is expected to be 'up to speed' in the subsequent role" (p. 102). While there is no standard for an 'appropriate' duration, this may be examined in relative terms between study participants, with the a priori understanding that "a long transition period tends to ease the transition and be perceived as more positively valent than a short period" (p. 103).
- Reversibility, or the ability to reverse a role transition or exit a role and resume a career "almost as if they had never entered the role in the first place: (p. 103), can be examined through assessing how impactful the transition process is on an individual's identity, how much time and effort were required to obtain and master the knowledge and set of skills required for the new role, and whether or not the individual experiences any sense of stigma associated with returning to their previous role (Ashforth & Humphrey, 1995).

- Regularity refers to “a regular transition . . . that occurs at more or less the same time . . . in more or less the same manner” (Ashforth, 2001, p. 105). This attribute applies more to micro transitions, or transitions between *simultaneously* held roles than to the macro transition of moving sequentially to a new role, and in context of this study does not apply.

For this study, the movement from a traditional patient-centric nursing role to one focused on research and enacted in the corporate environment of a biopharmaceutical or medical device company is assumed to be of high magnitude. When a role is not recognized by one’s own profession, the usual rites of passage from separation through transition to reincorporation into the profession do not exist (Schouten, 1991; van Gennep, 1960), creating a set of circumstances that is, in Ashforth’s (2001) terms, high magnitude. High magnitude transitions tend to be difficult, often require the acquisition of multiple new skills, and may be experienced as negative events. While clinical research nurses have reported their role transition away from patient care to be challenging, (Spilsbury et al., 2007), they have also embraced this challenge in a positive manner for its novelty and the ability it affords them to bring a holistic perspective to this new nursing role (Raybuck, 1997).

Ashforth (2001) also recognizes that major transitions may be positive experiences, may allow the individual to place their role in a richer context, may be valued for the challenge they represent, and may be exactly what is required to affirm the distinctiveness of oneself in context of the social matrix within which the role is played. While research indicates that nurses leave traditional patient care roles for a number of reasons, Duffield and Franks (2002) contend that the traditional focus on negative issues

may have limited our ability to appreciate the positive reasons to effect a role transition including wishing to explore new opportunities, the opportunity for further personal development, and the self-esteem boost associate with being actively recruited by an attractive employer.

Two additional key concepts related to Ashforth's (2001) Role Identification model that may be of importance in this study are those of role de-identification (a part of the transition phase where the individual begins to separate the self from their role identity discussed earlier), and role dis-identification (an active disengagement from role identity as a way of differentiating the self when a role contradicts or challenges core personal values). To effectively achieve role identification, fulfill the psychological motives, and engage in a "virtuous cycle" (p. 73), it may first be necessary to separate the self from the role. This de-identification gives the individual in transition the opportunity to achieve affective and cognitive distance from their current role, a step that may be necessary when high magnitude transitions are engaged in (Ashforth, 2001).

While Ashforth's Role Identification model appears to be well-suited as a lens for this study in terms of its basis in social identity theory in context of the highly socially constructed world of professional nursing (Currie et al., 2010; Ohlen & Segesten, 1998), it does relatively little to address the research subquestions regarding barriers, supporters, and facilitators in the transition process itself. To examine this, a second lens, compatible with Ashforth in its grounding in social identity theory and emphasis on psychological constructs such as affect and cognition will be applied, Nicholson's (1984, 2013) Work Role Transition Theory.

Nicholson's Work Role Transition Theory

In seeking to develop theory on work role transitions, Nicholson (1984) focused on two key questions:

1. "How are change and stability interrelated?
2. How does the interaction between individuals and social systems affect either?" (p. 172)

Nicholson's underlying premise is that individual characteristics, behaviors, and dispositions have a mediating influence on the relationships between change and stability, and the individual's reaction and situational adjustment to the transition experience. Drawing from the work of Strauss (1959), Nicholson views transition as an experience that is both influenced by and influences the individual's skills, values, frame-of-reference and underlying identity. Transition is seen as an adjustment process that can be engaged in along a continuum that flows from adapting the person to the role through shifts in self-concept and values, to proactively adapting the role to the person by initiating changes in things such as work content, materials, and basic perspective, what Nicolson refers to as *role innovation* (p. 175).

In his most recent adaptation of his transition theory to concepts of leadership, Nicholson (2013) further maintains that the individual's affective and cognitive perceptions of change along the dimensions of *destiny, drama, and deliberation* will also influence how transition is perceived and experienced. For example, for individuals who see life as following a predictable course where destiny dominates, transition may be experienced as something that occurs outside the self and over which the person in transition has little control. Conversely, for those who view destiny as something that

"has both to be found and transcended" (p. 198), reliance upon deliberation, or the ability to reflect and choose, may be evident in their transition behaviors. Individuals who embrace change and engage with drama (defined as everything in life transitions that is not culturally scheduled and thus unpredictable) as opportunities to "seize the moments before [they] settle into acceptance" (p. 197), may approach transition proactively, seeking opportunities to manage through the encounter and adjustment phases deftly (Nicholson, 1984). On the other hand, for individuals who experienced exceptionally high levels of drama, or viewed drama as threatening, the magnitude of the transition may be so high as to make role adjustment almost overwhelming (Ashforth, 2001; Nicholson, 2013).

Applying Nicholson's model to studying work role transitions of American expatriate managers in Japan, Black (1988) found that successful role adjustment was strongly correlated to social support systems and job knowledge prior to role entry, whereas role ambiguity or a lack of clear role understanding had a negative impact on transition adjustment. In a subsequent study of a similar population, Shay and Baack (2004) argue that Nicholson's emphasis on *how* adjustment occurs, while useful for understanding transitions occurring at lower levels of an organization, did not well address adjustment issues for individuals transitioning into higher level positions.

Nicholson (1984) defines work role transition as "any change in employment status and any major change in job content" (p. 173), and poses that transitions are normal, regularly occurring, and recursive phenomena that follow three basic assumptions. First, the pursuit of equilibrium is futile and change is a non-linear dynamic process (Nicholson, 2013). Reflective of Erikson's seminal work on life cycle transitions

(1959, 1980), this assumption acknowledges that transitions are part of being human, and suggests that the transition process be viewed as part of an individual's personal development. In a 1995 study of 295 business school graduates, Ashforth and Saks (1995) tested Nicholson's assertion that the personal development that occurred was a process of adapting oneself to a new role, concluding that while the model was sound, it could be enriched by recognizing that not only do both the person and the role develop over time, but that these development processes were not independent of one another, but instead interacted in determining the nature of the transition experience.

Nicholson's second assumption (Nicholson & West, 1989) is that transitions progresses in four *psychosocial* stages: (1) preparation, (2) encounter, (3) adjustment, and (4) stabilization. Preparation refers to the "processes of expectation and anticipation before change" (p. 182), encounter is conceptualized as the "affect and sense making during the first days of job tenure" (p. 182), adjustment reflects the "subsequent personal and role development person-job misfit" (p. 182), and stabilization represents the "settled connection between person and the role" (p. 183). Because these stages are envisioned as iterative and cyclical, after leaving the fourth stage of stabilization, reentry into preparation is expected, and described as "the renewal of the cycle" (p. 183). In a study examining transition from clinical nurse to an advance practice role, Glen and Waddington (1998) characterized Nicholson's (1984) first three stages as periods of socialization to the new role and proposed that the transition experience occurs primarily in stage number four. Drawing upon this conclusion and focusing on the first three phases of Nicholson's (1984) model as a socialization process, Price (2009) examined the role that socialization and the socially enacted environment plays in career choice for nurses,

concluding that the availability of mentors and role models to define clear career expectations was key to both recruitment and retention of professional nurses.

This recognition that the transition experience moves beyond the individual to include a socially constructed and enacted environment (characterized as an "induction-socialization process," by Nicholson, 1984, p. 173) is key to addressing the more complex career pathways nurses in research experience today. Using Nicholson's (1984) model, West and Rushton (1989) examined the relative level of match between person and environment following a macro work role transition from student nursing to the health care setting. While they were able to confirm some level of interdependence between phases, they also discovered that nurses who valued control but were expected to work in low-discretion environments often engaged in a good deal of what Nicholson described as "role innovation" (p. 175) seeking newer and more creative outlets for their work. This tendency of individuals to react to transition challenge by changing their environment to improve fit has been identified and examined across a variety of industries (Lu, Lu, Du, & Bakker, 2014; Chen, Yen, & Tsai, 2014), however, key to success in engaging in the necessary pursuit of learning and fit to the new environment, is a release, or disengagement from the psychological attachments to the prior work role (Niessen, Binnewies, & Rank, 2010).

Nicholson's (1984) third assumption that the various stages in the transition process are interdependent, meaning that the process and outcome of one stage may influence another, is especially useful to examining the research nurse in transition, as it may help to define the potential relationship between the nurse's pre and post transition identity, and explore the interdependence that each stage has on the ability of the nurse to

take advantage of or adjust to any challenges encountered. Adjustment is discussed in terms of identity and behavioral adaptation in Nicholson's theory, and is defined in four modes: replication, absorption, determination, and exploration. Replication represents minor adjustments used to address relatively inconsequential changes to role requirements. Absorption is characterized essentially as the process of learning the new role and incorporating the new skills and psychosocial requirements to be able to enact it. Determination leaves the individual's identity intact, but results in a situation where the role occupant may fundamentally alter the new role by placing their special brand or imprint on it, whereas exploration results in the simultaneous change of both the role occupant as well as the role itself as each sits in reflexive tension, simultaneously shaping the other.

According to Nicholson (1984), the two characteristics of roles that directly impact the ability of the individual in transition to adjust are role discretion, a concept related to power and flexibility, and role novelty. Kittler, Rygl, Mackinnon, and Wiedemann (2011) examined the concepts of discretion and novelty in a study of German expatriates working in Russia. Self-reported data were collected and analyzed revealing that there was a positive association between role flexibility, or discretion and role adaptation, but the inverse was true when adaptation had to occur in roles with high novelty. Defining adaptability as "individuals' capacity to constructively regulate psycho-behavioral functions in response to new, changing and/or uncertain circumstances" (p. 58), a research team from Australia studying a group of 2,731 adolescents, further found that when presented with novel situations, higher levels of education and life satisfaction, and key personality traits such as extraversion, conscientiousness, and openness were all

positively correlated to an individual's ability to actively address and succeed under novel conditions (Martin, Nejad, Colman, & Liem, 2012). Consistent with Martin et al.'s (2012) findings, Nicholson (1984) maintains a central premise that individual characteristics and the unique nature of each transition mediate how adjustment and stabilization are experienced. This connects in a rather profound way to Shannon' (2011) findings that the nurse's perception of their professional role after working in the biopharmaceutical industry had essentially been re-crafted through reframing and adaptation to preserve the core value they hold for their nursing identity.

Summary of the Literature Review

To date, no previous research has been conducted examining the nature and process of work role transition for the professional nurse choosing to make a career change to clinical research specialist in industry. To be able to guide nurses who wish to explore this career field, and to help those who choose to enter it be successful, the essential nature of this transition process must be better understood. For this reason, a qualitative research approach, designed to explore and examine was chosen, and phenomenology specifically selected as a method to enable this first foray into this topic to reveal the nature of this lived experience.

The review of literature identified several areas for exploration from which interview questions and lines of inquiry can be developed. It is suggested, for example, that transitions vary in duration and difficulty, and may be stressful and negatively valenced (Ashforth, 2001). There also appears to be a fair amount of agreement that global and role identity are intertwined, may impact or be impacted by the transition experience, and that there is a significant affective component to how identity is

experienced in transition (Ashforth, 2001; Nicholson, 1984). Exploring the affective experience and its association with identity from the time a transition was first entertained throughout the transition process will be a key factor in gaining insight to the nature of this lived experience. There is also good agreement in the literature that the identity of the professional nurse is a highly socially constructed one that begins formation in nursing school and continues into worklife (Currie et al., 2010; MacIntosh, 2003), and while there is very little research in this area, there are limited data to support the possibility that the nurse seeking a role transition away from traditional nursing to industry may experience very little support from their profession in making this career change (Shannon, 2011). The interplay between social support and transition success was discussed in many of the articles and studies examined, and merits additional exploration from the perspective of its impact on both the person and on the transition experience itself. Additionally, literature indicates that nurses may be unprepared educationally to meet the demands of the role of Clinical Research Coordinator (Redman et al., 2006; Reynolds, 2004). To the extent that this applies to nurses seeking careers in industry as Clinical Research Associates is unknown, but given the implications for the integrity of the clinical enterprise, understanding how it has been addressed and experienced is important. Finally, in addition to the role that psychosocial support and resources may play in shaping and determining how an individual moves through the stages of transition (Ashforth, 2001; Nicholson, 1984), there are also data to suggest that there may be certain personality or psychological characteristics that may enable some to succeed where others in a similar situation may not (Martin et al., 2012; Nicholson, 1984). Because the participants in this study are comprised of individuals who have all

successfully transitioned, it may be of interest to examine if there are any patterns or similarities in either their person or their experience that may add to the limited understanding that currently exists on this topic.

CHAPTER 3:

METHODS

The goal of this study was to gain insight into the nature and process of the professional nurse's transition experience from direct patient care to clinical research in the biopharmaceutical and/or medical device industry. The problem behind this focus of inquiry is that clinical research is a discipline quite distinct from direct patient care nursing, yet this role is poorly understood and largely unsupported by the nursing profession (Davis et al., 2002; Raybuck, 1997). This lack of support from the profession translates into little or no focus on practice and educational standards (Spilker, 1991), placing both research participants as well as the global clinical research enterprise at risk (Redman et al., 2006; Reynolds, 2004).

One primary research question guides this study:

RQ: What is the nature and process of the transition experience from direct patient care to a clinical research specialist role for the professional nurse?

Two sub-questions will also be explored:

SQ 1: What barriers and supports are encountered during the transition process?

SQ 2: What facilitates successful work-role transition from direct patient care to clinical research nursing?

This chapter outlines the overall research methodology and methods selected, and defines research procedures for the study. Specifically, the rationale for the application of a qualitative research framework, and for the selection of phenomenology as the research methodology is explained. Procedures for participant selection, recruiting, the administration of informed consent, interviewing, data collection, and data analysis and

interpretation is described, and methods for identifying and managing the potential for researcher bias and ensuring trustworthiness is defined.

Inquiry Paradigm and Methodological Approach

Yardley (2000) asserts that when dealing with a subjective experience, one must recognize that "truth, knowledge, and reality are actively created by the communal construction and negotiation of meaning (p. 217), implying that there can be no objective criteria for these constructs, and no possibility, therefore, to credibly research them in a quantitative paradigm. The individual transition process is, by nature, subjective and socially constructed (Ashforth, 2001). As a result, to study transition in this context, a qualitative paradigm for inquiry was selected. Creswell (2007) defines qualitative inquiry as a

> process of understanding based on distinct methodological traditions of inquiry that explore a social or human problem. The researcher builds a complex, holistic picture, analyzes words, reports detailed views of informants, and conducts the study in a natural setting. (p. 249)

Lichtman (2010) describes ten critical elements of qualitative research beginning with a requirement that it engage in in-depth inquiry and description of a human experience, that it be dynamic and unprescribed, that it should be inductive, holistic, non-linear, and conducted in a natural setting, and that the researcher is not only engaged in data collection, analysis and interpretation, but must be aware of and actively seek to minimize the potential influence that their own bias may have on both study participants and conclusions.

This study of the nature and process of transition is well matched to these elements. Because the research questions are about the nature of a lived experience

(Creswell, 2007), and the individuals participating in the study have engaged in a work role transition process that is neither previously researched nor defined in any current literature, set of educational requirements, or professional standards, a dynamic, highly descriptive, holistic and non-linear approach to inquiry was required.

To capture the essence of the transition experience, the qualitative methodology selected was phenomenology. This method was chosen for its ability to allow the researcher to contemplate and find shared meaning in the ways things manifest in the human experience (Moustakas, 1994; Vagel, 2014). It was also selected due to a philosophical underpinning that allows the sensor (researcher) and that which is being sensed to stand in dynamic tension between being both apart and as one, a state that reflects the reality of a research experience where the researcher is both observer as well as a would-be participant in the phenomenon under study (Merleau-Ponty, 1962).

Phenomenological Philosophy as Applied to this Study

Phenomenology has been described as "the science that studies truth" (Sokolowski, 2000, p. 185). Phenomenological research philosophy emerged from concern that other scientific research traditions failed to address the connection between human consciousness and the forces and elements of the world in which people live (Biemel, 1970). Phenomenology is comprised of four major concepts: intersubjectivity, intentionality, *lifeworld*¸ and embodied consciousness, or essence (Gibson & Hanes, 2003). Schwandt (2000) proposes that the primary concern phenomenological inquiry and analysis is designed to address is how the everyday, inter-subjective world is constituted and experienced by the individual participant. The transition experience for the research nurse has been described as a lonely one (Raja-Jones, 2002), and as such,

examining it with a qualitative lens that recognizes the individual nature of lived experience is appropriate.

Merleau-Ponty (1962) defines phenomenology as, “the study of essences” according to which, “all problems amount to finding definition of essences: the essence of perception . . . of consciousness, for example. But phenomenology is also a . . . transcendental philosophy . . . which offers an account of space, time, and the world as we *live* them” (p. vii). Creswell’s (1998) definition echoes the statement that through phenomenology, “researchers search for essentials, invariant structure (or essence) or the central underlying meaning of the experience and emphasize the intentionality of consciousness where experiences contain both the outward appearance and inward consciousness based on memory, image and meaning.” (p. 52). The concept of *essence* has been described differently depending upon the philosophical tradition to which the researcher adheres. Husserl (1970), for example, viewed essence as a structure of consciousness apart from the body that can be systematically examined through the manner in which the mind manipulates symbolic representations to bring the external world into internal consciousness to create knowledge (Koch, 1995). Heidegger (1961), a student of Husserl, however, rejected the assumption of a mind-body split, transforming Husserl’s focus on knowledge to one of understanding. *Essence*, therefore, from Heidegger’s perspective, was a reflection of a person’s understanding of their *lifeworld*, a concept that characterizes reality as inextricably connected to the world and relationships in which one participates (Lopez & Willis, 2004). Core to phenomenological logic, therefore, is the assumption that the person and the world through which they experience life are inextricably interrelated through the lived experience of that world (Berger &

Luckmann, 1966; Creswell, 2006; Gadamer, 1976; Heidegger, 1961; Husserl, 1970; van Manen, 1990). To study the transition from a strong socially constructed identity and profession (Ohlen & Segesten, 1998) to one that is not linked to a clear educational or professional pathway requires that the researcher not assume that the experience of one is the same as another, and that *truth* is constructed as a composite of multiple experiences over time.

Setting of the Study

The study was conducted in the United States, with participants drawn from a wide geographic area. The actual setting for individual interviews varied based upon the environments available, but in all cases, the researcher traveled to a location convenient for each research participant, and, consistent with Lichtman's (2010) key elements, conducted interviews in a setting that is natural to the work and life of each interviewee.

Population Definition and Characteristics

There are two primary populations of research nurses, those who work directly for the institution or physician conducting and coordinating clinical trials (clinical research coordinators—CRCs), and those who work in a clinical affairs role in the biopharmaceutical and medical device industry in designing, managing, and monitoring research for the development of new commercial products (Clinical Research Associates – CRAs, or monitors, Clinical Research Managers, Clinical Research and Product Safety Associates, etc.). For this study, only nurses with experience working directly for (either as employees or contractors) biopharmaceutical or medical device companies were selected. This population was selected for the fact that they have not only transitioned to

clinical research as a full-time career, but have also left the health care setting for industry, making the probable magnitude of the transition higher, and, therefore, more impactful (Ashforth, 2001).

The level and type of nursing education has also been identified as a potentially significant differentiator between nurses (Duffield et al., 2004; Duffield & Franks, 2002; Jacobs et al., 1998). In the United States, there are three different educational pathways to earning licensure and registration as a nurse: diploma programs, associate degree programs (ADN), and baccalaureate programs (BSN) (Goodin, 2003), and it has been proposed that the better educated nurse may be fundamentally different from his/her colleagues in a number of ways, including the higher likelihood to seek additional education and to be attracted to research (Jacobs et al., 1998; Kidder & Cornelius, 2006). Additionally, the professional nurse in industry is more likely to have a higher level of education than his/her counterparts in a traditional hospital setting (Shannon, 2011). As a result, only nurses with a baccalaureate degree or higher were enrolled.

As a surrogate indicator of transition success, nurses selected for this study were also limited to individuals who made their initial transition from direct patient care to industry at least two years ago. While the researcher recognizes this criterion is subjective by nature, two years was selected because national certification exams recognize two years of full time work in role as the primary qualification criteria for certification eligibility (ACRP, n.d.-b).

No research or other data were identified that suggested that time since transition played a significant role in the ability of individuals to recall the transition experience successfully. While the researcher realized that there may be specific instances where the

initial transition occurred many years ago, as long as the participant was still employed in the biopharmaceutical or medical device industry, no upper limit on time since transition was established.

Sampling Methodology and Sample Size

Beginning with existing contacts through the Association of Clinical Research Professionals, a purposive sampling method was employed, and initial enrollment was targeted at individuals who self-identified as research nurses working in industry. In addition, an individual known to the researcher as a person who transitioned successfully many years ago and who has worked for a variety of different pharmaceutical companies over the years was approached, both as a potential participant as well as a resource for other potential referrals. Purposive selection of study participants worked as expected to produce fertile exemplars capable of yielding "information-rich cases . . . from which one can learn a great deal about issues of central importance to the purposes of the research" (Patton, 1990, p. 169). Once three key individuals from different areas of industry and geographic locations had been identified and enrolled, snowball sampling was used to find additional participants (Miles & Huberman, 1994) until enrollment was completed. Specific efforts were made to maximize the variation in participants, including ensuring that participants were drawn from a variety of companies, from different parts of the country, reflected a range of years in nursing experience level, and previously worked in a variety of therapeutic nursing environments or clinical specialties. Even with best efforts applied, however, the final study population yielded an unexpectedly high number of nurses with backgrounds in highly specialized and technical areas of nursing such as

critical care, the cardiac catheterization lab, and the operating room. Recruitment materials are provided in Appendix A.

Determining an adequate sample size for phenomenological research can be problematic, as there is some disagreement regarding how many participants are enough to reach the level of saturation required to achieve reliable results (Glaser & Strauss, 1967; Vagel, 2014). Seidman (2006) recommends that an adequate sample size has been achieved when the selected population is representative of the range of the population under investigation, and when saturation has been reached to the point that additional query generates no new information. Seidman does not, however, provide a specific recommendation for an adequate sample size in a phenomenological study. Creswell (1998), on the other hand, suggests that sample sizes for phenomenology should range from 5 to 25, and Ritchie, Lewis, and Elam (2003), while not suggesting a particular number, proposes that an adequate sample size for a qualitative study should be based upon seven criteria: "the heterogeneity of the population; the number of selection criteria; the extent to which 'nesting' of criteria is needed; groups of special interest that require intensive study; multiple samples within one study; types of data collection methods use; and the budget and resources available" (p. 84). Population heterogeneity, including minimizing the potential for special interest groups, was managed through the selection criteria discussed above. Given that more data do not necessarily lead to more information, and conceding to some practical limitations regarding how much data can be collected and adequately managed and interpreted in a reasonable amount of time and budget, the final sample size was 10. Basic demographic and background data was collected for all study participants, and each was carefully instructed to focus their

attention and recollection on their first transition experience into a full time role in the biopharmaceutical or medical device industry to further reduce potential heterogeneity effects. Saturation was obtained by the third interview with the eighth participant. Nevertheless, 3 interviews each were conducted with the remaining 2 participants that had been scheduled, and this further improved the robustness of data collected.

Data Collection

Interview Protocol

In-depth, qualitative interviews were conducted following the 3-interview design proposed by Seidman (2006). "Interviewing," Seidman asserts,

> provides access to the context of people's behavior and thereby provides a way for researchers to understand the meaning of that behavior. A basic assumption in in-depth interviewing research is that the meaning people make of their experience affects the way they carry out that experience . . . Interviewing allows us to put behavior in context and provides access to understanding their action. (2006, p. 4)

Seidman frames the researcher's role as one in which learning and insight are realized from not only the interaction with participants, but also about self in the process of conducting the interviews. As a result, the researcher maintained a constant conversation with self during the interview process in an effort to remain aware of the intersubjective nature of her relationship with research participants (Dilley, 2004) and reflect upon her previously held instincts and beliefs or experiences to assess for consistency (Seidman, 2006). Because the researcher in this study comes from the same population she is learning about, Seidman's (2006) emphasis on meaning as understandings that are both individual while transcending beyond the specific is quite useful. In addition, the recognition of the intersubjectivity in relationships and the value placed upon the role of

the researcher's experience also served to both guide and inform inquiry under these circumstances.

The first interview in each series of 3 was conducted to both establish rapport and capture a basic history and details of the transition experience. The second interview was used to gain additional information about the transition experience and process, and further explore impressions or questions that arose after interview number one. The third interview was used as an opportunity for reflection on the meaning of the transition experience, asking participants to use imagery and other descriptive techniques to enhance the richness of descriptions, and to further explore or expand upon what had been discussed throughout the interview process. Each interview was loosely-structured, focusing on a very small number of open-ended questions designed to gain trust and elicit thick descriptions. Interviews lasted from seventy-five to ninety minutes. Interview questions were reflective of the interpretive phenomenological paradigm and were thus designed to explore perceptions, feelings, and the nature or essence of the experience (Creswell, 2007; Moustakas, 1994).

In preparation for interview one, once informed consent was obtained (see Appendix B), each participant was asked to provide a basic resume or curriculum vitae. In two instances where a printed resume was not available, verbal job and education histories were solicited and recorded in the researcher's notes. These documents were reviewed with each participant to verify both experience level as well as to discuss past and current job responsibilities. Basic demographic and career progress data, including type and level of education, length of time in practice and specialty focus of direct patient care experience, time between graduation from nursing school and the decision to

transition, and approximate time in current and previous industry-based roles were also collected. Interview one opened with verification that all demographic and background data had been captured accurately, followed by a discussion of the overall research process to set the stage for the loosely-structured interview, beginning with a small number of prepared questions. While the initial intention was to space all three interviews from approximately three days to 1 week apart whenever possible (Seidman, 2006), allowing time for reflection and review between conversations, there was a need to travel a great distance to collect some of the interview data, in three instances (Nurses E, F, and G). As a result, interviews one and two for this subgroup of participants were separated by only two days, and the period of time between interviews two and three had to be increased to two weeks. Due to heavy work travel schedules for other study participants (Nurses H and I), interviews one and two were separated by two weeks, followed by the third interview approximately one week later. Interviews were recorded and transcribed in most cases within 72 hours of recording, and the transcript of each interview was read carefully by the researcher and provided to the study participant to review. When both were satisfied that the data from the first interview were captured accurately, additional questions were generated for interviews two and three. The interview guides are provided in Appendix C.

All interviews were transcribed by a professional transcriptionist after a confidentiality agreement was obtained (See Appendix D) to facilitate data analysis. In addition, the researcher took notes, and participants in some instances choose to append notes to their copy of each transcript as well. All transcripts were checked against these

notes to ensure that the transcripts were complete and accurate, and that all available data were usable for analysis.

All three transcripts for the first two participants were shared with both a peer reviewer and faculty advisor to ensure consistency, assess for potential of researcher bias, and to assess the effectiveness of interview questions and technique in obtaining robust, thick descriptions required for answering the research questions. It was recommended that the researcher ask participants to describe their transition in terms of telling a story or painting a picture. This was added in the third interview for all study participants as suggested.

Data Processing and Analysis

Seidman (2012) defines three fundamental steps required for interview data analysis as "reducing interview data to what the researcher considers important, labeling important excerpts into categories, either to develop a profile of a participant or to explore themes that may be embedded in the excerpts, [and] sorting those labeled excerpts into files that are easily identifiable and retrievable for study" (p. 132). This process is designed to reduce the data collected to the essence of the transition experience (Moustakas, 1994; Seidman, 2006).

Transcript analysis is an iterative process. The first read through the transcript was done while listening to the audio recording to gain a general understanding of the information contained therein and to ensure that all transcribed language matched what was actually being said. During this read, notations and comments were recorded in the margin of the transcript whenever something interesting was identified, and a list of potential follow-up questions for subsequent interviews was made (Seidman, 2012).

Additional read throughs of each transcript were then conducted as needed to identify and group information into broad categories, and later, as saturation was reached, to further break this information down into identifiable themes or codes. While note taking was a continuous process, no in-depth data analysis began until all interviews had been completed to avoid the potential of "imposing meaning from one participant's interviews on the next" (Seidman, 2012, p. 116).

Utilizing Moustakas' (1994) process for coding or *horizonalizing* and labeling, key categories and themes were paired with a descriptive phrase or term (coded). As the iterative reading of transcripts proceeded, codes were revised and refined as needed until a master set of codes had been generated. Peer code checking was used to validate the integrity of the coding process (Seidman, 2006). To summarize, the following protocol was employed to conduct data analysis:

Step 1: Initial transcript review: The transcript was read straight through for basic understanding of content and context (Seidman, 2012) by the researcher, and where available, participant notes were also reviewed to ensure comprehensive capture of all information available at that time.

Step 2: Second transcript read through and initial horizonalizing and labeling: Specific attention was given to particularly relevant, compelling, or unique statements (Moustakas, 1994), and careful attention was paid to identify situations where data appeared to be discordant between, or within each study participant's transcripts (Seidman, 2012). For any passage previously identified as interesting that did not appear to fit within any of the emerging labels, a brief memorandum was made for later re-review and consideration for additional labeling. Seidman (2012) suggests that this

practice of memoranda writing may assist the researcher with understanding why a particular statement is of interest and may lead to a deeper understanding of meaning.

Step 3: Coding check by a peer for the first 2 sets of interviews (i.e. all three interviews of the first 2 participants) to ensure accuracy of labeling and to assess for potential researcher bias: Parallel coding was conducted by both the researcher and the peer reviewer for each transcript, beginning with participant one, interview one and proceeding through all subsequent interviews until all six transcripts had been coded. Post coding teleconferences were held following the review of each transcript to assess for agreement and refine coding accordingly until uniform agreement for coding was achieved.

Step 4: Third transcript read through with comprehensive review, revision, and grouping of previous labeling (coding) as deemed necessary to facilitate refinement and reduction: If sufficient refinement was not achieved with this step, an additional read through the transcripts or listen to the audio recording was conducted.

Step 5: Entry of codes into a Microsoft Excel spreadsheet with recorded exemplar quotes from participants, generating a codebook that was submitted to the faculty advisor for review: Codes and associated exemplar quotes were assessed and revised in this review process to ensure accurate and consistent alignment until the codebook received approval from the faculty advisor.

Step 6: Assimilation of a set of master codes with further categorical grouping, and development of a thematic, descriptive phrase (Moustakas, 1994) for each of the essential experiences identified: This set of master codes was submitted to the faculty advisor for review and approval. All transcripts continued to be read and/or audio

recordings listed to as a means to ensure the necessary consolidation had occurred and that no key data had been missed.

Step 7: Preparation of individual participant profiles with selection of verbatim examples of each primary label identified: When profiles are created, Seidman (2012) notes that it is important to "be faithful to the words of the participants" (p. 124), and to make it clear when information is paraphrased or placed into the language of the researcher. The first three profiles were subjected to both peer and faculty advisor review to assess for this faithfulness, ensure consistency, and assess for potential of researcher bias. Adjustments were made to profiles accordingly before profiles of the following 7 participants were developed. Once completed, all 10 profiles were subjected to a similar round of faculty advisor review.

Step 8: Analysis: Having completed the initial distilling and coding of transcript language, in-depth analysis and descriptions of the data began (Seidman, 2012). Composite descriptions of identified phenomena were developed, including, as appropriate and useful, individual descriptions of *what* each study participant experienced in transition, descriptions of *how* transition was experienced (this includes both the *nature* and the *process* of transitions as described by each participant), and an overall composite description of the essential nature of the transition experience from direct patient care to clinical research nursing (Moustakas, 1994).

Step 9: Final distillation and thematic categorization: Utilizing the thick descriptions created in the previous step, the nature of the transition experience was further distilled into a final set of themes or categories. To specifically address the portion of the research questions regarding the nature and process of transition, barriers

and supports, and success facilitators, exemplar statements about the experience were identified, and grouped, and any key features/elements, including the nature of the meaning of these features/elements and their relationship to the transition experience was further assessed and characterized.

Identifying Researcher Bias

Identification and recognition of the researcher's personal biases and biases that may be introduced from experience are essential activities in phenomenological research (Moustakas, 1994; Seidman, 2012). Seidman (2012) maintains that "to make sure that the interviewer is not infused with anger, bias, or prejudice, [the] interviewer must come to the transcript prepared to let the interview breathe and speak for itself" (p. 120). To address this concern, prior to each day of interviewing, the researcher re-read Seidman's (2006) chapter on interviewing techniques, identifying and revisiting her personal beliefs and subjectivity, reflecting upon their meaning or how that meaning had shifted throughout the study, and making a notation of any pre-interview thoughts, feelings or biases. In addition, post interview debriefing with a peer reviewer and the faculty advisor was engaged in for the first six interviews conducted (participants one and two) to both identify any potential bias impact evidenced in the transcript and to further hone researcher awareness.

Ensuring Trustworthiness

Concerns regarding trustworthiness are common in qualitative research (Sandberg, 2005). As a result, objectivity in qualitative research is maintained through the faithful representation of texts, but even so, is never considered absolute as readers

will interpret research findings within their own frame of reference (Fleming, Gaidys & Robb, 2002). To facilitate trustworthiness efforts to manage bias are discussed above. Further, Lincoln and Guba (1985) propose that to enhance trustworthiness, four basic criteria must be met. These are credibility, transferability, dependability, and confirmability.

Credibility refers to the authenticity of data. To address this criterion, prolonged engagement with each research participant and persistent observation with cross checking of data by different investigators was engaged in. This included debriefing with both the faculty advisor and peer reviewer, and iterative code review for the first three participants (6 transcripts) with a peer reviewer to identify potential bias, along with ongoing researcher self-reflection, to manage, differentiate, and bracket evidence where judgment and opinion may be influencing interviewing and data analysis processes (Moustakas, 1994). Member checking, or the solicitation of confirmation of responses from study participants (Schwandt, 2007), as well as data triangulation, achieved through the use of both interview transcripts and researcher/participant notes, was also used to ensure credibility of data (Lincoln & Guba, 1985).

Transferability speaks to the relevance and to the degree of similarity, or *fittingness,* of research findings to similar studies in other contexts (Lincoln & Guba, 1985). Transferability was managed through collection and generation of enough description and data to allow comparison, thus ensuring that other researchers can adequately assess degree of similarity or goodness of fit. (Lincoln & Guba, 1985). This criterion was addressed through the collection of thick descriptive data and the critical

selection of exemplars for narrative development, allowing others to judge for themselves the value of data collected and conclusions drawn (Schwandt, 2007).

The third criterion of dependability is the requirement that the research process remain stable and consistent across methods over time (Miles & Huberman, 1994). Higgenbottom (2004) also maintains that for research data to be considered dependable, there must be a high level of transparency. To meet these criteria, documentation of the researcher's various decisions during the analysis process and adherence to clearly definable steps in the research process was engaged in. In addition, ongoing note taking and periodic comparison of participant audio recordings to transcripts was also done as needed.

Confirmability, or internal coherence and assurance of the logic of data inferences (Lincoln & Guba, 1985), was managed by the careful assembly and archiving of an auditable data trail. Specific attention was paid to the documentation of all participant recruitment and referral activities and results, and the careful archiving of all study materials, including consent forms, interview transcripts, and audio recordings. A research or study annotated calendar and electronic correspondence was also kept detailing overall study progress, the interview schedule, and any other relevant evidence of regular meetings with transcriptionists, peer reviewers, and the research advisor.

Human Participants and Ethics Precautions

The protection of human research subjects is a cornerstone tenet in research and the key mechanism through which this is accomplished is informed consent (National Institutes of Health, 2010). Informed consent is defined as a research participant "being given adequate information . . . (to gain) . . . understanding . . . voluntarily accepting the

terms . . . (and) agreeing to cooperate" (Spilker, 1991). The level of risk to the research participant anticipated in this study is minimal. Nevertheless, throughout the course of this study, each participant was afforded the highest regard and level of assurance possible to uphold their right to privacy and ethical treatment. An IRB approved written informed consent document (Appendix B), detailing the voluntary nature of participation, confidentiality and storage of data, disclosure of the research questions, method of analysis, research participant rights and possible benefits, and researcher contact information was provided to each study participant, and separate confidentiality agreements (Appendix B) were generated and executed for any other members of the research team (such as a transcriptionist or peer reviewer) who was working with original data.

To reinforce participants' right to confidentiality, all research participants were assured that neither they nor their employers would be identified, and that no one other than the researcher and those authorized to review or read the research data (including the transcriptionist, peer reviewer, and the study advisor) would have access to the data. All data collected were be de-identified, substituting a participant letter for actual participant names, and every effort was made to ensure that no information collected as part of the study was clearly attributable to any particular study participant.

A study information sheet for potential research participants (Appendix A) was created to invite nurses to join the study. This sheet provided each research participant with information regarding the purpose of the study, the research problem to be addressed, and a statement regarding the potential significance of the research. Information regarding participant qualifications and a description of the interview

process, including interview duration and frequency, was outlined, and a short bio of the researcher was provided, including disclosure that the researcher is also a nurse who has transitioned from direct patient care to a career in clinical research. While the researcher shares the same profile as the individuals sought for study participation, a high level of awareness with frequent checks for bias were designed into the study. As a result, it was not anticipated that a conflict of interest would exist, and the similarity between the researcher and participants is believed to have had no significant bearing on participant selection, the interview process, data collection and analysis, or final dissemination of study results.

An iterative dialogue was maintained with all research participants throughout the study, feedback regarding research findings was provided to allow for reciprocity (Miles & Huberman, 1994), and all field notes and interview recordings were considered and treated as strictly confidential materials and were not collected without the expressed permission of each research participant. While these materials will be retained for archives to add to the confirmability of the study, written permission from all study participants was be secured before doing so. In the event that consent had not been granted or was withdrawn, field notes and recordings would have been destroyed via a secure and confidential method.

Summary

This chapter attempts to describe the rationale for selection of a qualitative research paradigm and phenomenological methodology for application to a study of the nature and process of the professional nurse transitioning from a traditional work role in patient care to the corporate world of biopharmaceutical and medical device research.

Participant profile, selection methodology, and interviewing plans were outlined, and plans and activities surrounding data collection, transcription, analysis, and interpretation were defined and described. Methods for ensuring data trustworthiness, credibility, dependability, and transferability were described, and specific attention was paid to describing key measures to ensure the protection of human research participants.

CHAPTER 4:

FINDINGS

This chapter presents the findings of the phenomenological inquiry guided by the research question: What is the nature and process of the transition experience from a direct patient care role to a clinical research specialist role for the professional nurse? Two subquestions were also explored: What barriers and supports are encountered during the transition process? What facilitates successful work role transition from direct patient care to clinical research?

The report of the findings is organized as follows: (a) description of participants, (b) individual profiles, (c) major themes emerging from the data, including: 1) I am alone: transition can be an isolating experience, 2) I am unprepared: transition requires mastery of unfamiliar skills and knowledge, 3) I am scared and sometimes overwhelmed: transition is associated with a lack of security, structure and balance, 4) I can do it: self-reliance and resourcefulness facilitate successful work-role transition, 5) I need to build new bridges: transition requires networking and support from others, 6) I am becoming: the transition experience can be empowering and offers opportunity for growth, and 7) I am still a nurse: nursing identity and values endure through transition (d) composite description of the transition experience, and (e) summary of findings.

Description of Participants

While all nurses enrolled in this study possess at least a baccalaureate degree in nursing, there are significant differences in their educational and experience background. For example, while all participants achieved and have maintained their credential as a

registered nurse, 4 of the 10 enrolled did not begin their careers in the nursing field. Similarly, once a decision to become a nurse was taken, 4 of the 10 participants began their nursing careers at the associate degree or diploma level (requiring 2 to 3 years of post high school education), while 6 of the 10 have achieved a masters level education (3 MSNs, 2 MBAs, and 1 MEd). The average number of years since initial transition to industry is12.7 (range 2 to 22), and half have 15 years or greater of industry experience.

In spite of the variances identified, there are also a number of similarities. For example, 7 of the 10 nurses enrolled began their careers in research as clinical research coordinators, a role that is characterized by hybrid activities of direct patient care and research, and the majority (8/10) experienced direct patient care in technically intense nursing specialties such as critical care, neonatal intensive care, Care Flight, coronary care, and the operating room. Additionally, while events leading to an opportunity to enter the research field varied, most (9/10) expressed a belief or hope that this new career path might offer them greater security and work-life balance, and/or opportunity for personal and professional growth.

Because transition to industry-based clinical research roles follows an average period of time of 13.8 (range 4-22) years in direct patient care and is also frequently preceded by a career period in the hybrid clinical research coordinator role, most study participants did not make the definitive role transition to industry until they were in their 30s or 40s. Also, while not identified in the literature as a factor in transition, thus not asked, it is estimated that the age range for participants at this time is between the low 40s and high 50s. A general profile of all participants is presented in Table 3.1.

Table 3.1
General Profile of Participants

Participant code	Educational background	Nursing was first career	Focus of nursing practice	Years in direct patient care prior to transition	Research coordinator prior to entering industry	Years in industry	Current nursing license
Nurse A	ADN, BSN, MBA	Yes	Critical care	22	Yes	7	Yes
Nurse B	Diploma in Nursing, BSN, MSN	No	Med/surg	4	No	6	Yes
Nurse C	ADN, BSN, MBA	No	Critical care	22	No	6	Yes
Nurse D	ADN, BSN	Yes	Telemetry Critical care OR	16	Yes	19	Yes
Nurse E	BSN	Yes	Psych NICU CareFlight Pedi Card	19	Yes	15	Yes
Nurse F	BSN	Yes	Gen surg Critical care	12	Yes	22	Yes
Nurse G	BSN, MSN	Yes	NICU Oncology	12	Yes	21	Yes
Nurse H	BSN	Yes	Telemetry Cath lab Coronary care	15	No	20	Yes
Nurse I	BA Psych, BSN, MSN, nurse practitioner	No	Med/surg Pedi psych	9	Yes	2	Yes
Nurse J	BS Athletic Training, M.Ed., BSN	No	Student health OR	7	Yes	9	Yes

Participants for the study reside across the United States, and have worked for a variety of pharmaceutical, biotechnology, and medical device companies. To ensure their confidentiality, participants are referred to as Nurse or Participant A through J, and all references to specific people or employers have been redacted and replaced with language such as [Name] or [Company Name] for this report. With this exception, all quotations are presented verbatim, and ellipses are utilized when truncating long passages

from pages of the transcripts. In addition, to ease comprehension and avoid the possibility that certain speech idiosyncrasies may reveal the identity of a participant, phrases such as "you know," "if you will," "so like," and stuttering or repeating of words have been deleted from quotations used. Additionally, because the quotations represent in many cases, answers to specific questions asked, where it is necessary for clarification to provide a transition or context in a long passage, the researcher's own words may appear in brackets.

Individual Profiles

The following individual profiles were created to capture an overall portrait of each nurse's transition experience. Representative portions of the transcripts were selected to provide seemingly important individual key descriptions of events or experiences in transition, to identify comments that appeared to be important to participants regarding the nature and process of that experience, and to highlight key supports and barriers encountered. In addition, key statements were selected for each nurse participating in the study to demonstrate how their nursing identity is experienced through the transition process.

Profile of Nurse A

Nurse A began her nursing career with a 2 ½ year community college level nursing degree. She defines her decision to become a nurse as one of convenience, simply following a suggestion made by her high school counselor. Once becoming a nurse, however, she describes her time working in direct patient care with great affection, and specializes in one of the more technically challenging fields of nursing, intensive care.

She achieved certification in Critical Care Nursing and moved on earn a Bachelor of Science in Nursing, and a Master's in Business Administration. Her transition to a full time position in industry was gradual as she continued to work in direct patient care while simultaneously moving into a career as a clinical research coordinator for several years, only moving full time to industry approximately 7 years ago.

Key description(s) of how the transition from direct patient care to industry was experienced:

> Growth . . . both as an individual based on the knowledge and the exploration and the opportunities that were provided to me, but also growth just in the traditional sense of moving up and moving into roles of greater responsibility and evolving, . . . new experiences, going from a bedside nurse to a clinical researcher . . . and having opportunities that I just never, ever would have envisioned as a bedside nurse would become available to me.

Most important comment(s) regarding the nature and process of the transition experience:

> I would speak to isolation . . . when I say isolation, I'm referring to the lack of support, lack of training, lack of knowledge, lack of understanding, and being left to find my own way through all of that, to navigate all of that. Not having peers to speak to. . .I felt very isolated as a nurse trying to find my way in that role, in that whole process.

> At the beginning of the journey, there was, first, no way of knowing where it was going. Second, no way of knowing if I would be able to get there and then the pride, when I did, LOL. . . . but I didn't know anyone else that had done something similar or had any experience in this so I felt all alone in that journey.

Most important comment(s) regarding supports encountered during the transition experience:

> The 'profession' didn't support me. Nowhere was there the opportunity to choose research as a practice setting, . . . but I still felt my research was nursing, and that was my rock. Until you have actually had a caregiver-patient relationship and understand the dynamics of that, and until you've had [chuckle] sometimes the

> things that can go wrong even just in a regular visit or interaction with a patient, I don't think you can – I just don't think that you're going to have the expert knowledge that we want them [clinical research professionals] to have.

Most important comment(s) regarding barriers encountered during the transition experience:

> . . . .my struggle in the first two years, first of all because I was ill-prepared . . . all I kept thinking was well it's not life and death, . . . when doing my work at the hospital it really was in many instances life or death . . . I couldn't understand the rigor being applied to the Research when it didn't seem life or death to me. . . . I like to think had I been appropriately trained and had that big picture then I would have seen the impact, but because it was all just so fragmented and I didn't understand it, I could only compare it to my nursing.

Important comment(s) regarding how nursing identity is experienced through transition:

> So first and foremost, yes, I still feel I'm a nurse and I don't think that will ever go away; I hope that never goes away.

Profile of Nurse B

Nurse B describes her decision to become a nurse as one that was strongly influence by family members. She did not begin her adult life in the nursing field, working instead in a number of different jobs, but chose to enter nursing once her children were all in school. Her entry into the profession was achieved through a 3-year hospital-based diploma program. While she discusses having strong positive feelings about being a nurse, her description of her experiences as a direct patient care nurse was largely not positive as she encountered numerous challenges. Nevertheless, she moved rather rapidly from her diploma through both a Bachelors and Masters of Science in Nursing, transitioning to industry after only 4 years in direct patient care.

Key description(s) of how the transition from direct patient care to industry was experienced:

> I can tell you that I have had an epiphany . . . I joined a department where most of the people were either biomedical engineers or lab techs and I thought, 'what am I doing here?' . . . but just recently . . . the person that I found to be my preceptor was one of the co-founders of an employee resource group . . . the Nursing Innovation Council of Excellence. This group is all about exactly what we're talking about. It's being advocates for the profession. It is volunteering, offering your nursing knowledge and expertise in different business areas that one would never even think nurses would have anything to do with . . . serving on advisory boards, focus groups, research and development ideas, product improvement ideas and it's, . . . Wow!

Most important comment(s) regarding the nature and process of the transition experience:

> At first, I just need to do exactly what they tell me to do, exactly how they tell me to do it. . . . I must follow the process to get the foundation under me, to prove to them that I can do it. . . . It will be two years next month [since I transitioned], and I've been able to get involved in a lot of new things. I have a future with upward mobility and I'm learning. I don't think that nurses who remain in the patient care environment year after year ever get the opportunity to stretch their legs . . . and make an attempt to take old knowledge and apply it in a new way . . . . It's not the laying on of hands so much anymore but it's the laying on of the mind.

Most important comment(s) regarding supports encountered during the transition experience:

> We are taught from day one in nursing school you have got to develop critical thinking skills. It's the only way you'll be able to survive . . . APIE [Assess, Plan, Implement, Evaluate], that process . . . takes over the way you think about everything, how you approach every problem whether it's healthcare, whether it's a problem with your child, . . . it gives you a complete different mindset of how to approach problems and be creative and find solutions.

Most important comment(s) regarding barriers encountered during the transition experience:

> When I started, I'd think to myself I don't know how to do anything else [besides nursing] now. This is all I know to do. I don't have the knowledge that they are going to require me to have so they're not going to be interested in me and I don't have the faith in myself that I can meet those requirements. I've never done it before. I don't know how to do it.

Important comment(s) regarding how nursing identity is experienced through transition:

> I'm a nurse . . . I'm not laying hands on them, I can't see what's going on with them with my eyes, but yet they're coming to me because they trust me, that I know what they're asking . . . – I'll never lose that. . . . So that's the 'aha.' It's kind of like I made the transition . . . I'm not answering call bells all night anymore, I'm actually . . . helping people who are telling me that they trust me.

Profile of Nurse C

Nursing was a second career for Nurse C. Motivated by a desire for job security and her admiration of a good friend who was also a nurse, she chose an associate degree RN program, rolled directly into a baccalaureate program in nursing, and later pursued a Master's in Business Administration. Nurse C practiced critical care nursing for over twenty years before deciding to make the transition to a career in industry.

Key description(s) of how the transition from direct patient care to industry was experienced:

> The one agency that I worked for when I was doing clinical nursing that led me to the opportunity to get into industry, I would have to say that they were pretty much responsible for introducing me to all the other areas I've explored . . . I think it helped make the transition because remembering how that particular nurse manager opened doors that I never thought were possible helped me to explore that again and again with other people and other opportunities as I made my journey.

Most important comment(s) regarding the nature and process of the transition experience:

It's one challenge after another and that's why I think the success has become a little easier as you go. Once you make that initial hurdle, take that first risk, or you reach that first peak and you realize that there's still another one ahead of you, and there's probably a million more ahead of you that you just say this is part of the process and so you just keep going.

Most important comment(s) regarding supports encountered during the transition experience:

I remember . . . them saying to us that if you could become a nurse you can do anything! And I really believed it . . . [as nurses] we were always taught to plan ahead, constantly re-evaluate, act accordingly and not give up, not be distracted, just forge on, and so I truly did apply that to everything in this transition. . . . It just is automatic and some people . . . may be frustrated with me sometimes when I just move onto the next thing . . . find out what else works.

Most important comment(s) regarding barriers encountered during the transition experience:

There's a saying, something about a gate or a prison is locked on the inside when you have a kind of self-limitation. At first, that's what I was doing. I was holding myself back . . . for what reason I have no idea. And so when I realized that I really could do it if I put my mind to it, I found a way.

Important comment(s) regarding how nursing identity is experienced through transition:

Just recently someone asked me my occupation, I don't remember whether it was for my taxes or whatever. I just said Registered Nurse, and someone else said 'Oh that's not what you do.' They wanted me to give my job title, and I said no, that's just the job title . . . I still consider my occupation to be that of a registered nurse. . . . I just kind of boil it down to that, but it's so much more than that. . . . Somewhere along the line I was able to let go, and realize that nursing isn't just about getting your hands dirty or being at the bedside or taking a blood pressure, that it's not just what you do but it's what you know, and so that I rely on every single day.

Profile of Nurse D

The decision to become a nurse was made during Nurse D's first year of college. The college she attended offered a 2 year ADN program which she completed. She began her nursing career on a telemetry unit, moving into critical care within two years, and later to the operating room. Over the next several years, she earned a Bachelor of Science in Nursing, and after a decade and a half of direct patient care, took a position as a research nurse in the Department of Surgery at a local university. Developing a relationship with a field monitor from a pharmaceutical company, Nurse D was soon invited to interview and was hired for a position in industry as a Clinical Research Nurse (CRN).

Key description(s) of how the transition from direct patient care to industry was experienced:

> Shortly after I became a full-fledged CRA we were given an oncology trial . . . the first product that had been proposed for colorectal cancer as a new agent in almost 30 years and they opened enrollment . . . and I would read charts where people were driving hundreds of miles every week to get this product, and I don't know, it just seemed like that I was part of really making something possible for an individual – it was changing their life and prolonging their life . . . that was really a special period of time.

Most important comment(s) regarding the nature and process of the transition experience:

> She came in one morning for a couple hours to tell me about the study and then it was more or less Tag-You're-It. There were other research coordinators at the university that – as the months went on I learned were resources to me, but it wasn't a mentoring program or anything that was really formal in the transition or the education, so I just learned by reading and doing and asking questions and making mistakes.

Most important comment(s) regarding supports encountered during the transition experience:

> Once I went into industry, they were adamant to ensure that everyone in that role had the most current expertise, was proficient with the most current knowledge out there, so they ensured that we knew all the ICH GCPs and the FDA Guidelines and the Best Clinical Practice and we were supported with trainers and mentors and just a wonderful group of very seasoned professional nurses that I was very proud to be a part of.

Most important comment(s) regarding barriers encountered during the transition experience:

> I don't think that I had very much of an expertise in the business area. I didn't understand – I had never been in a corporate headquarters or worked in corporate America at all, so the whole business and the budget of a study, or why they're doing this, or the finances . . . I was also not very skilled in writing. . . . It was a lot to take in, and there were days when I thought I might just . . . throw in the towel because it could easily be overwhelming.

Important comment(s) regarding how nursing identity is experienced through transition:

> I still feel very strongly that I am functioning as a nurse in clinical research. I don't feel I'm wavering in that commitment.
>
> I feel very much a nurse. I think that there are many different aspects of nursing. I don't think the Operating Room nurse can walk into the Emergency Room tomorrow and clock in and go to work without some basic skills and learning what it's like there. . . . There are different fields of practice in nursing and I feel like clinical research is one of those fields.

Profile of Nurse E

Nurse E entered university knowing that she wanted to become a nurse. Upon earning her BSN, she began her career in pediatric psychiatry, and ten years later, transitioned to two of the most challenging fields of nursing, neonatal intensive care and

CareFlight. Eventually, desiring a less dangerous career focus, she moved to pediatric electrophysiology. In this role, she experienced her first glimpse into research through the coordination of clinical trials for a team of attending physicians and cardiac surgeons. She later entered into a career in industry as a CRA through fostering a relationship with a former nursing colleague who had transitioned several years earlier and was then working as an executive in a Clinical Research Organization (CRO).

Key description(s) of how the transition from direct patient care to industry was experienced:

> Initially, I thought it might be a bad thing to change positions. I knew I felt comfortable with what I was doing [in direct patient care]. But going into clinical research took me out of that environment. I think a nurse that is in clinical research has more independence, more autonomy, and the expectation is different. . . . You're always taking a step, growing, and elevating yourself by building a stronger foundation by all that knowledge you have below you, . . . It feels elevating and empowering to educate yourself. . . . It also takes a certain kind of character to do that and do it well, well rounded, . . . and the ability to handle other people, deal with difficult situations and obtain positive results. You become more of a leader and people want to follow you.

Most important comment(s) regarding the nature and process of the transition experience:

> It'd almost be like a little video, a YouTube video, showing me in my scrubs and my lab coat and just walking through the hospital hall, and then walking into a professional building, and changing into professional clothes, and each step becomes a stairway . . . , and there's still more stairs that I could climb, . . . , I could go to George Washington! . . . Learn some more. Broaden my horizons. Network. Build more relationships. It's a whole side of nursing I never imagined.

Most important comment(s) regarding supports encountered during the transition experience:

> I relied on networking . . . or having that intuition of knowing I have that inner strength, probably because I think things in the background can happen, and you

> forget you have that inner strength. But when you have your friends or your network around you and your relationships around you, they go: Oh you can do that, [it's a] piece of cake, then you begin to believe in yourself.

Most important comment(s) regarding barriers encountered during the transition experience:

> In the beginning I didn't feel like I had enough time to get everything done. That's the tough part about research . . . if you're traveling to a site and you don't have enough time that can be the downside of feeling successful. You can't get everything monitored in one day or two days, you can only do what you can do, and I really had to re-teach myself how to do it for me . . . whatever I needed to do so that I'm not overwhelmed, because if I get overwhelmed, and I tend to do that to myself, I don't do a good job. I fail . . . epically.

Important comment(s) regarding how nursing identity is experienced through transition:

> I have to say that it was so important to me to become a nurse . . . , that it is 90 percent of my personality and my identity even today – and being a nurse, and how you treat your patients with respect and dignity is the same way I translate it to the sites, and I think that's why I receive so much cooperation, so I've always been a nurse.

Profile of Nurse F

Nurse F described knowing that she wanted to become a nurse at the age of fourteen. She applied and was accepted to a baccalaureate program and graduated with her BSN four years later. Her nursing career began on the med-surg floor, but within a couple of years, stating "I wanted the most difficult nursing experience I could find," she chose to shift her career focus to intensive care at a large teaching hospital. It was through the relationships she developed with surgeons in the ICU that she first became aware that the institution had an open position for a research nurse. After applying and securing this position, she began coordinating clinical trials for a number of

pharmaceutical company sponsors and, leveraging her relationships with the individuals representing these companies, she eventually transitioned to a full time position in industry.

Key description(s) of how the transition from direct patient care to industry was experienced:

> Somewhere two or three months into the transition, I remember thinking: I don't know what the heck I'm doing. I'm going back to the ICU with its structure and its timesheets and checklists . . . , but then I remember the sense of actually going back into the ICU as a research nurse, . . . and feeling a little *special* because I had this different role . . . it was just a different perspective, and . . . helping patients potentially in a different way, helping patients across the globe with these new drugs and therapies we were working on. It made me feel special and valued, . . . and it was an exciting and growing experience.

Most important comment(s) regarding the nature and process of the transition experience:

> After committing myself to this uncomfortable zone for a year, and you learn to be uncomfortable in clinical research, . . . you sort of learn to accept that things will constantly change . . . it's just the nature of the business. So . . . you find your rhythm, . . . the starting of the study, the screening of patients, the actual enrollment, following of the study visits, there is a rhythm and a pattern to it all, . . . it is very much structured, and you start to actually enjoy the challenge, and thinking that the work is pretty cool, interesting, special.

Most important comment(s) regarding supports encountered during the transition experience:

> Just having that RN behind your name . . . that's my support, having that RN gives me some leverage in my profession, I think, in my career in research. . . . I have a nursing background, so presumably I've been trained and have physiological knowledge, and even with the internet, people still ask me questions 'Well you're a nurse . . .' People don't really know how to interpret what they're reading, and I do have the experience and many years as a nurse.

Most important comment(s) regarding barriers encountered during the transition experience:

> Oh there are a lot of barriers. It's hard to bridge [to industry] – we all talk about that. It's not so difficult I think to get into a study coordinator role if you have a nursing background, . . . but then from study coordinator to CRA, everyone wants to hire a CRA with experience. It's the classic 'well how do you get experience if no one will hire anyone but CRA's with experience?' and it's the vicious cycle. You pretty much have to pay your dues and succeed as a study coordinator, two to three years, and then be lucky.

Important comment(s) regarding how nursing identity is experienced through transition:

> I'm proud to be a nurse. Nursing in general has so many opportunities, different areas. I always encourage young people to definitely consider nursing because you don't just have to work in a hospital and take care of patients if that's not what you want to do, of course that's wonderful, but look at me, I'm a shining example of another opportunity related to nursing.

Profile of Nurse G

Nurse G describes wanting to become a nurse from a very young age. She chose a BSN for her level of entry into practice and moved directly into neonatal intensive care after graduation. Two years into practice, she was introduced to clinical research through a group of research nurse coordinators working for an affiliated medical school and soon transitioned to a similar role in oncology. Over the next 7 years, she became a Director of Research, eventually transitioning to a parallel role in the pharmaceutical and medical device industry.

Key description(s) of how the transition from direct patient care to industry was experienced:

> They explained in general the role but still, no one went into detail about the different roles within the industry. That was so challenging and frustrating, just trial by error. It was scary because I tend to be a very ethical person and I didn't want to do any harm, so I did a lot of self reading on my own.

Most important comment(s) regarding the nature and process of the transition experience:

> On the job, by myself. I mean literally I walked in the first day and this was what the training was. It was like, 'Well here's the IRB renewals that need to be done. There's the file cabinet. You can look at the applications from last year and figure it out.' A lot of learning on your own and just learning from mistakes.

Most important comment(s) regarding supports encountered during the transition experience:

> When I went to [Company Name] I learned a lot there, not only because of the great mentors, but also because of all the training. And then I began doing the training. Because you had to research a lot of the topics . . . to present training materials to others, you learn so much.
>
> I think lots of times it's just inner strength that makes it possible, and I think that nursing draws out a certain type of personality and characteristics in an individual. It's usually people who want to help others, and usually you see it's the compassionate people who tend to be strong. It takes strength, and then just you tend to learn how to network and reach out to people who can assist and help.

Most important comment(s) regarding barriers encountered during the transition experience:

> Things are presenting themselves to you and you don't know quite what they are. And you're trying to relate them to something that you've experienced in the past but you can't make the connection because it's so different, and at that point fear overcomes you. You're trying to get through to the other end as fast as you can, . . . and experiencing the scary things.

Important comment(s) regarding how nursing identity is experienced through transition:

> I believe I am [still a nurse] and I remind people here quite frequently, because I don't think that they know. . . . There will be times I walk around here and I go 'Well, you know I am a nurse!' I think that part's hard, because although they appreciate that knowledge that you bring, I think sometimes they forget that resource that you are.

Profile of Nurse H

Nurse H was first introduced to nursing through an internship program offered while she was in high school. Encouraged by a family member who was also a nurse, she earned her BSN and began her nursing career on a telemetry floor, moving eventually to cardiac medicine and the cardiac catheterization lab. After fifteen years in nursing and becoming frustrated with health care staffing models that reduced the number of registered nurses available to deliver patient care, she eventually turned to a fellow nurse working in the pharmaceutical industry for advice. Upon discovery that the company was seeking new research associates with cardiovascular medicine expertise, she applied and was hired within six months.

Key description(s) of how the transition from direct patient care to industry was experienced:

> So many things are thrown at you when you start this job. You don't have time to absorb and comprehend the rules and why the rules are there, but you can and you must. . . . In research there really are a lot of different things you can do. I've done everything from heart transplant to pediatrics. It's broadening, and opening doors. . . . and sometimes overwhelming.
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> So I'm standing in an airport looking at the monitor that says what gate you're supposed to go to and I feel myself welling up with tears. I don't know what airport I'm in. I don't know where I'm supposed to go. Now I have my itinerary, but I have been traveling so much I just – I lost it. I said I think I need to stop traveling.

Most important comment(s) regarding the nature and process of the transition experience:

> I can honestly say I cried every Friday for the first few months. It was awful. Working in pharmaceuticals, it's 24/7, because you're thinking of your next meeting, you're thinking we have this report to write. I have to look up such and such and bring that to the table. I'd start 7 in the morning work until 7 at night. I was on multiple studies, multiple brands. . . . I would read the protocol onto a cassette tape and I listen to it on my travel to the site, depending on what study I was working on.
>
> So you made the decision and now you're surviving the change. It was a huge change. It was a huge change. I mean not only location but clothes, expectations of what I deliver. At this point there was no repetition so I could not draw on my past. With research I could draw on my medical knowledge but not on my research knowledge because I had none. I had to learn new skills. It was – it was like being basically reborn.

Most important comment(s) regarding supports encountered during the transition experience:

> My mentor was a nurse . . . she is a nurse, and I said I just need to know I'm on the right track. . . . As soon as I expressed that need, in a very professional way, not whining, she would put me under her wing, 'Okay. We're going to do this. We're going to do that.' She partnered.

Most important comment(s) regarding barriers encountered during the transition experience:

> I knew I had to get my game up—get knowledge – because these people would expect nothing less. They're not going to talk to you if you don't know what you're talking about. So I had to get my knowledge base up on the drug, the indication, . . . That's a little anxiety provoking.

Important comment(s) regarding how nursing identity is experienced through transition:

> I still think of myself as a nurse. When I travel, sometimes I'll say I'm in clinical research and sometimes I'll say nurse, RN. , because I am a nurse!! I still have my license.

Profile of Nurse I

Prior to becoming a nurse, Nurse I spent many years working in the information technology field. Already holding a BA degree in Psychology, when she made the decision to become a registered nurse, she chose a BA to BSN bridging program. Within 5 years' time, she had earned both her BSN and MSN, and was credentialed as a Nurse Practitioner. She eventually settled on a career in pediatric psychiatry, taking a position that was half patient care focused and half clinical research. Over time, she developed a strong professional relationship with a Clinical Research Associate (CRA) for one of the pharmaceutical companies sponsoring the studies she coordinated and was encouraged to pursue a job in industry.

Key description(s) of how the transition from direct patient care to industry was experienced:

> When this window opened up, I was delighted and I knew that I had to make a job [change]. I had prayed and prayed, and this was like a miracle. During transition, however, I'd catch a glimpse of myself and it's like oh you poor thing, you just look exhausted. . . . I arrived home at like 9:30 and was thinking – I can't even fix myself dinner, I'm too tired to get myself something to eat. I just wanted to be home and go for a walk, cook a nice dinner . . . it's a lot of sacrifice.

Most important comment(s) regarding the nature and process of the transition experience:

> Transition can be very isolating, and it's the same thing when you're on the road and you're traveling and then you're working from home. It doesn't even come into it for me because I've lived alone for so long, but the isolation is part of the transition, especially women, there are some of them that will not be able to handle it.
>
> When I first transitioned the terrain felt like a beautiful meadow . . . , it's warm, it's peaceful, it's nice, it's exciting because you're rested physically and now you can move onto where mentally you can be doing something that you really want to do. As you continue your transition, now the ice is starting to form. It's getting

> very difficult to maneuver. I still don't mind doing it, but the struggle between where I want to be mentally and what I think I can do mentally when I get the physical fatigue, it just, to me it's just so overwhelming.

Most important comment(s) regarding supports encountered during the transition experience:

> I would say that so much of what I learned to do as a nurse helped make me successful . . . The amount of medical knowledge that you have to gain, the anatomy, the physiology, . . . I feel very, very comfortable with that. I know what it's like in the real world.
>
> The wonderful woman who is still a good friend of mine, who was the monitor who got me this job to begin with, [Name], I mean she's been wonderful, and she's not always available to talk to because she travels quite a bit too and she's quite a bit older, but she's been a wonderful help.

Most important comment(s) regarding barriers encountered during the transition experience:

> The other big factor is the isolation. If you're going to feel like you're lonely or you can't go into a restaurant for dinner on your own, this is not the field for you. Certainly not monitoring, maybe some kind of office work.

Important comment(s) regarding how nursing identity is experienced through transition:

> If people ask me what I am I don't say nurse first. The first thing that comes to mind is monitor, clinical research monitor which of course nobody knows what that means until you tell them. It's not really a well-known occupation.

Profile of Nurse J

Nurse J began her career as an athletic trainer working for a major university. She eventually chose to pursue a BSN, and not wanting to leave the university environment, began her nursing career working in student health. After two years, she moved to a position as an operating room nurse with a sports medicine physician. It was in this role

that she was first exposed to clinical research as her employer was asked to be a principal investigator for a pharmaceutical study. Enjoying research, she soon took a position as a Clinical Research Coordinator (CRC) in the Department of Anesthesiology, and tapping into her network of colleagues in industry, eventually secured an entry level position for a major pharmaceutical manufacturer.

Key description(s) of how the transition from direct patient care to industry was experienced:

> I remember sitting in a meeting and there was this one lady who had ten studies to herself, and I was like 'I want to do that,' so I was able to get a position doing that and I did that for about a year. I thought that was great because we actually did a lot more onsite stuff. We started traveling to the Phase I sites, reviewing the consents and observing the dosing, and we did a lot more review of the medical histories and making sure they're eligible, so that's totally my – it's still my passion.

Most important comment(s) regarding the nature and process of the transition experience:

> Honestly, there were so few people, no team, I felt isolated, tried to, did, send out letters, tracked documents, work . . . work . . . work, or make it look like you were working. I had a cubicle in a large building where all the halls looked the same, no opportunities to learn until someone finally took some interest in me.

Most important comment(s) regarding supports encountered during the transition experience:

> Networking, it's definitely really important. I don't know if I realized how important it was until last year when the economy was bad and I found myself looking again, and with all the mergers and acquisitions in this area you know it's a little tougher.

Most important comment(s) regarding barriers encountered during the transition experience:

> When I went to [Company Name], leaving the healthcare environment, I hated it, absolutely hated it, cried like – not at work but cried leaving work, and I couldn't understand. And you would try to help and get help from your colleagues to put some structure around it, but there was backstabbing . . . it was just a crazy environment.

Important comment(s) regarding how nursing identity is experienced through transition:

> I don't know if I ever still thought of myself specifically as a nurse, really. I think I thought of my nurse training as being helpful, and I rely on it a lot, but I can't say that I ever defined myself as a nurse once I moved to industry.

Major Themes Emerging from Data Analysis

Seven key themes emerged from the analysis of the data. Reflecting the personal nature of the ABC (affective, behavioral and cognitive) Ashforth (2001) transition model, and work role transition theory (Nicholson, 1984, 2013) lenses applied, themes are expressed as first person, declarative statements such as 'I am' and 'I must.' The themes are: 1) I am alone: transition can be an isolating experience, 2) I am unprepared: transition requires mastery of unfamiliar skills and knowledge, 3) I am scared and sometimes overwhelmed: transition is associated with a lack of security, structure and balance, 4) I can do it: self-reliance and resourcefulness facilitate successful work-role transition, 5) I need to build new bridges: transition requires networking and support from others, 6) I am becoming: the transition experience can be empowering and offers opportunity for growth, and 7) I am still a nurse: nursing identity and values endure through transition. Each theme is described below.

I Am Alone:

Transition Can Be an Isolating Experience

The theme of isolation and feeling alone in transition was highly prevalent in statements made by participants. The isolation described falls into three broad categories, physical isolation or 'aloneness,' isolation from needed support factors, and professional isolation, characterized as a lack of recognition or support from the nursing profession. While the number of times each participant reflected upon isolation feelings and experiences varies, all related stories or examples of being alone, feeling unsupported, lacking connections to other people to provide them with the resources or mentoring they needed, feeling that the nursing profession did not support them, or having to function in physical or professional isolation from others.

In speaking to the physical isolation or 'aloneness' of the transition experience, one nurse compared it to a journey. "I'm setting out and the terrain is not flat by any means, there's hills, and there's that sense of excitement with the exploration aspect, but it's just the isolation, it's just me going on the walk" (Nurse A). Participants also described having to learn and work alone. "Nowadays in a lot of companies you are doing your online training all by yourself, in your office, you have no one to ask," (Nurse E), "In the [company name] environment we never got together, we completely worked remotely," (Nurse F), and "I was my own IT, my own Pitney Bowes and FedEx person, I was my own copier. I got to know the Staples nearby really well, the Post Office . . . I was a team of one," (Nurse H). A number of participants also focused on the potential negative consequences of physical isolation. For example, Nurse B related that "our manager is in another country . . . [chuckle] so it's very difficult in my opinion to effectively have a grievance or an idea for that matter and bring it to the people who do

make decisions when you don't ever have contact with those people," and Nurse I concluded that "If you're going to feel like you're lonely or you can't go into a restaurant for dinner on your own, this is not the field for you."

Lack of support or resources was a common part of the isolation dialogue, and the potential consequences were discussed in several instances. For example, Nurse D recalls "She [the study manager] came in one morning for a couple hours to tell me about the study and then it was more or less Tag-You're-It. . . . [there] wasn't a mentoring program or anything that was really formal in the transition or the education, so I just learned by reading and doing and asking questions and making mistakes. The emotional impact of the lack of support was commented on also. "They explained in general the role but still, no one went into detail about the different roles within the industry. That was so challenging and frustrating, just trial by error. It was scary" (Nurse G), and "They weren't willing to help. They weren't willing to spend time to explain things. I just really felt thrown into the lions' den without being prepared" (Nurse B).

Professional isolation, in terms of feeling separated from or unsupported by the nursing profession was discussed by a large majority of participants in the study. In describing an industry-based professional association started by nurses, Nurse A laments that "it's unfortunate it took another separate group to do so [create a place for nurses in the pharmaceutical industry] instead of it being able to come out of the nursing side . . . the fact that they never recognized that as a gap that they could fill. It's disappointing." A similar call for direct support from the nursing profession was made by Nurse C, "I don't really see any particular support from nursing . . . they're not doing too much to really give direct support to a nurse in this kind of role," and frustration was expressed that

recognition of clinical research as a nursing role has not been embraced by nursing educators. Note, for example, the statements "We as nurses are in the clinical research profession and it should be recognized, . . . and the opportunity for nurses to work in clinical research should be explored in the bachelor program" (Nurse D), and "Even now when you look at trying to do Continuing Education Units or to maintain the nursing license, when you look out there for anything on clinical research that has a CEU tied to it, . . . I don't see any nursing associations putting things like that out there for nurses who are in this field" (Nurse G). Finally, and with humor, participants also noted that the lack of recognition by the nursing profession for the nurse in clinical research manifests in some interesting ways. "When you relicense, renew your license and turn in your contact hours, there's a form that has to be filled out about 'what kind of nurse are you?' I check 'other' and I write in Clinical Research Associate. It's not even on the list (LOL). That's one of the things that strikes me as odd, that they don't even have that concept of how nurses could utilize their skills in clinical research" (Nurse E), and "I read the [State Name] Board of Nurse Examiners issues that come and there's really nothing in there about those of us that do research – it's always more sort of clinical related nursing topics . . . I don't know if 'ignored' is the right word or not recognized. It's just missing, not really addressed at all, like we don't really exist (LOL)" (Nurse F).

These statements make it clear that isolation is an important and multifaceted part of the transition experience for this group of professional nurses leaving direct patient care for a career in research. Nurse A sums it up in this way:

> I would speak to isolation . . . when I say isolation, I'm referring to the lack of support, lack of training, lack of knowledge, lack of understanding, and being left to find my own way through all of that, to navigate all of that. Not having peers to

> speak to . . . I felt very isolated as a nurse trying to find my way in that role, in that whole process.

Because all participants made statements regarding isolation along one or more of the three dimensions identified, it appears that isolation features prominently in understanding the nature of the transition experience.

I Am Unprepared:

Transition Requires Mastery of Unfamiliar Skills and Knowledge

The experience of feeling and being unprepared for and during transition was remarked on by almost every nurse participating in the study. Comments reflect an interesting mix of distress or angst caused by a lack of knowledge or skills, as well as excitement at the opportunity to embrace the challenge of learning and exploring new avenues of study. The distress of working without adequate training and knowledge is palpable, for example, in the following statements:

> There was no training . . . that was the horrible part . . . again I'm the type of person that just takes what I'm doing very, very seriously and I would assume 99.9 percent of the nurses are the same way. You act with integrity and ethically in everything that you do. . . I can't tell you the crisis I went through knowing that for two years I wasn't doing what I should have been doing, through no fault of my own. I was mortified when I actually found out that GCP [Good Clinical Practices, an ethical and operational standard for research practice] existed and regulations existed and I had no idea. It was a hard realization to come to. . . . That to me is fundamentally flawed. It shouldn't be acceptable for the work that we're doing as clinical researchers with human beings. There should never be someone that does not know what they're doing. (Nurse A)

> We didn't really have an emphasis on research [in nursing education] other than a statistics class and how you calculate means and medians and that type thing—just the mechanics of it. I really had no idea of what I was getting into at the time, and that could be a little scary. (Nurse D)

> It was just a whole new realm. Prior to [entering industry] I had no idea. . . . I do remember somewhere two or three months into it thinking: I don't know what the heck I'm doing. I'm going back to the ICU. (Nurse F)

> I knew I had to get my game up—get knowledge – because these people would expect nothing less. They're not going to talk to you if you don't know what you're talking about. So I had to get my knowledge base up on the drug, the indication, . . . That's a little anxiety provoking. (Nurse H)

As noted above, however, reaction to the lack of preparation was not always experienced as a negative event. Several nurses commented positively on the opportunity for learning and growth this represented to them. Nurses D, E, F and J, for example, describe this part of the transition experience as enabling, an opportunity to help others in a new way, exciting and motivating, and cool.

> It was always the latest breakthrough in science, maybe a new test that they were developing. I've always loved to learn and so it enabled me to really delve deeper, to understand the why we're using this product this way, is there a different way to do this, and all the knowledge and science behind why we give a product to this person this way. (Nurse D)

> What I love about clinical research is learning a new protocol, learning it well, learning a new compound, learning a new therapeutic area, if possible. I like to see what's coming down the pipeline, what's out there to help people become well. (Nurse E)

> You learn about a new drug or another way of studying a drug that you'd previously worked on, and it was always an exciting and growing experience. . . . Increasing your knowledge, . . . It just is motivating. I remember . . . coming home so excited and hopeful that maybe we found some eureka drug for cancer. (Nurse F)

> I think clinical research is a great window for curiosity. There's just so much, especially in investigational medications or devices that's s all new and has to be learned. It's cutting edge, so it's really quite cool. (Nurse J)

While several of the nurses characterized the lack of preparation as challenging (Nurse A,B, E, and F), there was a notable tone of pragmatism in their response to this challenge. Nurse A, for example, describes spending "hours poring through the FDA website and reading all the guidance documents" in her effort to build standard operating procedures that would ensure regulatory compliance, Nurse B, while acknowledging "I

never really thought that it was something that I could do because I've only had one course in research as part of my curriculum," goes on to say "I just felt . . . if they'd be willing to teach me, . . . I'm very teachable," and Nurse E advises "You have room for growth. . . . Take it slow until you learn – and you have to give yourself about a year I think to feel comfortable at what you're doing."

The challenge of feeling or being unprepared was not only described as a part of the transition experience, but was also discussed as an inherent part of the nature of working in the pharmaceutical and medical device industry. Consider, for example, the following statements:

> Even if it's just that you did a certification, . . . you can't just rest on that, because things change so quickly that in order to just be marketable . . . you have to keep learning. (Nurse C)

> I think we're challenged almost on a daily basis in clinical research because . . . the industry is so dynamic. It has never stayed the same. It is constantly new systems, new technologies, new regulations. I've always said if I were to take even a year off in this industry I would be so behind the eight ball trying to get back in. . . . The thinking can change and technologies will change and that has been a challenge. It's just a fact of the industry and you have to be on your toes and you have to be flexible to change and willing to change because if you can't, this is not the environment for you to work in. (Nurse F)

> You're dealing with Ph.D.s, with statisticians, pharmacists and physicians, and on more of an academic level. I think you have to be more on the cutting edge. You have to constantly be more aware of what's current and what's out there. (Nurse H)

Thus, a lack of preparedness, in terms of skills and knowledge was a common experience reported by the nurses participating in this study. While this was frequently described as challenging and stressful, it was also commented on as presenting the opportunity to grow, to be a part of new scientific developments, and to contribute to improved patient outcomes.

I Am Scared and Sometimes Overwhelmed:

Transition is Associated with a Lack of Security, Structure and Balance

The experience of being scared during transition was often paired with comments regarding feeling somewhat overwhelmed, and expressed in terms of experiencing a lack of security, a need for structure and reliability in the environment, and a desire for better balance between work and life demands. Every nurse on the study described times during transition when she struggled with either feeling physically or mentally insecure or anxious (Nurse A, G, H, and J), needing or missing the structure in her environment to feel comfortable and safe (Nurse A, B, D, and F), or struggling to achieve an acceptable level of work-life balance to avoid stress or hardship (Nurses C, F, and I). These situations and stories were characterized as scary (Nurse B, C, E, G, H, and I), overwhelming (Nurse, A, F, H, and I), and possibly threatening (Nurse H).

Various sources of insecurity during transition were identified by study participants. For example, in discussing how much she missed seeing and spending time with patients during her transition period, Nurse A states “I never had the opportunity to interact with them [patients] anymore . . . It was disappointing and made me feel insecure, sad.” Also comparing the clinical research environment to direct patient care nursing, Nurse G, describes missing having other nurses with which to work. “There would be days I missed it [direct patient care nursing] . . . because at least in nursing if you had a bad day . . . there was somebody else there picking up that patient after you left. . . . That was always a relief, but not so in clinical research and that can be a little unnerving.” Nurse H also perceives separation from former colleagues as a source of insecurity:

> I still needed my roots so I still kept with my old friends . . . I think that was like a safety net. It was familiar . . . I was extremely scared. I felt like a traitor that had left my friends of 16 years. . . . We're not going to be 'the team' anymore. . . . I remember being extremely emotional. . . . I think it was shock.

In a very direct example of issues around security, Nurse J reflects on it in terms of employment stability. Describing the lack of job security that stems from working in an industry subject to frequent employer mergers and acquisitions, she notes:

> Then the company was sold, so I actually went on as an independent contractor. That was a hard decision . . . and then they too ran out of work, probably because they were getting ready to be sold, so they tightened up and I was out on my own again.

For just some of the study participants, structure was also identified as critical to their sense of security. In describing her reaction to the lack of structure she faced while working for a small biotechnology company, Nurse A relates:

> They had nothing, they just literally were back where I was in 1995. They didn't know what they were doing from a clinical point of view, and what you had to do from a compliance point of view as the sponsor related to the clinical side. So I put all of that structure in place for them. I had to [introduce structure] to survive.

Further describing her frustration with a lack of structure, Nurses B states:

> I get very frustrated when I see other people deviating from the way that we all agreed that things need to be done in order to have the outcome that we need to have. It scares me.

And, after reflecting on how a lack of structure had the potential to impact her commitment to continue with her transition, Nurse F said:

> I do remember somewhere two or three months into it thinking: . . . I'm going back to the ICU with its structure and its timesheets and checklists and medication times.

This insecurity related to unpredictability and structural threats in industry can be experienced as scary. As Nurse C relates, “There actually was a recent change in my company within the last year, and we had a staff meeting and it was said to us that a whole other department that we worked with was being eliminated and it was sad, scary,” and when asked to think about their transition in terms of telling a story or writing a book Nurses G and I offer particularly vibrant descriptions:

> If you had to equate it to maybe a book that you would read, it would be going into a forest that’s dark and scary and fearful, and things are presenting themselves to you and you don’t know quite what they are. And you’re trying to relate them to something that you’ve experienced in the past but you can’t make the connection because it’s so different, and at that point fear overcomes you. (Nurse G)

> The journey, going from nursing [to clinical research], the terrain was like being in the mountains, and sharp mountains like the Rockies, and cliffs, and you have to get down and you don’t even have the right shoes on to get down, [but] you just have to get out of there. (Nurse I)

Transition from bedside care to clinical research was coupled with the experience of feeling overwhelmed at some time for a majority of the nurses participating in this study. Feeling overwhelmed was associated with a lack of understanding for the importance of the work (Nurse A), but it was more often associated with feelings of insecurity generated by the disruptive nature of major change (Nurse D, F, and H). In discussing how little she knew about research prior to transition, for example, Nurse D laments “I really had no idea of what I was getting into at the time, and that could be a little overwhelming.” Moving further into the transition period and reflecting on the challenge of dealing with disruption, Nurse F recollects “It was a little out of control . . . was just a disruptive and challenging environment to work in. . . . They maybe had to . . . change quickly trying to maneuver and figure out how to get their compounds positioned.

It was just a bit of a struggle and a little overwhelming," and Nurse H succinctly states "it's overwhelming sometimes to make a change."

Trying to balance normal day to day commitments, yet add the responsibility for huge volumes of a new kind of work also lead to the feeling of being overwhelmed for a number of the nurses on the study (Nurse E, F, and I). As transition has been achieved for this group of participants, the conversations around this topic took on a somewhat nostalgic quality, but the level of detail in the descriptions indicates that this experience continues to resonate loudly in memory. For example:

> In the beginning I didn't feel like I had enough time to get everything done. That's the tough part about research . . . Never mind about your family, if you're traveling to a site and you don't have enough time, that can be the downside of feeling successful. You can't get everything monitored in one day or two days, you can only do what you can do, and I really had to re-teach myself how to do it for me . . . whatever I needed to do so that I'm not overwhelmed, because if I get overwhelmed, and I tend to do that to myself, I don't do a good job. I fail . . . epically. (Nurse E)

> Well it was overwhelming, it was all the work – all the work that goes in to filling out those books, all the handwritten data, then each page had to be pulled. It was all the measurements and lab results and vital signs, there's so much work in those books, and to see it floor to ceiling and wall to wall, . . . because of all the various studies. I understand it now (LOL), but back then, it made me feel ill. (Nurse F)

> When I first transitioned the terrain felt beautiful . . . it's warm, it's peaceful, it's nice, it's exciting because . . . now you can move onto where mentally you can be doing something that you really want to do. As you continue your transition, now the ice is starting to form. It's getting very difficult to maneuver. I don't mind doing it, but the struggle between where I wanted to be mentally and what I thought I could do mentally . . . to me it's just so overwhelming. (Nurse I)

Stories regarding the challenge of achieving and maintaining work-life balance were related by about a third of the study participants. "When I think back on that time when I was so stressed out, . . . I'm amazed that I'm alive today, because I don't know how I went through it. . . . I really strive to have balance in life, work-life balance . . . and

it was completely missing" (Nurse C), "If you're in a home office environment there's always something you could work on, calling you, pulling you, and your family sees that too—maybe to their detriment at times" (Nurse F), and "I know it comes with the job [traveling], but it's so hard . . . . If it's going to be research, if you're going to go into the monitoring field, this is what it's going to mean, and if you have a family or if it's going to be a hardship then you'd better think long and hard about it" (Nurse I).

The requirement to travel to where the research is conducted was reported as a key source of distress, and in one case was experienced as a possible threat. Nurse H described it in this way:

> So I'm standing in an airport looking at the monitor that says what gate you're supposed to go to and I feel myself welling up with tears. I don't know what airport I'm in. I don't know where I'm supposed to go. Now I have my itinerary, but I have been traveling so much I just – I lost it. I said I think I need to stop traveling.
>
> She goes on to say:
>
> I felt anxiety. Did I make the right choice? . . . And it actually continued because I was traveling, which brought another set of anxieties. I remember – because I was single and I remember saying to my brother . . . I'm going to tell you when I travel. Okay? Now, I want you to check on me to make sure I get home. What if something happens to me in the parking lot in the airport?

While it is apparent that no two transition experiences are alike, feeling afraid and overwhelmed, being insecure, and longing for structure and better work-life balance were experiences shared by many of the nurses on this study.

I Can Do It:

Self-Reliance and Resourcefulness Facilitate Successful Work Role Transition

While the transition experience was generally noted to be challenging by all study participants, one feature of a successful transition that ran through almost every interview was that as transition progressed, a growing sense and level of self-reliance and resourcefulness, or the ability to figure things out, occurred. This was experienced in three psychological stages, reflecting adjustments in how each individual viewed themselves and their environment, including 1) embracing the challenge, characterized by a period of struggle leading to commitment to task after initial encounter with the new role, 2) adapting to change, characterized as a period of psychological adjustment and the development of new ways of working, and 3) settling in, or a period during which the participant has adapted to the new role and seeks to exploit the opportunities it presents.

Embracing the challenge: Transition success was not always assumed to be possible by the nurses participating in this study when they first encountered their new role. To embrace the challenge, a first step was often described as recognition that a key impediment to success was self (Nurse C, F and H).

> There's a saying, something about a gate or a prison is locked on the inside when you have a kind of self-limitation. At first, that's what I was doing. I was holding myself back . . . for what reason I have no idea. And so when I realized that I really could do it if I put my mind to it, I found a way. (Nurse C)

> [I had to adopt] a positive attitude, take on the challenge, you can get this done, that sort of thing, because you *can* get it done . . . you *can*. You have to have a can-do attitude. Nothing is impossible, right? (Nurse F)

> I think a lot of times when I'm unsure you can get your ego knocked down and your self-confidence knocked down, and that can put you in a hole mentally. You're afraid to do more, you're afraid to reach out, you're afraid to be all you can be. . . . And then, you're not as strong, you're not showing your full potential.

> I think there was a potential to wallow in that, to stay in that, or to choose to basically say screw you, and get going, get yourself out of the hole. (Nurse H)

Reflecting a growing understanding that reliance on self was key to success, a number of participants reported making a conscious decision to stay the course. Nurse C describes it in this way:

> Once you make that initial hurdle, take that first risk, or you reach that first peak and you realize that there's still another one ahead of you, and there's probably a million more ahead of you, you just say this is part of the process and so you just keep going," and further states, "When I finally took the limits off, I realized that's when I really started to take off with my career, . . . opportunity is all around and it's truly what you make it, . . . it's just a matter of whether you'll take it or not.

This experience of taking personal responsibility for one's success is also reflected in the following quotes as well: "If I could succeed with that challenge and feel comfortable about my new knowledge, then it just builds on my experience and my foundation and my personality and I can bring more to the table. I like that about myself" (Nurse C), "No one is going to hand it to you. You really have to . . . not be afraid to find things out for yourself, do your own – be your own search engine" (Nurse H), and "You just have to do this, you have to do what you have to do and that's the way it is. I'm okay. I can keep up with everything, it's just [up to] myself" (Nurse I).

Embracing the challenge was further characterized by a number of study participants as a period or moment in time when they realized that if they were to be successful, they needed to figure things out for themselves. For example:

> So I think once . . . the exploration . . . [phase passes] then that was an opportunity where I could be challenged because I had to start trying to figure out how to make things better. . . . better like you do when you're a nurse, you're always trying to make things better. (Nurse A)

> When I think of success, I think you have to gain knowledge to be successful, you have to implement it, you have to have a bit of an analytical mind to sort it out, to figure out the bits and pieces, know what you're missing or you need to get more of. . . . Now you're in a whole different field. You made the decision. You're going to stick with the decision. You have to figure it out. (Nurse H)

> You have to be able to meet sometimes unreasonable deadlines. Are you comfortable with that? Are you willing to go the extra distance sometimes, hopefully not always? Are you good at organizing your own time? . . . You have to be good at trying to figure it out. (Nurse I)

Adapting to change: Once the challenge was embraced, the second stage, adapting to change, was addressed specifically by Nurses G and H. In acknowledging that her first year after transition required that she accept that change was inevitable, Nurse G says, "You learn to be uncomfortable in clinical research. You can't really ever get comfortable in clinical research, not too anyway, because it is very dynamic, but you sort of learn to accept that things will constantly change . . . it's just the nature of the business." Further, using an analogy in which she likens the way she adapts to change during transition to a walk through a forest, Nurse G goes on to say:

> You're kind of learning how to do it on your own. So for example, [in a forest] you might find that a noise is really not a scary monster, . . . it is kind of familiar to you yet a little different, so maybe it's not a scary a creature . . . And then as you keep learning about the different things within that forest you would begin to see that there is a new path and then at the end of the day it's not a dark and scary forest, but it could be a bright, cheery, comforting forest that you've learned how to deal with through self.

Similarly, Nurse H relates "So you made the decision and now you're surviving the change. It was a huge change. I mean not only location, but clothes, [and] expectations of what I deliver." The description of this part of the transition process as 'surviving' is notable, because as Nurse H moves through her transition story, the negative affective

valence of surviving shifts to a much more positive experience, indicating that adaptation has occurred. Consider the following excerpt from this same participant:

> I'd start at 7 in the morning, work until 7 at night. I was on multiple studies, multiple brands. . . . I would read the protocol onto a cassette tape and I'd listen to it on my travel to the site, depending on what study I was working on. . . . I was like whoa, this is kind of weird, but I liked it.

Settling in: Settling in and beginning to not only embrace, but exploit the new role, as the third stage of experiencing 'I can do it,' resonated in numerous statements across a majority of study participants. This stage was described as exciting (Nurse A), an opportunity (Nurses A and C), surprising (Nurse B), rewarding (Nurse E), enjoyable and interesting (Nurse G), and "the best time of independent learning that I had experienced as a nurse" (Nurse D). Nurse A, for example, relates "Once I actually did start to understand that this was an industry with an actual wealth of information available, then I started to get really excited and I started exploring, and I started reading and teaching myself and learning as much as I could, and that was exciting. I enjoyed it." In reflecting on how much she learned during her transition period, Nurse B notes "I'm surprising myself to this day . . . that knowledge is there, like how did I know that? I think it kind of makes me realize that I often times don't give myself enough credit for what I did," and Nurse E reflects "I guess it's a reward in itself to overcome new information and be able to share it and teach it or just learning it myself." Finally, while musing about what she would tell others considering a similar transition, Nurse H offers the following advice:

> Think, I can be self-sufficient. I can stand on my own. . . . Have a very positive outlook on life. We certainly had a few dark moments but it was a plow-through-and-get-it-done type of mentality, and like anything, you see the light getting bigger and shinier, brighter, as you go. [The] thing you need to do is look at yourself and write down what are your skills, ensuring you have a potential for

> being a good fit, and the skills I think you need to be good in research are to be inquisitive, ethical, personable, and charming wouldn't hurt (LOL).

Thus, by recognizing skills, resources, and traits already possessed and relying upon and utilizing those as a means to address the challenges of transition, study participants were able to embrace their new environment, adapt, and appreciate significant potential in their future role.

I Need to Build New Bridges:

Transition Requires Networking and Support from Others

Leaving direct patient care for a career in clinical research entails the need to establish and develop many new relationships and build new bridges for support. The important role played by networking in both opening doors as well as providing ongoing support during the transition experience was commented upon by every nurse participating in the study. Some participants related a story of a specific encounter with an individual in their professional network as their primary point of introduction to the new role of clinical researcher. For example:

> I was actually approached by [name] probably in my fourth year of being at [name of hospital], in that role, and she and another person came to talk to me to encourage me to come work for them . . . I remember asking, what is it you do? What . . . would the role be? And I didn't take the job at that time. And then the next year we kept in touch and she asked me again and I made the leap. (Nurse E)

> I would not have pursued this probably, it was just the timing of the doctor walking in and – at the right time, at the right moment and I had to thank him and in fact I did thank him even long after he left. Thank you so much for opening this window, this door for me into a whole new area of nursing. (Nurse F)

For nurse H, the member of her network who first introduced her to the idea of developing a career in research was another nurse and close family member who had transitioned several years earlier. She says," I remember having a conversation with my

sister-in-law and she said, well why don't you come into research? She said, they need people in the cardiovascular section at [company name], why don't you consider that? . . . so she helped me write a resume." Other nurses used new relationships they developed in the research coordinator role to help them bridge to monitoring for industry. Nurse I relates, "One of the monitors . . . said, this company where I work has a wonderful program for coordinators who haven't had monitoring experience to attend a class, and that they would pay for your training, and then you'd go be a monitor, so that's what I've been doing for two years," and Nurse G relays a story of how one networked opportunity may lead to another:

> When I was a coordinator at [company name], because of a networking connection, I found out about the CRO [Contract Research Organization]. From there, once you got into the CRO world . . . you . . . were working with the sponsor personnel, and when you would go into their environment, you would see what the roles of the different people were . . . whether it was study management . . ., regulatory, whatever the case may be, and you could use that to take your next step.

While networking as a means to find a point of entry was a noted facilitator to success, the general importance of networking for support once transition had begun was commented upon by almost every nurse in the study. Networking was discussed as an important activity to combat the initial period of isolation (Nurse A and I) in transition, to obtain the training and education required (Nurse A, F, and G), to receive ongoing support and have access to resources (Nurse C, D, E, G, and H), and to explore new potential opportunities for growth and career development (Nurse B, F, and J). In discussing how networking through professional associations helps to combat isolation, Nurse A remarks, "ACRP [Association of Clinical Research Professionals], can actually help with the transition process. . . . first of all, in providing networking opportunities. I

know at least in the isolation stage I didn't know anyone else that had kind of made this transition, so that the networking and the mentoring and the access to individuals that had done it was important." Nurse I echoes this feeling in her comment, "You must try to make a network, try to network and think about joining organizations like ACRP. Find more nurses that have gone into research, and if you can, somehow, talk to them. Transition can be very isolating."

Networking as a means to obtaining education and training is reflected in comments by Nurse F, "Had I been alone with no training it would have been a really difficult position to sort of grab onto, to understand on my own. . . . Just to have . . . our sponsor monitors [who] you can call for questions, and . . . the support of study teams," and Nurse I succinctly states," Networking can facilitate transition through educational opportunities." Nurse A adds dimension to the impact of networking for education by pointing out that it was through her professional association network that she was able to obtain the training she needed to achieve her clinical research certification:

> When my new director came in, and I had the opportunity to . . . become an ACRP member and to do their training and to actually understand the regulations, . . .[it] afforded me so many opportunities. So, I became an ACRP member two years after starting my research career, and I became certified [two years later] as soon as I was eligible.

The more general importance of networking as a key support and facilitator in successful transition was voiced by several study participants as reflected in the following statements:

> To continue to network . . . having that other person sometimes directly come along side me to coach me through it or to point me in the direction of another person who could mentor me so I just found that maintaining those kinds of relationships were vital in the whole process and they just still continue to be so. (Nurse C)

> I went to work for the sponsor and there they had a trainer who I actually had interactions with for 20 years. She stayed in that same role, but just a great person, an excellent teacher, and just a great resource that helped so much with my transition. There were no stupid questions, there's the ability to call up and just say something just feels funny about this, a real strong influence. (Nurse D)

> I think . . . about how relationships can move you through a career, how they helped me in my transition . . . Those relationships they can form so quickly when you're like-minded. . . . to have a thought and a dream and people that support you . . . you can do it. You can do it. (Nurse E)

And, the overall impact of good networking relationships as you develop in a new role is clearly reflected here in this statement by Nurses G:

> Networking is very important because there are times where you do need to reach out because you're not going to know everything or have always been afforded in the past a situation that might occur, so you need someone who can be a mentor or bounce things off of, a collaborator . . . you want to be able to have a group that you can go to.

Once transition had begun, networks were relied upon to secure and develop new or better career opportunities in industry. Nurse B, for instance, talks about networking as a means to demonstrate competence and generate recognition in her new role. "So when I say I'm networking it's because I want people to see that I'm a dedicated employee who's continuing her education, who's trying to complete projects and knows how to reach out and get help . . . to have a successful outcome," and Nurse J reports being very grateful for her network when job security is threatened. "Networking, it's definitely really important. I don't know if I realized how important it was until . . . I found myself looking [for a new position]." Finally, discussing her movement from an internal support position in industry to her first field level assignment, Nurse F says "Out of the blue a friend who I'd worked with at the internal position in [name of city] had gone to work for [company name] and she loved [company name] . . . she said you have to try this

company, it's so wonderful, and cited all these reasons why she loved it, and . . . I took the leap of faith and I accepted the position,"

The leap of faith mentioned above was discussed in numerous ways by study participants, and for Nurses A, C, and J was facilitated by a somewhat unique member of their network, an individual not well known to them who became a personal champion. Discussing a new director for her research unit, for example, Nurse A states, "She recognized I guess in me that I loved it, that I responded well to it and that I had probably the skills and ability to help her. . . . She afforded me so many opportunities and made it much easier to take that leap of faith to new things." In a broader sense, Nurse C comments on how vital this champion relationship was to her during transition.

> You still have to get your foot in the door, but once you're in you have to prove yourself and so typically it helps to have someone who's already on the inside of wherever it is you're going, so they can kind of pull you in as you're pushing your way in. . . . I think it helped make the transition, because remembering how that particular manager opened doors that I never thought were possible helped me to explore that again and again with other people and to make the leap to other opportunities.

For Nurse J, transition to industry started out slowly. Note the role, however, that finding a personal champion played in the following description of her early career progression:

> I started out as administrative for about a year and then finally somebody took a chance on me. She actually talked about it at the conference last week in front of everybody. She said I saw somebody who stood out with their work and I went to my supervisor and said, 'could we hire her for our study?' and she said she would take full responsibility, which was very nice. So once I got into that role . . . that was when it started getting a lot better.

Stories and comments regarding seeking the help and support of others for success in transition were very common in this study and began at the earliest stage of the

transition journey. In most cases these 'others' were mentors assigned or engaged with through industry.

The importance of industry- based mentors was a theme of many conversations with participants, as is evident in the following statements, "Mentoring and the access to individuals that had done it was so important" (Nurse A), "Once I went into industry they were adamant to ensure that everyone in that role had the most current expertise, . . . [and was] supported with trainers and mentors, and just a wonderful group of very seasoned professional nurses that I was very proud to be a part of" (Nurse D), "You need someone who can be a mentor or bounce things off of, a collaborator" (Nurse G), "My mentor was a nurse . . . she is a nurse, and I said I just need to know I'm on the right track. . . . As soon as I expressed that need, in a very professional way, not whining, she would put me under her wing, 'Okay. We're going to do this'" (Nurse H), and Nurse I summed up the importance of mentors with the following advice:

> Make sure that you make friends with other people whether it's on your team, other monitors, and talk to them. . . . If you can get yourself a mentor, just like with any job in any field, you're really well ahead of the game. Just somebody you can run things by, especially if they have a lot more experience than you do.

Whether it is developing networks, finding a champion, or developing and learning from mentoring relationships, study participants universally agree that having the ability and willingness to build new bridges and seek support from others is key to being successful in the transition process. Once these bridges are built however, a clear voice of increasing confidence is evident and becomes a significant factor in a successful transition experience.

I Am Becoming:

Transition Can Be Empowering and Offers Opportunity for Growth

The transition experience was described as a process of becoming or evolving by a number of the nurses in the study. The 'becoming' process was described as a series of stair steps or a mountain to be climbed (Nurse E), discussed in terms of as growth over time (Nurses A, C, D, E, and F), said to be empowering (Nurses C and E), and characterized as transformational (Nurse E). Several nurses reported being surprised by the opportunities for growth and development that moving to industry provided to them. As an example, responding to a question regarding what transition had meant in her life, Nurse A said without hesitation:

> Growth . . . both as an individual based on the knowledge and the exploration and the opportunities that were provided to me, but also growth just in the traditional sense of moving up and moving into roles of greater responsibility and evolving . . . new experiences, going from a bedside nurse to a clinical researcher . . . and having opportunities that I just never, ever would have envisioned as a bedside nurse would become available to me.

This experience of finding opportunities to engage in new activities that were unexpected or un-envisioned while in direct patient care nursing is rather excitedly discussed by Nurse B as well:

> I can tell you that I have had an epiphany. . . . The person that I found to be my preceptor was one of the co-founders of an employee resource group . . . the Nursing Innovation Council of Excellence. This group is all about . . . volunteering, offering your nursing knowledge and expertise in different business areas that one would never even think nurses would have anything to do with . . . serving on advisory boards, focus groups, research and development ideas, product improvement ideas and it's, . . . Wow!

And while recognized as a part of transition, this process of growth and exploration of heretofore unexplored opportunities, occurs in concert with a sort of re-integration to the

original self, including basic nursing skills and knowledge that the nurse entered transition with. Hear, for example, both the excitement regarding the opportunity as well as the incorporation of the original self as Nurse E discusses feeling transformed:

> I also think that the upside of going from nurse to Clinical Research Associate, is you're always taking a step, growing, transforming, and elevating yourself by building a stronger foundation by all that knowledge you have below you, all those stair steps you have below you. . . . it feels elevating and empowering to educate yourself. . . . it also takes a certain kind of character to do that and do it well, well rounded, . . . ability to handle other people, deal with difficult situations and obtain positive results – you become more of a leader, your old self, but better, and people want to follow you.

Taking this reintegration concept a bit further, note how Nurse F, as a result of transition, recrafts her definition of nursing, integrating her perceptions of herself and actions as a clinical research professional into her core nursing identity, including her evaluation that clinical research has helped her to become more:

> You're not . . . actually touching the patients, taking care of them, but now you're thinking about them, you're reading progress notes, you're understanding differential diagnoses more, you're looking at labs, . . . you're helping to evaluate I think more so, and it was part also of my nursing, just growth. You and your nursing become more.

Feeling empowered was largely recognized as a gradual development across the transition experience, and coupled with a growing sense of confidence, in spite of acknowledgement that there had been difficult times. Nurse C, for example discloses that "The road I took was a little bit rocky in the beginning. I think of that as maybe a mountain in the dark that's covered with ice," but pragmatically adds, "Whatever it is you're going through, . . . you think you will never be able to do it when you look at [it] from the beginning to the end. . . . it just seems so overwhelming, but if you just take it one day at a time, . . . and just be persistent with it, you realize you really can do it, and

then when you get through it, you feel like you could take on everything." Confidence and self-empowerment are products of not only achievement, but for Nurse E, intentional acts she associates with being successful:

> You must be passionate about what you do, driven, willing to take risks, mindful, thoughtful, because in this career you have to deal with lots of people. If you have good comprehension and power of personality, then you have an easier way of translating the information you have to other people and having the confidence [to say] if I don't know something, I'm curious enough to go and do some research.

And, reflecting on the empowering nature of the transition experience itself, Nurse C provides the following insight:

> Looking back on it all, I would have to say it's all been wonderful: the clinical part, the tough part and all the different roles that I've had in industry, they've all had something special that contributed to my professional growth, but even my personal growth. It has all been so empowering, and just all the different people that I've met along the way, [it] has just been wonderful.

Thus, the nature of the transition experience from direct patient care to clinical research harbors the ability to transform as well as either create or awaken a sense of personal power and for the professional nurse. Through exposure to learning and professional opportunities previously not envisioned, the nurse in transition experiences growth and a rise in personal confidence.

I Am Still a Nurse:

Nursing Identity and Values Endure Through Transition

The nursing identity remained highly salient with a positive emotional valence throughout and following the transition experience for a large majority of the nurses interviewed. Participants reported that they "loved" nursing when in direct patient care (Nurses A, D, H), but similarly, reported that they felt very positive about being a nurse

during and after transition, and saw their research activities as a new application of previously acquired nursing skills (Nurses A, B, C, D, E, F, G, and H). Describing a 'picture' of her transition journey, for instance, Nurse A talks about traveling across hilly terrain with a walking stick. When asked what the walking stick represented to her, she replied, "I think the walking stick represents my nursing. It's always there for me to lean on. It gets me further, it helps me, it's a part of me. I couldn't navigate that terrain without it." Nurse B also discusses how important nursing identity is to her in transition, "I'm a nurse . . . I'm not laying hands on them, . . . but yet they're coming to me because they trust me. . . . I'll never lose that," and Nurse C reflects, "It's funny because somewhere along the line I was able to let go [and see that] nursing isn't just about getting your hands dirty or being at the bedside or taking a blood pressure, that it's not just what you do but it's what you know and who you are, and so that I rely on every single day."

The saliency of the nursing identity persisted for most of these nurses, in spite of reporting that upon transition, people in their lives, especially other nurses, no longer saw them as 'real nurses.' Rejection by the profession and former nursing colleagues, however, caused significant distress for several individuals. Note the following examples:

> I think there can be almost like a dismissiveness if you're not at least . . . a Critical Care Nurse, because that's where I spent so much of my career, then you're not a real nurse, . . . we're smarter and busier than everybody else and nobody else is as good as us. I hope that they would see the value in every component of nursing, . . . how you're applying everything that makes you who you are as a nurse and your nursing skills to clinical research. (Nurse A)

> Other people looking at it were saying well you're not a real nurse anymore, then really the only answer I have to that [is] that's a really sad misunderstanding on your part. If you can't see beyond the patient room in nursing, it's really a disservice to nursing. (Nurse B)

> But once I was in clinical research, if you would see them [previous nursing colleagues] again they would think you're not a real nurse, and then I would kind of relate it to: Well what about case management nurses, are they still a real nurse!? . . . It hurts! It hurts! (Nurse G)

In discussing what they would like to share with their profession regarding their perception of its failure to recognize nurses in clinical research, participants adopted a strikingly similar tone. Nurse A, for instance, said "I would tell them that they're missing an opportunity and they're not serving part of the profession." Nurse E commented, "You might be working with other nurses [in the clinical research industry] who will support you, but the nursing profession per se, . . . and the nursing schools, really don't support you," and reflecting on this lack of support from nurse educators, Nurses C, D and G lament:

> It seems that in nursing school . . . they don't seem to really advertise all the other options. It almost seems as though all of these opportunities really have been there all along, since day one, and I didn't learn about them until out of desperation [I had to find] something else to do. . . . I have to wonder why they never introduced us to those other areas. . . . I don't remember ever learning about them through nursing school. (Nurse C)

> I would love for nursing schools to provide students with – even if it's one hour their senior year of: What is a Clinical Research Coordinator and what is a CRA and what is this about? . . . We as nurses are in the clinical research profession and it should be recognized, and the avenue for nurses and the opportunity for nurses to work in clinical research should be explored in the bachelor program. (Nurse D)

> I just wish that as a bachelor's degree nurse that there was exposure to this industry. I feel like it's a well-kept secret. It's a secret that I'm glad I found, but I just wish I was exposed to it sooner and I think that even from the nursing profession, . . . it's a great career path that nurses can take and it's exciting because, again, I feel that although people say I'm not a nurse, I'm still tied to the patient. (Nurse G)

The tenacity of the nursing identity did not appear to dissipate over time. As noted in Table 3.1, there is a wide range of time intervals since beginning the transition process

for the nurses participating in the study. This appears to have, however, no impact on how strongly participants identify with their nursing self. Nurses D, F, G, and H, for example all made their initial transition around twenty years ago. Nevertheless, in discussing how they refer to themselves when asked about their profession, their replies remained consistently tied to nursing; “Registered Nurse . . . that’s always my first answer because I do feel like that’s what I am degreed to do and that the field of clinical research is a division of my role as a Registered Nurse in the sphere of healthcare” (Nurse D), “On my tax form when it says ‘what is your occupation?’ [I write] RN! . . . I’m a nurse! I say I’m a nurse. . . . I’m a nurse first” (Nurse F), “I believe I am [still a nurse] and I remind people here quite frequently because I don’t think that they know. . . . There will be times I walk around here and I go, well, you know I am a nurse” (Nurse G), and “When they ask me what I do, sometimes I’ll say clinical research and sometimes I’ll say nurse, RN. . . . Because, I am a nurse! I still have my license. I think that defines me better than clinical research” (Nurse H).

Nursing values also appear to be persistent throughout transition, specifically, the importance of maintaining high ethics, compassion, and patient advocacy. Nurse F put it this way:

> Not only was I able to very easily and with experience read difficult patients charts and understand what was going on, I had learned to be disciplined and organized, and was able to prioritize, and do so along with the high sense of ethics and confidentiality from nursing, those all came into play from working in the clinical arena. It’s another broader way to help humanity as a whole. It stems back to my wanting to help people. . . . I’m proud to be a nurse.

These values are echoed in the statements of many other participants as well. For example, “I value the health and welfare of individuals, my contribution to that, my role in that process” (Nurse A), and “When you think about what we do . . . we’re dealing

with human lives and every person is different, and the way people react to medications or interventions is different, so I think that the other side of that scale is the standards and the measures that are put in place to help eliminate risk or try to minimize risk and to ultimately increase the potential benefit . . . it's a nice safety net" (Nurse C). Nurse D eloquently explains the role of values in the following way:

> I do feel like, as many who came from nursing, that the patient is at the heart of what you do, that if we get all the answers right but we compromise the safety or the ethical concerns of a patient, then we didn't do our job well. . . . I think that it's a characteristic that you have, and that as you work with patients as a nurse and you spend your life with them, that it's something that grows and develops.

It should be noted that a small minority of the nurses studied did not report being aligned with their nursing identity. Nurses I and J, as examples, said the following:

> If people ask me what I am, I don't say nurse first, the first thing that comes to mind is monitor, clinical research monitor, which of course nobody knows what that means until you tell them. It's not really a well-known occupation. (Nurse I)

> I don't know if I ever still thought as a nurse, really. I think I thought of my nurse training as being helpful, but I can't say that I ever defined myself as a nurse once I moved to industry. (Nurse J)

One interesting demographic that differentiates these nurses from the others studied is that they both held college degrees and had professional careers in fields other than nursing prior to seeking their BSN. Although not apparent at the time of recruitment, for these two participants, it appears that nursing represents more of a differentiator and door opener in the job market than a core component of their identity. Consider the following statement:

> I said I started out as a Clinical Research Coordinator with a nursing background, which maybe is a little bit different than nursing, than saying 'I am a Clinical Research Nurse'. So I think I, again, I utilize it because it does help open doors, but I'm not sure I identify myself, necessarily, as being a nurse. . . . I think

> nursing definitely opens a lot of doors and I think it has for me. I think that even when I go to apply for jobs now I think the nursing stands out. (Nurse J)

Nevertheless, while not closely self-identified as a nurse, Nurse I voices a sincere appreciation for the contribution her nursing background has made to her success in clinical research:

> The sponsors will often go for somebody with nursing. . . . They know that the nurses will pick up – it may be very subtle things that might be an indication that they're going to have side effects. . . . I wouldn't say so much as what I learned to do as a nurse helped make me successful, as much as just having gone through nursing school. . . . the nursing helped tremendously with the medical and just the process, the logical thinking process.

It is apparent that not everyone defines clinical research as a nursing role, and that not every nurse working in clinical research is tightly bonded to her nursing identity. However, the durability of that identity and values, in spite of what was characterized as a lack of support from nursing peers, nursing schools, and the nursing profession at large was evident in the information shared by most study participants. Nurses participating in this study largely continue to define themselves as nurses both during and long after transition, and their commitment to the ethical and conscientious practice of the nursing profession in clinical research was a common message. In the role of clinical research professional, study participants continued to defined themselves as nurses as their nursing identity broadened to incorporate new dimensions of work in a new career and work environment. In short, nursing became more (Nurse F).

Composite Description of the Transition Experience

Transition from direct patient care to clinical research for the professional nurse can be a lonely experience. Leaving the familiar direct patient care environment for work

in a very different industry separated the nurses studied from prior relationships and previously relied upon support systems. Nurses entering transition relayed stories of being almost completely unfamiliar with the nature of this job, as they were not introduced to this career alternative as part of their nursing education. They were largely unprepared academically, and had little or no exposure to the world of clinical research and the skills required to function in that field. As a result, the initial transition period is described as stressful, scary, and sometimes overwhelming by the majority of nurses participating in this study, and associated with a lack of resources and support required. These elements can serve as key barriers to a successful transition process, and more than one nurse participant described a period of time when she considered going back to the patient care environment as a result.

Most of the nurses in this study came from some of the most technically intense fields of practice in medicine, including critical care, the operating room, the cardiac catheterization lab, and Care Flight, and as a result, were accustomed to having to manage resource-rich dynamic and, in many cases, life or death situations as part of their nursing career. As transition progressed, these nurses reported a growing understanding that they needed to be self-reliant and resourceful, and this was achieved through embracing the challenge and adapting to new ways of working and work environments until they could settle into the new role.

Once settled, a period of exploration, growth and learning ensued, and the nurses reported becoming excited, feeling rewarded, and enjoying the new opportunities they faced. New bridges were built through networking and finding expected or unexpected support from others in industry, and served as key facilitators for their success going

forward. While most nurses acknowledged that transition was a very challenging period, with new skills and opportunities in hand, they were empowered and transformed by the growth that they were experiencing, and successful transition was achieved.

Working as a nurse in the field of clinical research came at a certain cost to many nurses participating in the study. Being told that they were not a 'real nurse' by former colleagues in nursing and feeling alienated by the nursing profession as they sought but found no support there, was a palpable source of distress for many. Nevertheless, the nurses reported feeling very good about being a nurse, feeling that their new role and skills had broadened their ability to have an impact as a nurse, and nursing identity remained strong throughout and following transition.

Chapter Summary

This chapter has summarized the findings of a phenomenological study of nurses in transition from direct patient care to careers in clinical research. Through an iterative interview process engaged in with ten professional registered nurses, both the nature and process of the transition experience were explored, and supports, barriers, and key facilitators identified. Profiles for each participant were presented highlighting key descriptions of how the transition from direct patient care to industry was experienced, and including the most important comments made regarding transition nature, process, supports and barriers. How nursing identity was experienced throughout transition was also highlighted in these profiles.

Seven key themes characterizing the transition process were identified. Each was presented in a somewhat longitudinal temporal fashion, including: 1) I am alone, 2) I am unprepared, 3) I am scared and sometimes overwhelmed, 4) I can do it, 5) I need to build

new bridges, 6) I am becoming, and 7) I am still a nurse. Feelings of being alone and unprepared, feeling insecure or scared, the need to build bridges and network, and the belief that in spite of transitioning away from patient care, I am still a nurse were the most universally shared experiences among study participants. The theme of 'I can do it, addressing self-reliance and resourcefulness, was less often discussed, but played a critical role in embracing the challenge for many study participants.

Overall, transition from patient care to clinical research was characterized as a journey that appears to progress in stages, beginning with a period of loneliness and unpreparedness, followed by a period of realization that the source of success lies in self, an active period of building networks and assembling resources, and culminating in a time of discovery, empowerment, and stabilization.

The final chapter addresses study conclusions, contributions to theory, and implications for future research. It also provides recommendations for practice associated with these findings.

CHAPTER 5:

CONCLUSIONS, CONTRIBUTIONS, IMPLICATIONS, AND RECOMMENDATIONS

This research was undertaken to shine light on the unstudied transition experience of professional nurses who left direct patient care for industry-based careers in the field of clinical research. Chapter five addresses the conclusions from the study, identifying potential contributions to theory and suggested implications for practice. Proposals and recommendations for future research are also provided.

Conclusions

The transition from direct patient care to a career in clinical research is a complex journey for the professional nurse. The following conclusions are drawn from the study findings:

Conclusion 1: Nature of the Transition Experience

> *The transition from direct patient care to a career in clinical research is an abrupt, socially and professionally isolating experience in which fear must give way to self-reliance and determination, requiring significant cognitive and behavioral adaptation for the professional nurse to effect engagement and mastery of the new role.*

Transition from direct patient care to a career in clinical research begins as an isolating and frightening experience for the professional nurse. Feelings of self-doubt and an overall lack of preparedness are common in the early transition period. As time in the new role progresses, however, a growing realization that the source of success lies in self

evolves, allowing fear to give way to intentional action, and a purposeful sense of self-reliance, empowerment, and growth. This is reflective of Nicholson's (2013) destiny, drama, and deliberation paradigm. As the nurses studied took the reins in their transition experience, destiny was both "found and transcended" (P. 198) and deliberate action was required to make transition successful.

Conclusion 2: The Process of Transition

> *Transition from direct patient care to clinical research is an adaptive process that begins with a precipitous event, progresses along a unidirectional path, and presents in three psychological stages: embracing the challenge, adapting to change, and settling in.*

Transition from bedside care to clinical research begins with little warning or preparation for the professional nurse, and is experienced as a linear, staged process. Progression from one stage to the next requires intentional actions to meet new cognitive and behavioral expectations and demands, with transition success predicated upon movement through all three. Nicholson's prediction that transition would begin in the psychological stage of preparation and that stages would be recursive is not, therefore, evident in these data.

Conclusion 3: Barriers

> *Barriers encountered during the transition from direct patient care to clinical research fall into three primary categories: cognitive, psychological/emotional, and relational.*

Nurses transitioning from bedside care to a career in clinical research consistently report being cognitively and educationally unprepared, experiencing initial feelings of fear and insecurity, and lacking needed support from nursing peers, educators, and the nursing profession. As predicted by Ashforth (2001), the cognitive and affective dimensions of role identification can function as potential barriers to success. Ashforth also maintained, however, that the need for social validation would be so strong as to function as a significant barrier to transition if it was not met. These data clearly demonstrate that there was little or no social validation available to study participants through parts of their transition experience, yet all made the transit successfully.

Conclusion 4: Supports

> *Supports encountered during the transition process lie in the ability to self-teach and identify learning resources, to be self-reliant and work independently, to build and utilize necessary networks, and to recognize and engage with mentors and personal champions.*

Cognitive supports identified in the study included the ability of study participants to self-teach and to actively incorporate new skills and knowledge, and behavioral supports identified included the ability to locate and obtain knowledge and educational resources with little or no support from others, and to purposefully engage in network building and finding mentors. This is consistent with Ashforth's (2001) prediction that cognitive and behavioral factors play an important role in adaptation throughout transition.

Conclusion 5: Facilitators

Facilitators of successful work-role transition lie primarily with the self and one's ability to form and nourish relationships with others.

Traits and behaviors such as self-reliance, positivity, feelings of empowerment, and active seeking of knowledge and development opportunities were identified as key factors in transition success. In addition, the ability to socially engage with others to form meaningful and positive mentoring and networking relationships was discussed as a highly valued and essential asset by all nurses participating in the study. Both Ashforth (2001) and Nicholson (1984) proposed that psychological support and resources would be essential to transition success, and the ability to develop and nourish relationships with others provided both to study participants.

Conclusion 6: Work Role Identity

The transition from bedside care to clinical research has little impact on core nursing identity as the professional nurse reframes the work of the clinical research and industry-based professional to fit within her definition of nursing practice.

In spite of pressure to do otherwise, the nurses studied largely reported holding steadfastly to their nursing identity throughout the transition process, cognitively reframing the work of the clinical research professional as an extension of their nursing practice instead of assuming the identity of a clinical research professional outside of nursing. This finding was not consistent with Ashforth's (2001) contention that identity and one's sense of self would be "largely grounded in the perceptions of others" (p. 215).

Instead, the nursing identity was reframed as an internal, self-directed activity, and the self-efficacy required to successfully transition remained intact.

Summary of Conclusions

Overall, transition from patient care to clinical research was characterized as an unexpected and challenging journey that appears to progress in stages, beginning with a period of loneliness and unpreparedness, followed by a period of realization that the source of success lies in self, an active period of building networks and assembling resources, and culminating in a time of discovery, empowerment, and stabilization

Based on these conclusions, the original conceptual frame for this study, shown in Figure 5.1, is revised to that shown in Figure 5.2. The major changes are a truncated, yet still linear work role transition process that is missing the Nicholson (1984) predicted preparation phase, and the reframing of the pre-transition identity versus a socially mediated evolution of role identification. These modifications are further detailed in the discussion of contributions to theory below.

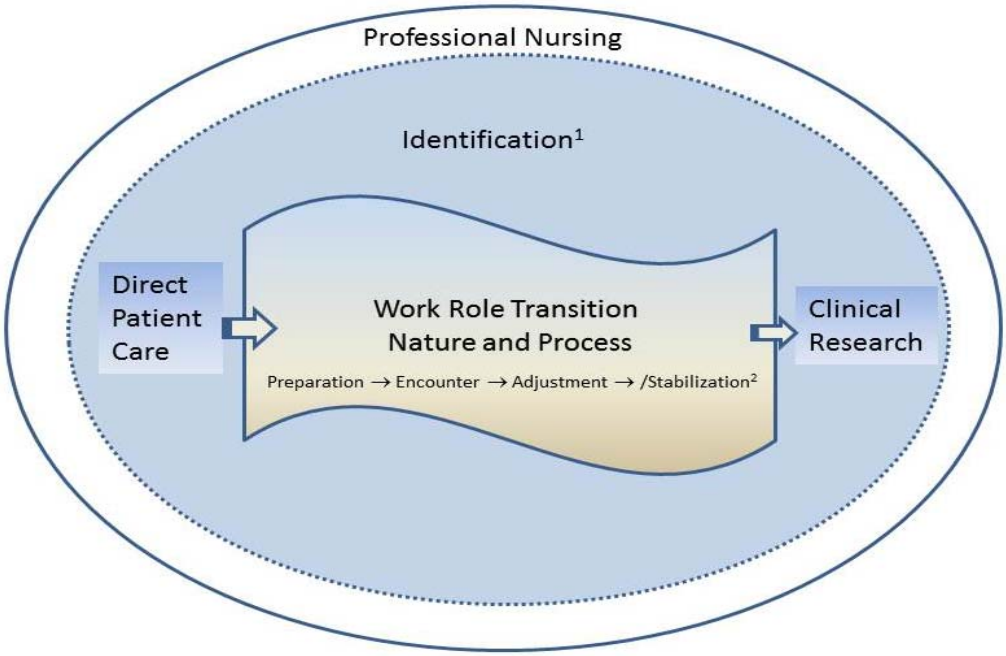

Figure 5.1. Original conceptual framework (Ashforth, 2001[1]; Nicholson, 1984, 2013[2]).

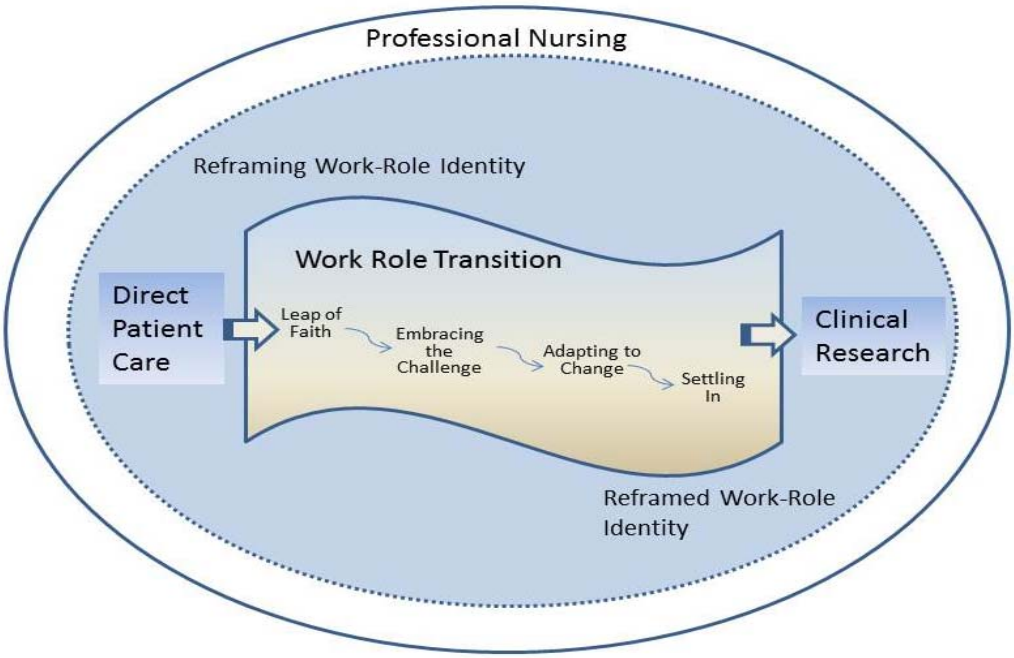

Figure 5.2. Remodeled conceptual framework.

Contributions, Implications, and Recommendations

This section outlines several insights with associated potential contributions to theory and implications for practice in the study of work-role transition for nurses transitioning from direct patient care to a clinical research career in the biopharmaceutical and medical device industry. Recognizing the limitations inherent imposed by both the literature selected and the scope of this study, additional recommendations for future research are also presented.

Contributions to Theory

As proposed in Chapter 1, Ashforth's (2001) ABC (affective, behavioral and cognitive) transition model and Nicholson's (1984, 2013) work role transition theory lenses were applied in analyzing data for this research. These lenses were selected due to their ability to reflect the personal nature of the transition experience and for their conceptualization of transition as a process. Overall, the lenses were extremely well matched to the types of stories and experiences shared by study participants, and as such, invaluable tools in gaining an understanding of the nature and process of a major work-role transition from direct patient care nursing to clinical research. There were, however, a number of ways in which research data varied from patterns predicted in the conceptual framework, as discussed below.

Ashforth's (2001) ABCs of Role Identification Theory. 1) Ashforth's ABCs of Role Identification Theory provides an effective lens for examining work-role transition in a professional nursing population, but his assumption that collective identity and social validation are central to role transition is not consistent with the findings of this study; 2) high magnitude, macro transitions do stress role boundaries, but may have less impact on

work-role identity in individuals for whom professional and personal identity are closely interwoven; 3) transition from bedside care to clinical research is a socially and psychologically mediated process in the professional nursing population, and 4) while physical and temporal role boundaries may exist, only cognitive, emotional, and relational boundaries have a significant impact on the transition experience when role entry is unanticipated and the population studied has no awareness or knowledge about the field into which they have entered.

1. *Ashforth's (2001) ABCs of Role Identification Theory provides an effective lens for examining work-role transition in a professional nursing population, but his assumption that collective identity and social validation are central to role transition is not consistent with the findings of this study.*

Ashforth, Harrison, and Corley (2008) contend that the ability to fully identify with and engage in a new role is linked not only to the core organization for which one works, but to the teams and networks in which one is engaged. As noted, the findings of this study do indicate that networking and social support are important factors in transition success. Ashforth's proposal, however, further suggests that social validation is a central factor in identification with the new role, while data for this study indicate that for the professional nurse transitioning to industry, work role and functions are internally and individually reframed to fit with the existing identity instead of the identity evolving through social validation to fit the new role. This is consistent with Shannon's (2011) finding that nurses working in the biopharmaceutical or medical device industry strove to recraft their professional identity to maintain the perception of self and others that they

were a nurse; hence transition success occurred without the need for social validation as proposed.

2. *High magnitude, macro transitions do stress role boundaries, but may not impact work-role identity in individuals for whom professional and personal identity are closely interwoven.*

Ashforth's (2001) suggestion that role boundaries (physical, temporal, cognitive, emotional, and relational) are significantly stressed by high magnitude, macro transitions and that this stress in turn would have a significant impact on identity was partially supported by this study. Whereas this high magnitude transition was consistently reported to be stressful, the primary sources of stress discussed by study participants were in the cognitive (lack of knowledge) and emotional (loneliness and insecurity) realms, and to a lesser degree with physical boundaries imposed by struggle with travel and maintaining work-life balance. Similarly, when examining the impact of role boundary stress upon identity, while participants consistently reported that their identity as a nurse was challenged, this challenge came largely from the relational aspect of their role boundaries, and had only a limited relationship to their new physical environment or their cognitive or emotional perception of themselves as a nurse.

Sluss and Ashforth's (2007) propose that identity is experienced on three different levels (personal, interpersonal, and collective) with some more salient than others, and that the identity most tenacious and resistant to disconfirmation is the personal identity. Currie et al. (2010) also conceptualize identity as a product of a socialization process, but conclude while collective level identity is central to the prospects for successful role transition, self-identity may transcend the collective role-based identity. Nurses studied in

this research project exhibited a high level of saliency in their identification as a professional nurse, actively resisting any attempts at disconfirmation from others, and insisting that in their new role, they were still a nurse. Consistent with this, in the only study identified that researched a nursing population that had transitioned to industry, Shannon (2011) concluded that each nurse's perception of their professional role after working in industry had been re-crafted through reframing and adaptation to preserve the core values they held for their nursing identity, indicating that professional identity was so tightly tied to personal identity as to be almost indistinguishable.

3. *Transition from bedside care to clinical research is a socially and psychologically mediated process for the professional nurse.*

Factors influencing transition success, such as emotional positivity, self and other empowerment, and the ability to form relationships and networks were key facilitators of transition success in this study. This finding is consistent with Ashforth's (2001) conceptualization of transition as a socially and psychologically mediated process, and Nicholson's (1984, 2013) contention that transition is both impacted and mediated by the cognitive and emotional nature of the individual.

4. *While physical and temporal role boundaries may exist, only cognitive, emotional, and relational boundaries have a significant impact on the transition experience when role entry is unanticipated and the population studied has no awareness or knowledge about the field into which they have entered.*

Ashforth (2001) defines a role boundary as something that marks the perimeter of a particular role and may thus serve as a key barrier or facilitator to successful transition. While Ashforth suggests that there are five types of role boundaries (physical, temporal,

cognitive, emotional, and relational), only the cognitive, emotional (including psychological), and relational boundaries appeared to be impactful in the data collected for this study. Without knowledge that a field of practice exists, cognizance of any physical or temporal barriers to transition in that field would be unlikely, and as such, may not apply to this particular study population.

The primary cognitive barrier described and discussed by every nurse participating in the study was a gap in knowledge and experience related to the practice of clinical research in the biopharmaceutical and medical device industry. This was consistent with previous findings of Redman et al. (2006), and was attributed to a failure of nursing educational programs to include this information in core curriculum, and of nursing specialization boards to recognize clinical research as a potential career field for nurses. Emotional and psychological barriers identified in this study included self-doubt, self-limiting thinking, and fear, and the primary relational barrier reported was a lack of support from fellow nurses, consistent with the findings of Mueller and Mamo (2002) and others that nurses working in industry are outside of the normal nursing education and social support framework, therefore receiving little of the basic education and professional support required to prepare them for a successful transition to this employment setting (Mueller, 2001; Raja-Jones, 2002; Redman et al., 2006).

Cognitive supports identified in the study included the ability of study participants to self-teach and to actively seek new skills and knowledge. This is consistent with Abbott's (1998) contention that education and specialty training are key steps in preparing and differentiating oneself as a professional, and with Mueller and Mamo's (2002) observation that education and training specific to the CRA role are necessary to

successful execution of that role. Supportive emotional characteristics, in the form of the ability to overcome the reluctance to work alone and to rely upon oneself were also frequently noted in participants' descriptions of experiences that helped to make them successful, and consistent with Ashforth's (2001) proposal that successful transition requires adjustments of the self.

One of the most commonly discussed facilitators and supports for transition was related to the concept of relational boundaries. For nurses studied, the ability to identify and form bonds with social resources and to build networks and mentoring relationships was identified as one of the most important factors in ensuring a successful transition to clinical research. This finding is consistent with Price's (2009) conclusion that the availability of role models and mentors plays an important part in defining clear role expectations, and with Heppner et al.'s (1994) contention that self-efficacy and the belief that transition is in one's control were key psychosocial constructs in transition success. It is also highly reflective of an underlying tenant of both Ashforth's (2001) and Nicholson's (1984) theories that role transitions are socially enacted and enabled.

Nicholson's (1984, 2013) Work-Role Transition Theory. 1) All three of Nicholson's (2013) dimensions of response influencing transition (destiny, drama, and deliberation) were evident in the data collected for this study with the prominent dimension varying based upon transition stage, 2) Nicholson (1984, 2013) described the transition process as regularly occurring, recursive, and continuous, but for the professional nurse, a transition to the world of clinical research was consistent with none of these descriptions, 3) The four psychological stages of the transition process

(preparation, encounter, adjustment, and stabilization) described by Nicholson (1984), were only partially supported by this study.

1. *All three of Nicholson's (2013) dimensions of response influencing transition (destiny, drama, and deliberation) were evident in the data collected for this study with the prominent dimension varying based upon transition stage.*

Nicholson's (2013) proposal that transition is perceived and experienced along three dimensions of influence (destiny, drama, and deliberation) was fully supported by the stories collected from participants in this study. A key point of divergence in this study, however, from Nicholson's description of destiny, drama, and deliberation is his suggestion that individuals respond to transition in one of the three ways described. The nurses participating in this study responded in all of the three ways described, pairing different response modes to different stages in the transition process. For example, the third theme of the study, I am scared and sometimes overwhelmed, speaks to the importance placed upon security, structure and balance, features associated with events and parameters external to oneself. This is consistent with the concept of destiny in which individuals experience transition as something occurring outside of self and therefore out of one's control.

Nicholson's (2013) dimension of drama is also apparent in data collected, as he proposes that high levels of drama (transitions that are culturally unscheduled and unpredictable) may be seen as threatening to adjustment and emotionally overwhelming. Drama, however, did not dominate throughout transition, for in spite of these initial feelings, the nurses in this study moved fairly quickly from this to a period of reflection and a deliberate decision to become self-reliant as a means to secure transition success.

Nicholson describes deliberation as proactively "seiz(ing) the moments" (p. 197) and consciously choosing to seek opportunities and make adjustments to manage through the encounter, a description well fit to themes four (I can do it), five (I need to build new bridges), and six (I am becoming) of this study, as it reflects the same types of intentional affective and cognitive adaptations described by study participants.

2. *Nicholson (1984, 2013) described the transition process as regularly occurring, recursive, and continuous, but for the professional nurse, a transition to the world of clinical research was consistent with none of these descriptions.*

Almost uniformly, nurses participating in this study describe their first encounter with the field of clinical research as an unexpected occurrence for which they were unprepared and about which they knew essentially nothing, suggesting that there was nothing 'regular' about this particular transition experience. Nicholson's (1984, 2013) assumption that transition requires adjustment of the self is consistent with study findings, in that all nurses relayed stories of many personal adaptations they had to make to be successful in their new work environment and role, but his second assumption that transition is recursive and cyclical is not consistent with the experiences reported by nurses in this study. Instead, the transition process from bedside care to clinical research almost universally began with what was described as a "leap of faith," an unprepared for jump into an unknown field, followed by a step-wise progression from realization that one is alone and unprepared, to becoming frightened and overwhelmed, to a commitment to self-reliance, culminating in a series of intentional acts designed to secure the necessary education and support to ensure transition success.

Nicholson's (1984, 2013) third assumption that transition is continuous was difficult to evaluate in this study. While the longevity of engagement in their research careers for most nurses in this study would suggest that there may have been many different transitions since entering industry, because the focus of the interviews with study participants was on the initial transition experience from bedside care to research, the question of whether transition beyond this period was experienced as continuous or episodic was not explored.

3. *The four psychological stages of the transition process (preparation, encounter, adjustment, and stabilization) described by Nicholson (1984), were only partially supported by this study.*

Because neither nurse educators, nor the profession at large expose the professional nurse to clinical research as a potential career alternative, and none of the nurses studied anticipated their first move from the direct patient care to careers in the clinical research arena, the stage of preparation was entirely absent for the nurses participating in this study. Instead, the first stage of transition for these professional nurses began with a bold leap into the unknown, followed by a period of significant isolation and insecurity until an active decision to engage was made. For this reason, the stages of transition in this study are described as embracing the challenge, adapting to change, and settling in. Stage 1, embracing the challenge is similar to Nicholson's (1984) encounter stage, but moves beyond the sense-making activities described by Nicholson into a period of intentionality and action on the part of the nurse in transition. Stage 2, adapting to change, reflects the adjustments involved in finding one's way in the new role consistent with Nicholas's third stage, however, his contention that early success and

swift performance feedback are important to adjustment was not evident in the data collected. Study participants, for example, lamented the difficulty in obtaining feedback on performance, especially when working in isolation, yet all transitioned successfully. Finally, the fourth stage in Nicholson's theory, stabilization, aligns well with what this researcher describes as 'settling in.' In this stage, the drama of the transition has been endured, and the new role has been assumed.

Overall, Nicholson's contention that the four stages of transition are interdependent, iterative, and recursive does not appear to fully fit with the stories shared by participants on this study. While all nurses interviewed were successful in their transition and thus, completed the cycle, the order of the stages of transition was highly consistent across all participants. Each stage did appear to build upon the previous one, suggesting that some level of interdependence may have been in play, but stages were neither iterative nor recursive, suggesting that transition may not have been successful had the stages repeated or occurred in an order different from the one experienced.

In summary, the nature and process of work role transition from direct patient care to clinical research for the professional nurse

Implications for Practice

This study delves into the previously unexplored nature and process of the transition experience for the professional nurse leaving direct patient care for a career in the clinical research industry. The National Sample Survey of Registered Nurses (NSSRN) (U.S. Department of Health and Human Survey Services, 2010) estimated that approximately 10,000 currently licensed RNs were working in the biopharmaceutical and medical device industry, suggesting that conclusions from this study may have value to

nursing educators, nursing professional and credentialing organizations, and professional nurses considering a transition to a career in industry. Findings from this study suggest the following: (1) Core baccalaureate nursing curriculum should include an introduction to clinical research ethics and practices in the biopharmaceutical and medical device industry. This introduction should make it clear that this is a viable and recognized career path for the professional nurse; (2) Nursing professional and credentialing organizations should embrace the professional nurse working in the biopharmaceutical and medical device industry through the support and development of a recognized Clinical Research Nurse specialization process and certification; and (3) Professional nurses considering a transition to a career in clinical research should prepare themselves educationally and professionally through active engagement with organizations that target clinical research professionals and offer the necessary specialty education and networking opportunities required for transition success.

1. *Core baccalaureate nursing curriculum should include an introduction to clinical research ethics and practices in the biopharmaceutical and medical device industry. This introduction should make it clear that this is a viable and recognized career path for the professional nurse.*

Participants in this study noted that when they entered the field of clinical research they were both academically and socially unprepared to engage effectively. This is consistent with Redman et al.'s (2006) observation that nurses in clinical research were often scientifically, socially, and personally unprepared to meet the demands of this role, thus placing patients and the research process at risk. At the same time, the synergies between the skills and core values of nursing and clinical research were remarked upon

by every nurse participating in this study, indicating that part of what they lacked was basic clinical research curriculum in their education and recognition by schools of nursing that clinical research is a field in which professional nurses often engage, and can be experienced as an extension of nursing practice.

To explore the types of coursework or topics that schools of nursing should consider offering as part of baccalaureate curriculum, the Association of Clinical Research Professionals (ACRP) certification website was accessed (ACRP, n.d.-b). ACRP is an industry-based professional association that has been serving the clinical research community since 1976, and has offered an accredited certification for Clinical Research Associates for two decades. Key clinical research topics the ACRP certification exam targets are investigational product management and development, clinical research protocol development (including research integrity, design, and statistical analysis), the assessment and management of adverse events, clinical trial management and oversight (including research roles, interfacing with IRBs and Ethics Committees, informed consent management, and collection and recording of clinical trial data), and research ethics and the protection of human subjects.

2. *Nursing professional and credentialing organizations should embrace the professional nurse working in the biopharmaceutical and medical device industry through the support and development of a recognized Clinical Research Nurse specialization process and certification.*

As noted, study participants largely continue to consider themselves professional nurses and define the clinical research activities they engage in as nursing practice long after transition to industry. They report utilizing skills and knowledge they obtained in

nursing school and practice in their current work environment, but acknowledge that additional knowledge and education are required to meet the requirements of this specialized field. Following Peplau's (2003) logic that the characteristics of a nurse specialist include a broad undergraduate nursing education, strong theoretical base, a thorough knowledge of the specialty area of focus, and the ability to collect and communicate data and function independently, research participants' suggestion that clinical research should be a nursing specialty makes sense, and there is precedence for this. While many currently recognized and certified nursing specialties have a direct patient care focus, there are others that do not. For example, the American Association of Legal Nursing Consultants (AALNC) offers a nursing specialty certification for nurses who work with attorneys to interpret and analyze patient medical records, an activity quite similar to a common function of the Clinical Research Associate (Mueller, 2001; Spilker, 1991). The American Board of Nursing Specialties (2015), sister accreditation provider to the AALNC, maintains that the nursing credentialing and certification boards set and ensure practice standards and the certification process serves to validate the capabilities of nurses to meet those standards, thus improving patient care and overall health outcomes. Because the professional nurse working in the biopharmaceutical and medical device research arena goes largely unacknowledged by the nursing profession at present (Mueller & Mamo, 2002), the nursing specialty and credentialing organizations have no viable means to examine, establish, or measure standards of practice for nurses working in this industry, and therefore, have no current ability to exercise the positive impact to the patient and public that specialty certification brings.

3. *Professional nurses considering a transition to a career in clinical research should prepare themselves educationally and professionally through active engagement with organizations that target clinical research professionals and offer the necessary specialty education and networking opportunities required for transition success.*

The nurse transitioning from direct patient care to clinical research is fundamentally unprepared academically to engage conscientiously with this field of practice (Raja-Jones, 2002; Redman et al., 2006). Participants on this study provided numerous statements regarding how little they knew about clinical research roles and practice standards, how unfamiliar they were with the industry and regulations, and how unprepared they were for the more rigorous scientific information and data they were expected to navigate. As a result, a key implication for practice is that any nurse considering a similar transition from direct patient care to industry should prepare through joining and availing themselves of the educational resources provided by professional associations and other organizations focused on the clinical research enterprise. In addition, to facilitate success in the transition process, active engagement with peers already working in the biopharmaceutical and medical device industry to begin building networks and professional relationships should be sought. The social and professional isolation detailed by study participants is a common experience for nurses entering research roles in industry, and the critical impact of networks and mentors on the interplay between social support and transition success has been noted by several other researchers (Redman et al., 2006; Reynolds, 2004). In addition, reflecting upon how frequently study participants commented upon how uninformed and unprepared they

were when they entered the role of clinical research professional, it becomes clear that a lack of educational and social preparation is common, distressing, and may place the integrity of research practice and the patient involved in clinical trials at risk (Redman et al., 2006; Reynolds, 2004).

Recommendations for Research

The nature and process of transition for the professional nurse leaving direct patient care for a role in the biopharmaceutical and medical device industry was essentially unstudied prior to this research. In light of the relatively large number of nurses who have made this transition and how little is known about this group of individuals, findings and conclusions of this study indicate the following possibilities for future research should be considered: (1) a focused exploration of the role identification process for the nurse in this transition experience; (2) the development of an assessment tool designed to measure potential for transition success; (3) assessment of the impact of providing a pre-transition education and training seminar on biopharmaceutical and medical device development, emphasizing good clinical research practices, standards, and regulations; (4) the conduct of a similar study utilizing an organizational culture lens; and (5) the conduct of a similar study in a group of participants from nursing specialties other than critical care, the operating room, the emergency room and other high intensity areas of patient care.

1. A focused exploration of the role identification process for the nurse in this transition experience. Ashforth (2001) predicted a negative impact from a lack of social validation on identification. This did not occur with participants in this study, as their nursing identity largely remained intact in spite of rejection by nursing peers and being

surrounded by new peers who did not recognize them as nurses. As a result, further study is needed to understand the underlying forces in the role identification process for this study population.

2. The development of an assessment tool designed to measure potential for transition success. In examining the themes, findings suggest there may be value in the development and validation of an assessment tool designed to measure comfort with being alone, resiliency, self-reliance and self-efficacy, speed and accuracy of knowledge transfer, emotional and social intelligence, and self-confidence as possible factors in predicting transition success.

3. Assessment of the impact of providing a pre-transition education and training seminar on biopharmaceutical and medical device development, emphasizing good clinical research practices, standards, and regulations. Multiple researchers noted basic unpreparedness and a lack of education and knowledge regarding clinical research standards and practices to be a significant concern (Raja-Jones, 2002; Redman et al., 2006; Reynolds, 2004; Spilker, 1991). This concern is consistent with study findings and indicates that an opportunity exists to generate insight on the impact of providing pre-transition specialty education on the transition experience.

4. The conduct of a similar study utilizing an organizational culture lens. Markus and Kitayama (1991) maintain that the self-system or self-schemata core to identity development and the identification process are socially constructed and a reflection of culture, and Geertz (1973) proposes that cultures generate a socially constructed meaning for experiences. In addition, in defining a professional, Zerwekh and Claborn (1997) specify that a professional identifies with a specific subculture as part of

their profession and the organizations within which they develop. While there was some evidence in this study that nursing and industry culture may have played a role in the transition experience, this was not examined, creating an opportunity for further study and a broader understanding of the nurse in transition.

5. The conduct of a similar study in a group of participants from nursing specialties other than critical care, the operating room, the emergency room and other high intensity areas of patient care. A large majority of nurses participating in this study came from technically intense nursing practice specialties such as the operating room and intensive care. This was not intentional, and should be acknowledged as a potential influencing factor on study data. As a result, additional research should be conducted with specific intent to draw participants from nursing specialties other than those with high technical intensity.

Reflections on the Research Study

As a professional nurse who made a similar transition to industry almost 25 years ago, I approached this study with a keen awareness that my experiences had the potential to color my impressions and bias my interactions with study participants. In fact, however, because I worked for a number of years in a non-nursing profession between my time in patient care and my transition to industry, I discovered that my transition journey differed in a number of significant ways from those of most study participants, allowing me to more easily manage this concern and become a rapt listener and learner in the research process. Identifying and enrolling study participants was much easier than I expected as almost every nurse I approached eagerly agreed to join the study. Scheduling and conducting the interviews was a challenge, however, due to the demanding work-

related travel schedules of most participants. This prevented me from adhering to the neat interview timetable I desired, but allowed for some creative location solutions such as airline lounges and long limo rides. I found it a little difficult to focus the first couple of interviews on getting the data I needed to answer the research questions, but a suggestion by my advisor to encourage storytelling and visualization made the process not only flow better, but a lot of fun.

In analyzing the data, I learned a great deal about my own way of processing information. I found that I couldn't simply sit down to write. I had to read and re-read the transcripts, allowing the information to flow through me until patterns formed. It was a slow and sometimes frustrating process, but once I saw the patterns, Chapter 4 wrote itself. This research process has allowed me to test and challenge many of the assumptions and beliefs I have about nurses working in industry, and provided me with a new resolve to find a way to bring the incredible work they do to the attention of a profession they love and desire to be recognized by.

REFERENCES

Abbott, A. (1998). *The system of professions—a study of the division of expert labour.* Chicago, IL: University of Chicago Press.

AFL-CIO. (2012). *Nursing: A profile of the profession* [DPE Fact Sheet]. Retrieved from http://dpeaflcio.org/programs-publications/issue-fact-sheets/nursing-a-profile-of-the-profession/

Aiken, L. H., & Sloane, D. M. (1997). Effects of specialization and client differentiation on the status of nurses. *Journal of Health and Social Behavior, 38*(3), 203-222.

American Association of Critical Care Nurses. (2014). *Interdisciplinary education and practice*. Retrieved from http://www.aacn.nche.edu/publications/interdisciplinary-education-and-practice

American Board of Nursing Specialties. (2015). *Approved Certification Programs.* Retrieved February 11, 2015, from http://www.nursingcertification.org/accreditation/approved-certification-programs/

American Board of Nursing Specialties. (2015). *A position statement on the value of specialty nursing certification.* Retrieved from http://cpancapa.org/pdf/value_certification.pdf

American Nurses Credentialing Center. (2015). *Advanced forensic nursing.* Retrieved from http://www.nursecredentialing.org/NurseSpecialties/ForensicNurseAdv.aspx

AMN Healthcare. (2010). *2010 survey of registered nurses: Job satisfaction and career plans.* Retrieved from http://www.amnhealthcare.com/industry-research/552/1033/

Anderson, J. K. (2009). The work-role transition of expert clinician to novice academic educator. *Journal of Nursing Education, 48*(4), 203-208.

Apker, J., Ford, W. S. Z., & Fox, D. H. (2003). Predicting nurses' organizational and professional identification: The effect of nursing roles, professional autonomy, and supportive communication. *Nursing Economic$, 21*(5), 226-232.

Arthur, M. B., & Rousseau, D. M. (1996). Introduction: The boundaryless career as a new employment principle. In M. B. Rousseau & D. M. Rousseau (Eds.), *The boundaryless career: A new employment principle for a new organizational era* (pp. 3-8). New York, NY: Oxford University Press.

Ashforth, B. E. (2001). *Role transitions in organizational life: An identity-based perspective*. Mahwah, NJ: Lawrence Erlbaum Associates.

Ashforth, B. E., Harrison, S. H., & Corley, K. G. (2008). Identification in organizations: An examination of four fundamental questions. *Journal of Management, 34*(3), 325-374.

Ashforth, B. E., & Humphrey, R. H. (1995). Labeling processes in the organization: Constructing the individual. In L. L. Cummings & B. M. Staw (Eds.), *Research in organizational behavior* (Vol. 7, pp. 263-295). Greenwich, CT: JAI Press.

Ashforth, B. E., Joshi, M., Anand, V., & O-Leary-Kelly, A. M. (2013). Extending the expanded model of organizational identification to occupations. *Journal of Applied Social Psychology, 43*, 2426-2448.

Ashforth, B. E., & Kreiner, G. E. (1999). "How can you do it?": Dirty work and the challenge of constructing positive identity. *Academy of Management Review, 24*, 413-434.

Ashforth, B. E., Kreiner, G. E., & Fugate, M. (2000). All in a day's work: Boundaries and micro role transitions. *Academy of Management Review, 25*(3), 472-491.

Ashforth, B. E., & Mael, F. (1989). Social identity theory and the organization. *Academy of Management Review, 14*(1), 20-39.

Ashforth, B. E., Rogers, K. M., & Corley, K. G. (2010). Identity in organizations: exploring cross-level dynamics. *Organization Science, 22*(5), 1144-1156.

Ashforth, B. E., & Saks, A. M. (1995). Work-role transitions: A longitudinal examination of the Nicholson model. *Journal of Occupational and Organizational Psychology, 68*, 157-175.

Association of American Medical Colleges. (2008). *Clinical research training programs*. Retrieved from http://www.aamc.org/research/clinicalresearch/training/start.htm

Association of Clinical Research Professionals. (n.d.-a). *Certification*. Retrieved from http://www.acrpnet.org/MainMenuCategory/Certification.aspx

Association of Clinical Research Professionals. (n.d.-b). *CRA certification*. Retrieved from http://www.acrpnet.org/MainMenuCategory/Certification/CRACertification.aspx

Athens, L. H. (1995). Dramatic self change. *Sociological Quarterly, 36*(3), 571-586.

Bamford, O., & Gibson, F. (1999). The clinical nurse specialist role: Development activities that facilitate role evolution. *Advancing Clinical Nursing, 3,* 143-151.

Bandura, A. (1986). *Social foundations of thought and action: A cognitive theory*. Englewood Cliffs, NJ: Prentice-Hall.

Bandura, A. (1997). *Self-efficacy: The exercise of control* (First ed.). New York, NY: W. H. Freeman.

Barton, T. D. (2007). Student nurse practitioners: A rite of passage? The universality of van Gennep's model of social transition. *Nurse Education in Practice, 7,* 338-347.

Baumeister, R. F., & Leary, M. R. (1995). The need to belong: Desire for interpersonal attachments as a fundamental human motivation. *Psychological Bulletin, 117,* 497-529.

Berger, P. L., & Luckmann, T. (1966). *The social construction of reality.* Harmondsworth, UK: Penguin.

Biddle, B. (1979). *Role theory: Expectations, identities, and behaviors*. New York, NY: Academic.

Biemel, W. (1970). The decision phases in the development of Husserl's philosophy (R. O. Elverton, Trans). In R.O. Elverton (Ed.), *The phenomenology of Husserl* (pp. 148-174). Chicago, IL: Quadrangle.

Black, J. S. (1988). Work role transitions: A study of American expatriate managers in Japan. *Journal of International Business Studies, 19,* 277-294.

Bramstedt, K. A. (2004). A study of warning letters issued to clinical investigators by the United States Food and Drug Administration. *Clinical Investigation Medicine, 27*(3), 129-134.

Brewer, M. B. (1991). The social self: On being the same and different at the same time. *Personality and Social Psychology Bulletin, 17,* 475-482.

Brown, S. (1998). A framework for advanced practice nursing. *Journal of Professional Nursing, 14*(3), 157-164.

Bryant-Lukosius, D., DiCenso, A., Browne, G., & Pinelli, J. (2004). Advanced practice nursing roles: Development, implementation and evaluation. *Journal of Advanced Nursing, 48*(5), 519-529.

Buerhaus, P. I., Donelan, K., Ulrich, B. T., Norman, L., & Dittus, R. (2006). State of the registered nurse workforce in the United States. *Nursing Economic$, 24*(1), 6-12.

Bullough, B. (1976). The law and the expanding nursing role. *American Journal of Public Health, 66*(3), 249-254.

Canadian Nurses Association. (2000). *Advanced Nursing Practice. A National Framework*. Ottowa, Ontario, CA: Author.

Carlson, H. C. (1983). A model of quality of worklife as a developmental process. *Education and Training, 25*(1), 27-32.

Casey, K., Fink, R., Krugman, M., & Propst, J. (2004). The graduate nurse experience. *Journal of Nursing Administration, 34*(6), 303-311.

Castro, K., Bevans, M., Miller-Davis, C., Cusack, G., Loscalzo, F., Matlock, A. M., . . . Hastings, C. (2011). Validating the clinical research nurse domain of practice. *Oncology Nursing Forum, 38*(2), E72-E80.

Chadwick, L. R. (1992). Professional nursing with a new focus: Staff nurse to research coordinator. *Journal of Neuroscience Nursing, 24*(3), 170-172.

Chen, C., Yen, C., & Tsai, F. (2014). Job crafting and job engagement: The mediating role of person-job fit. *International Journal of Hospitality Management, 37*, 21-28.

Clore, G. L., & Ortony, A. (2000). Cognition in emotion: Always, sometimes, or never. In R. D. Lane & L. Nadel (Eds.), *Cognitive neuroscience of emotion* (pp. 24-61). New York, NY: Oxford University Press.

Cohen, H. A. (1981). *The nurse's quest for a professional identity*. Menlo Park, CA: Addison-Wesley.

Corbin, J., & Strauss, A. (2008). *Basics in qualitative research* (3rd ed.). Thousand Oaks, CA: Sage.

Corwin, R. G. (1961). Role conception and career aspiration: A study of identity in nursing. *Sociological Quarterly, 2*(2), 69-86.

Cotton, A. (1997). Power, knowledge, and the discourse of specialization in nursing. *Clinical Nurse Specialist, 11*(1), 25-29.

Creswell, J. W. (1998). *Qualitative inquiry and research design: Choosing among five approaches.* Thousand Oaks, CA: Sage.

Creswell, J. W. (2006). *Qualitative inquiry and research design: Choosing among five approaches* (2nd ed.). Thousand Oaks, CA: Sage.

Creswell, J. W. (2007). *Qualitative Inquiry and Research Design: Choosing Among Five Traditions* (2nd ed.). Thousand Oaks, CA: Sage.

Crocker, J., & Major, B. (2003). The self-protective properties of stigma: Evolution of a modern classic. *Psychological Inquiry, 14*(3,4), 232-237.

Currie, G., Finn, R., & Martin, G. (2010). Role transition and the interaction or relational and social identity: New nursing roles in the English NHS. *Organization Studies, 31*(07), 941-961.

Davies, B., & Hughes, A. M. (2002). Clarification of advanced nursing practice: Characteristics and competencies. *Clinical Nurse Specialist, 16*(3), 147-152.

Davis, A. M., Hull, S. C., Grady, C., Wilfond, B. S., & Henderson, G. E. (2002). The invisible hand in clinical research: The study coordinator's critical role in human research protection. *Journal of Law, Medicine, & Ethics, 30*, 411-419.

DeFillippi, R. J., & Arthur, M. B. (1994). The boundaryless career: A competency-based perspective. *Journal of Organizational Behavior, 15*(4), 307-324.

Dickens, C. (1994). *Martin Chuzzlewit* [Everybody's Library]. New York, NY: Alfred A Knopf. (Original work published 1843–1844)

Dilley, P. (2004). Interviews and philosophy of qualitative research. *Journal of Higher Education, 75*(1), 127-132.

Dingwall, R., Rafferty, A. M., & Webster, C. (1988). *An introduction to the social history of nursing*. London, UK: Routledge.

Dock, L. L., & Stewart, I. M. (1920). *A short history of nursing: From the earliest times to the present day*. New York, NY: G. P. Putnam's Sons.

Dorsey, E. R., de Roulet, J., Thompson, J. P., Reminick, J., I., Thai, A., White-Stellato, Z., Beck, C. A., George, B. P., & Moses, H. (2010). Funding of US biomedical research, 2003-2008. *Journal of the American Medical Association, 303*(2), 137-143.

Drexel University. (2014). *Online clinical research degree & certificate programs.* Retrieved September 20, 2014, from http:/www.drexel.com/online-degrees/biomedical-degrees/index.aspx

Duchscher, J. E. B., & Cowin, L. S. (2006). The new graduates' professional inheritance. *Nursing Outlook, 54*, 152-158.

Duffield, C., Aiken, L., O'Brien-Passas, L., & Wise, W. J. (2004). Nursing: A stepping stone to future careers. *Journal of Nursing Administration, 34*(5), 238-245.

Duffield, C., & Franks, H. (2002). Career paths beyond nursing and the contribution of nursing experience and skills in attaining these positions. *International Journal of Nursing Studies, 29*, 601-609.

Dukerich, J. M., Kramer, R., & McLean-Parks, J. (1998). The dark side of organizational identification. In D. A. Whetten & P. C. Godfrey (Eds.), *Identity in organizations: Building theory through conversations* (pp. 245-256). Thousand Oaks, CA: Sage.

Durkheim, E. (1961). *The elementary forms of the religious life.* New York, NY: Collier.

Ellerton, M. L., & Gregor, F. (2003). A study of transition: The new nurse graduate at 3 months. *Journal of Continuing Education in Nursing, 34*(3), 103-107.

Erikson, E. H. (1959). *Identity and the life cycle: Selected papers by Erik H. Erikson.* New York, NY: International Universities Press.

Erikson, E. H. (1968). *Identity, youth and crisis*. New York, NY: W. W. Norton.

Erikson, E. H. (1974). *Dimensions of new identity.* New York, NY: W. W. Norton.

Erikson, E. H. (1980). *Identity and the life cycle: A reissue*. New York, NY: W.W. Norton.

Ewens, A. (2003). Changes in nursing identities: Supporting a successful transition. *Journal of Nursing Management, 11*(4), 224-228.

Fagermoen, M. S. (1997). Professional identity: Values embedded in meaningful nursing practice. *Journal of Advanced Nursing, 25*(3), 434-441.

Festinger, L., & Carlsmith, J. M. (1959). Cognitive consequences of forced compliance. *Journal of Abnormal and Social Psychology, 58*(2), 203-210.

Findlow, S. (2014). Higher education change and professional-academic identity in newly 'academic' disciplines: The case of nurse education. *Higher Education, 63,* 117-133.

Fleming, V., Gaidys, U., & Robb, Y. (2002). Hermeneutic research in nursing: Developing a Gadamerian-based research method. *Nursing Inquiry, 10*(2), 113-120.

Gadamer, H. G. (1976). *Philosophical hermeneutics.* Berkeley, CA: University of California Press.

Gallop. (2013). *Honesty/ethics in professions*. Retrieved September 25, 2014, from http://www/gallup.com/poll/1654/honesty-ethics-professions.aspx

Gardner, W., Lidz, C. W., & Hartwig, K. C. (2004). Authors' reports about research integrity problems in clinical trials. *Contemporary Clinical Trials, 26,* 244-251.

Geertz, C. (1973). *The interpretation of cultures.* New York, NY: Basic Books.

George, L. K. (1993). Sociological perspectives on life transitions. *Annual Review of Sociology, 19*(1), 353-373.

Gibson, S. K., & Hanes, L. A. (2003). The contribution of phenomenology to HRD research. *Human Resource Development Review, 2*(2), 181-205.

Glaser, B. G., & Strauss, A. L. (1967). *The discovery of grounded theory: Strategies for qualitative research.* Chicago, IL: Aldine.

Glen, S., & Waddington, K. (1998). Role transition from staff nurse to clinical nurse specialist: A case study. *Journal of Clinical Nursing, 7,* 283-290.

Godinez, G., Schweiger, J., Gruver, J., & Ryan, P. (1999). Role transition from graduate to staff nurse: A qualitative analysis. *Journal for Nurses in Staff Development, 15*(3), 97-110.

Goodin, H. J. (2003). The nursing shortage in the United States of America: An integrative review of the literature. *Journal of Advanced Nursing, 43*(4), 335-350.

Hamrick, A.B. (1996). *Advanced Nursing Practice: An Integrative Approach* (4th ed.). Philadelphia, PA: WB Saunders.

Hanson, C. M., & Hamric, A. B. (2003). Reflections on the continuing evolution of advanced practice nursing. *Nursing Outlook, 51*(5), 203-211.

Hastings, C. (2010). *Clinical research nursing, 2010*. Retrieved August 3, 2010, from http://www.cc.nih.gov/nursing/crn/crn_2010.html

Hastings, C. E., Fisher, C. A., & McCabe, M. A. (2012). Clinical research nursing: A critical resource in the national research enterprise. *Nursing Outlook, 60*(3), 149-156.

Heidegger, M. (1961). *Being and time* (J. Macquarrie & E. Robinson, Trans.). New York, NY: Harper and Row.

Heppner, M. J., Multon, K. D., & Johnston, J. A. (1994). Assessing psychological resources during career change: Development of the career transitions inventory. *Journal of Vocational Behavior, 44*, 55-74.

Herbst, M. (2007). A critical shortage of nurses. *Business Week,* August 28.

Higgenbottom, G. M. A. (2004). Sampling issues in qualitative research. *Nurse Researcher, 12*(1), 7-19.

Hill, C. E., Thompson, B. J., Williams, E. N., Hess, S. A., & Ladany, N. (2005). Consensual qualitative research: An update. *Journal of Counseling Psychology, 52,* 196-205.

Holland, K. (1999). A journey to becoming: The student nurse in transition. *Journal of Advanced Nursing, 29*(1), 229-236.

Horton, K., Tschudin, V., & Forget, A. (2007). The value of nursing: A literature review. *Nursing Ethics, 146,* 716-740.

Husserl, E. (1970). *The crisis of European sciences and transcendental phenomenology* (D. Carr, Trans). Evanston, IL: Northwestern University Press.

Ibarra, H. (1999). Provisional selves: Experimenting with image and identity in professional adaptation. *Administrative Sciences Quarterly, 44,* 744-791.

Ibarra, H. (2003). *Working identity: Unconventional strategies for reinventing your career.* Boston, MA: Harvard Business School Press.

Jacobs, L. A., DiMattio, J. K., Bishop, T. L., & Fields, S. D. (1998). The baccalaureate degree in nursing as an entry-level requirement for professional nursing practice. *Journal of Professional Nursing, 14*(4), 225-233.

Joel, L. A. (2006). *The nursing experience: Trends, challenges, and transitions* (5th ed.). New York, NY: McGraw-Hill.

Johnson, M., Cowin, L. S., Wilson, I., & Young, H. (2012). Professional identity and nursing: Contemporary theoretical developments and future research challenges. *International Nursing Review, 59*(4), 562-569.

Jones, M. L. (2005). Role development and effective practice in specialist and advanced practice roles in acute hospital settings: Systematic review and meta-synthesis. *Journal of Advanced Nursing, 49*(2), 191-209.

Ketefian, S., Redman, R. W., Hanucharurnkul, S., Masterson, A., & Neves, E. P. (2001). The development of advanced practice roles: Implications in the international nursing community. *International Nursing Review, 48*(3), 152-163.

Kidder, M. M., & Cornelius, P. B. (2006). Licensure is not synonymous with professionalism. *Nurse Educator, 51*(1), 15-19.

Kittler, M. G., Rygl, D., MacKinnon, A., & Wiedemann, K. (2011). Work role and work adjustment in emerging markets a study of German expatriates in CEE countries and Russia. *Cross Cultural Management, 18*(2), 165-184.

Koch, T. (1995). Interpretive approaches in nursing research: The influence of Husserl and Heidegger. *Journal of Advanced Nursing, 21,* 827-836.

Kramer, M. (1974). *Reality shock: Why nurses leave nursing.* St. Louis, MO: Mosby.

Kreiner, G. E. & Ashforth, B. E. (2004). Evidence toward an expanded model of organizational identification. *Journal of Organizational Behavior, 25*(1), 1-27.

LaBar, K. S., & LeDoux, J. E. (2003). Emotional learning circuits in animals and humans. In R. J. Davidson, K. R. Scherer, & H. H. Goldsmith (Eds.), *Handbook of affective sciences* (pp. 52-65). New York, NY: Oxford University Press.

Lavoie-Tremblay, M., Viens, C., Forcier, M., Labrosse, N., Lafrance, M., Laliberte, D., & Lebeuf, M. L. (2002). How to facilitate the orientation of new nurses into the workplace. *Journal for Nurses in Staff Development, 18*(2), 80-85.

Lazarus, R. S. (1998). Emotion and adaptation. In J. M. Jenkins, K. Oakley, & N. L. Stein (Eds.), *Emotions: A reader* (pp. 38-44). Malden, MA: Blackwell.

LeDoux, J. E. (2000). Emotion circuits in the brain. *Annual Review of Neuroscience, 23,* 155-184.

Lichtman, M. (2010). *Qualitative research in education: A user's guide*. Thousand Oaks, CA: Sage.

Lillibridge, J., & Fox, S. (2005). RN to BSN education: What do the RNs think? *Nurse Educator, 30*(1), 12-16.

Lincoln, Y. S., & Guba, E. G. (1985). *Naturalistic inquiry*. London, UK: Sage.

Lopez, K. A., & Willis, D. G. (2004). Descriptive versus interpretive phenomenology: Their contributions to nursing knowledge. *Qualitative Health Research, 14*(5), 726-735.

Lu, C., Lu, J., Du, D., & Bakker, A. (2014). Does work engagement increase person-job fit? The role of job crafting and job insecurity. *Journal of Vocational Behavior, 82*(2), 142-152.

MacIntosh, J. (2003). Reworking professional nursing identity. *Western Journal of Nursing Research, 25*(6), 725-741.

MacNeil, M. (1997). From nurse to teacher: Recognizing a status passage. *Journal of Advanced Nursing, 25,* 634-642.

Maggs, C. (2006). A history of nursing: A history of caring? *Journal of Advanced Nursing, 23*(3), 630-635.

Malone, B. L., & Marullo, G. (1997). *Workforce trends among U.S. registered nurses: A report for the International Council of Nurses ICN Workforce Forum*. Washington, DC: American Nurses Association.

Markus, H. R., & Kitayama, S. (1991). Culture and the self: Implications for cognition, emotion, and motivation. *Psychological Review, 98(2),* 224-253.

Markus, H., & Nurius, P. (1986). Possible selves. *American Psychologist, 41,* 954-969.

Martin, A. J., Nejad, H., Colman, S., & Liem, G. A. D. (2012). Adaptability: Conceptual and empirical perspectives on response to change, novelty, and uncertainty. *Australian Journal of Guidance and Counseling, 22*(1), 58-81.

Maxwell, J. A. (1996). *Qualitative research design: An interactive approach.* Thousand Oaks, CA: Sage.

Mead, G. H. (1934). *Mind, self and society.* Chicago, IL: University of Chicago Press.

Merleau-Ponty, M. (1962). *Phenomenology of perception* (C. Smith, trans.). London, UK: Routledge & Kegan Paul.

Miles, M. B., & Huberman, A. M. (1994). *Qualitative data analysis.* Thousand Oaks, CA: Sage.

Mittelman, M. (2010). Our nation's health depends on expanding the nursing profession. *Alternative Therapies in Health and Medicine, 16*(1), 12-14.

Mosby. (2009). *Mosby's medical dictionary*. New York, NY: Elsevier Saunders.

Moustakas, C. (1994). *Phenomenological research methods.* Thousand Oaks, CA: Sage.

Mueller, M. R. (2001). From delegation to specialization: Nurses and clinical trial co-ordination. *Nursing Inquiry, 8*(3), 182-190.

Mueller, M., & Mamo, L. (2002). The nurse clinical trial coordinator: Benefits and drawbacks of the role. *Research and Theory for Nursing Practice: An International Journal, 16*(1), 33-41.

National Institutes of Health. (2012). *Clinical trials and clinical research*. Retrieved from http://www.nichd.nih.gov/health/clinicalresearch/

Nicholson, N. (1984). A theory of work role transitions. *Administrative Science Quarterly, 29*(2), 172-191.

Nicholson, N. (1987). The transition cycle: A conceptual framework for the analysis of change and human resources management. In K. M. Rowland & J. R. Ferris (Eds.), *Research in personnel and human resources management* (Vol. 5, pp. 167-222). Greenwich, CT: JAI Press.

Nicholson, N. (2013). *The "I" of leadership: Strategies for seeing, being and doing.* West Sussex, UK: John Wiley & Sons.

Nicholson, N., & West, M. (1989). Transitions, work histories, and careers. In M. B. Arthur, D. T. Hall, & B. S. Lawrence (Eds.), *Handbook of career theory.* New York, NY: Cambridge University Press.

Niessen, C., Binnewies, C., & Rank, J. (2010). Disengagement in work role transitions. *Journal of Occupational and Organizational Psychology, 83,* 695-715.

O'Neil, J. M., & Fishman, D. M. (1986). Adult men's career transitions and gender role themes. *Career Development Quarterly, 35,* 239-250.

Ocker, B. M., & Pawlik-Plank, D. (2000). The research nurse role in a clinic-based oncology research setting. *Cancer Nursing, 23*(4), 286-292.

Oermann, M. H., & Garvin, M. F. (2002). Stresses and challenges for new graduates in hospitals. *Nurse Education Today, 22,* 225-230.

Ohlen, J., & Segesten, K. (1998). The professional identity of the nurse: Concept analysis and development. *Journal of Advanced Nursing, 28*(4), 720-727.

Oliva, R., & Kallenberg, R. (2003). Managing the transition from products to services. *International Journal of Service Industry Management, 14*(2), 160-172.

Patton, M. Q. (1990). *Qualitative evaluation and research methods* (2nd ed.). Newbury Park, CA: Sage.

Pearson, L. J., (1996). Annual update of how each state stands on legislative issues affective advanced nursing practice. *The Nurse Practitioner, 21*(1), 10-70.

Pelke, S. & Easa, D. The role of the clinical research coordinator in multicenter clinical trials. *Journal of obstetric, gynecologic & neonatal nursing, 26*(3), 279-285.

Peplau, H. (2003). Specialization in professional nursing. *Clinical Nurse Specialist, 17*(1), 3-9.

Pharmaceutical and Medical Professionals. (2014). *Clinical research associate job description.* Retrieved January 19, 2014, from http://www.pmpconnect.com/research_associate_description.htm

Plimmer, G., & Schmidt, A. (2007). Possible selves and career transition: It's who you want to be, not what you want to do. *New Directions for Adult and Continuing Education, 114*, 61-74.

Polit, D. F., & Back, C. T. (2004). *Nursing research: Principles and methods (*7th ed.). Philadelphia, PA: J. B. Lippincott.

Price, S. L. (2009). Becoming a nurse: a meta-study of early professional socialization and career choice in nursing.

Pryor, E. R., Habermann, B., & Brown, M. E. (2007). Scientific misconduct from the perspective of research coordinators: A national survey. *Journal of Medical Ethics, 33,* 365-369. doi:10.1136/jme.2006.016394

Raja-Jones, H. (2002). Role boundaries—research nurse or clinical nurse specialist? A literature review. *Journal of Clinical Nursing, 11*(4), 415-420.

Raybuck, J. A. (1997). The clinical nurse specialist as research coordinator in clinical drug trials. *Clinical Nurse Specialist, 11*(1), 15-19.

Redman, B. K., Templin, T. N., & Merz, J. F. (2006). Research misconduct among clinical trial staff. *Science and Engineering Ethics, 12,* 481-489.

Reynolds, S. M. (2004). ORI findings of scientific misconduct in clinical trials and publicly funded research, 1992-2002. *Clinical Trials, 1,* 509-516. doi:10.1191/1740774504cn048oa

Rico-Villademoros, F., Hernando, T., Sanz, J.-L., Lopez-Alonso, A., Salamanca, O., Camps, C., & Rosell, R. (2004). The role of the clinical research coordinator—data manager—in oncology clinical trials. *BMC Medical Research Methodology, 4,* 6-9.

Ritchie, J., Lewis, J., & Elam, G. (2003). Designing and selecting samples. In J. Ritchie & J. Lewis (Eds.), *Qualitative research practice. A guide for social science students and researchers* (pp. 77-108). Thousand Oaks, CA: Sage.

Roberts, B. J., Jones, C., & Lynn, M. (2004). Job satisfaction of new baccalaureate nurses. *Journal of Nursing Administration, 24*(9), 428-435.

Robinson, W. P. (1996). *Social groups and identities: Developing the legacy of Henri Tajfel.* Oxford, England: Butterworth-Heinemann.

Rothbaum, F., Weisz, J. R., & Snyder, S. S. (1982). Changing the world and changing the self: A two-process model of perceived control. *Journal of Personality and Social Psychology, 42*, 5-37.

Sadler, G. R., Lantz, J. M., Fullerton, J. T., & Dault, Y. (1999). Nurses' unique roles in randomized clinical trials. *Journal of Professional Nursing, 15*(2), 106-115.

Saks, A. M. & Ashforth, B. E. (2000). Change in job search behaviors and employment outcomes. *Journal of Vocational Behavior, 56*(2), 277-287.

Sandberg, J. (2005). How do we justify knowledge produced within interpretive approaches? *Organizational Research Methods, 1*, 41-67.

Schlossberg, N. K. (1981). A model for analyzing human adaptation to transition. *Counseling Psychologist*, 9(2), 2-18.

Schouten, J. W. (1991). Selves in transition: Symbolic consumption in personal rites of passage and identity reconstruction. *Journal of Consumer Research, 17*, 412-425.

Schwandt, T. (2000). Three epistemological stances for qualitative inquiry. In N. K. Denizen & Y. S. Lincoln (Eds.), *Handbook of qualitative research* (2nd ed., pp. 189-213). Thousand Oaks, CA: Sage.

Schwandt, T. (2007). Judging interpretations: But is it rigorous? Trustworthiness and authenticity in naturalists' evaluation. *New Directions for Evaluation, 114*, 11-25.

Scott, C. R., Corman, S. R., & Cheney, G. (1988). Development of a structural model of identification in the organization. *Communication Theory, 8*(3), 298-336.

Sechrist, K. R., & Berlin, L. E. (1998). Role of the clinical nurse specialist: An integrative review of the literature. *AACN Clinical Issues, 9,* 306-324.

Secrest, J. A., Norwood, B. R., & Keatley, V. M. (2003). "I was actually a nurse": The meaning of professionalism for baccalaureate nursing students. *Journal of Nursing Education, 42*(2), 77-82.

Seidman, I. (2006). *Interviewing as qualitative research: A guide for researchers in education and the social sciences* (3rd ed.). New York, NY: Teachers College Press.

Seidman, I. (2012). *Interviewing as qualitative research: A guide for researchers in education and the social sciences* (4th ed.). New York, NY: Teachers College Press.

Shannon, E. M. (2011). *Immigrating in nursing: A grounded theory of how nurses process their professional practice specialization within the pharmaceutical/biotech industry*. Unpublished doctoral dissertation, Rutgers, The State University of New Jersey, Newark, NJ.

Shay, J. P., & Baack, S.A. (2004). Expatriate assignment, adjustment, and effectiveness: An empirical examination of the big picture. *Journal of International Business Studies, 35*, 216-232.

Sheehy, G. (1977). *Passages Predictable: Crisis of Adult Live.* Toronto: Bantam Books.

Showstack, J., Katz, P. P., Lake, J. R., Brown, R. S., Dudley, R. A., Belle, S., . . . Everhart, J. (1999). Resource utilization in liver transplantation: Effects of patient characteristics and clinical practice. *Journal of the American Medical Association, 281,* 1381-1386.

Sluss, D. M. & Ashforth, B. E. (2007). Relational identity and identification: Defining ourselves through work relationships. *Academy of Management Review, 32*(1), 9-32.

Sluss, D. M., Ployhart, R. E., Cobb, M. G., & Ashforth, B. E. (2012). Generalizing newcomers' relational and organizational identifications: Processes and prototypicality. *Academy of Management Journal, 55*(4), 949-975.

Society of Clinical Research Associates. (2010). *Introduction.* Retrieved from http://www.socra.org/html/certific.htm

Sokolowski, R. (2000). *Introduction to phenomenology.* New York, NY: Cambridge University Press.

Spilker, B. (1991). *Guide to clinical trials.* Philadelphia, PA: Wolters Kluwer Lippincott.

Spilsbury, K., Petherick, E., Cullum, N., Nelson, A., Nixon, J., & Mason, S. (2007). The role and potential contribution of clinical research nurses to clinical trials. *Journal of Clinical Nursing, 17*, 549-557.

Stonier, P. D. (2003). *Careers with the pharmaceutical industry* (2nd ed.). Chichester, West Sussex, England: John Wiley & Sons.

Strauss, A. I. (1959). *Mirrors and masks: The search for identity.* Glencoe, IL: Free Press.

Strauss, A. I. (1987). *Qualitative analysis of social scientists.* Cambridge, UK: Cambridge University Press.

Strauss, A. I., & Corbin, J. (1990). *Basics of qualitative research: Grounded theory procedures and techniques.* Newbury Park, CA: Sage.

Stryker, S. (1987). Identity theory: Developments and extensions. In K. Yardley & T. Honess (Eds.), *Self and identity: Psychosocial perspectives* (pp. 89-103). Chichester, England: Wiley.

Styles, M. (1996). Conceptualizations of advanced nursing practice. In A. B. Hamrick, J. A. Spross, & C. M. Hanson (Eds.), *Advanced nursing practice: An integrative approach* (pp. 25-41). Philadelphia, PA: W. B. Saunders.

Styles, M., & Lewis, C. (2000). Conceptualizations of advanced nursing practice. In A. B. Hamrick, J. A. Spross, & C. M. Hanson (Eds.), *Advanced nursing practice: An integrative approach* (pp. 33-51). Philadelphia, PA: W. B. Saunders.

Sung, N. S., Crowley, W., Genel, M., Salber, P., Sandy, L., Sherwood, L. M., Rimoin, D. (2003). Central challenges facing the national clinical research enterprise. *Journal of the American Medical Association*, *289*(10), 1278-1287.

Suominen, T., Kovasin, M., & Ketola, O. (1996). Nursing culture—some viewpoints. *Journal of Advanced Nursing, 25,* 186-190.

Sweet, H. (2007). Establishing connections, restoring relationships: Exploring the historiography of nursing in Britain. *Gender & History*, *19*(3), 565-580.

Tajfel, H. (1974). Social identity and intergroup behaviour. *Social Science Information, 13*(2), 65-93.

Tajfel, H. (1982). Social psychology of intergroup relations. In M. R. Rosenzweig & L. W. Porter (Eds.), *Annual review of psychology* (Vol. 33, pp. 1-39). Palo Alto, CA: Annual Reviews.

Tajfel, H., & Turner, J. (1986). The social identity theory of intergroup behavior. In S. Worchel & W. G. Austin (Eds.), *Psychology of intergroup relations* (2nd ed., pp. 7-24). Chicago, IL: Nelson-Hall.

Tajfel, H., & Turner, J. (2004). An integrative theory of intergroup conflict. In M. J. Hatch & M. Schultz (Eds.), *Organizational identity: A reader*. New York, NY: Oxford University Press.

Takase, M., Maude, P., & Manias, E. (2006). Impact of the perceived public image of nursing on nurses' work behavior. *Journal of Advanced Nursing, 53*(3), 333-343.

Tradewell, G. (1996). Rites of passage: Adaptation of nursing graduates to a hospital setting. *Journal of Nursing Staff Development, 121*(4), 183-189.

Turner, V. (1969). *The Ritual Process: Structure and Anti-structure.* Middlesex: Penguin.

Turner, J. C., Hogg, M. A., Oakes, P. J., Reicher, S. D., & Wetherell, M. S. (1987). *Rediscovering the social group: A self-categorization theory*. New York, NY: Basil Blackwell.

Tutton, E., Seers, K., & Langstaff, D. (2008). Professional nursing culture on a trauma unit: Experiences of patients and staff. *Journal of Advanced Nursing, 61*(2), 145-153.

U.S. Department of Health and Human Services, Health Resources and Services Administration. (2010). *The registered nurse population: Findings from the 2008 national sample survey of registered nurses.* Retrieved from http://bhpr.hrsa.gov/healthworkforce/rnsurveyfinal.pdf

Vagel, M. D. (2014). *Crafting phenomenological research*. Walnut Creek, CA: Left Coast Press.

van Gennep, A. (1960). *The rites of passage.* Chicago, IL: Chicago University Press.

van Manen, M. (1990). *Researching lived experience: Human science for an action sensitive pedagogy*. Ontario, Canada: Althouse Press.

Weick, K. E. (1995). *Sensemaking in organizations*. Thousand Oaks, CA: Sage.

Weiland, D. M., Altmiller, G. M., Door, M. T., & Wolf, Z. R. (2007). Clinical transitions of baccalaureate nursing students during preceptored, pregraduation practicums. *Nursing Education Perspectives, 28*(6), 315-321.

West, M., & Rushton, R. (1989). Mismatches in the work-role transitions. *Journal of Occupational Psychology, 62,* 271-286.

Willitts, G., & Clarke, D. (2014). Constructing nurses' professional identity through social identity theory. *International Journal of Nursing Practice, 2,* 164-169.

Woods, L. P. (1997). Conceptualizing advanced nursing practice: Curriculum issues to consider in the educational preparation of advanced practice nurses in the UK. *Journal of Advanced Nursing, 25*(4), 820-828.

Wright, J. R., Crooks, D., Ellis, P. M., Mings, D., & Whelan, T. J. (2002). Factors that influence the recruitment of patients to phase III studies in oncology: The perspective of the clinical research associate. *Cancer, 95*(7), 1584-1591.

Yanagawa, H., Takai, S., Yoshimaru, M., Miyamoto, T., Katashima, R., & Kida, K. (2014). Nurse awareness of clinical research: A survey in a Japanese university hospital. *BMD Medical Research Methodology, 14*(85). Retrieved from http://biomedcentral.com/1471-2288/14/85

Yardley, L. (2000). Dilemmas in qualitative health research. *Psychology and Health, 15,* 215-228.

Yetter, D. (2010). Preserving a positive image of nursing in a complicated healthcare environment. *Nursing Made Incredibly Easy, 8,* 5-7.

Zerwekh, J., & Claborn, J. C. (1997). *Nursing today: Transitions and trends.* Philadelphia, PA: Saunders.

APPENDIX A:

RECRUITMENT AND RECORD RETENTION MATERIALS

FOR POTENTIAL PARTICIPANTS

Study Information Sheet for Potential Participants

Title: From Direct Patient Care to Clinical Research:
Transitioning to an Emerging Nursing Specialty

Purpose of Study: This purpose of this study is to gain a better understanding of how the transition process is experienced by nurses who make a decision to leave direct patient care for a career in clinical research in industry.

Problem Addressed: Professional nurses working in the biopharmaceutical or medical device industry are engaged in a discipline poorly understood and largely unrecognized by the nursing profession, resulting in a lack of nursing-initiated practice and educational standards, and little or no professional support or recognition to assist the nurse with making this transition and sustaining his/her nursing identity.

Significance of the Study: This study will identify and explore experiences that may guide professional nurses who are considering a move from a direct patient care role to a position in the biopharmaceutical or medical device industry. In addition, this study will create a foundation for a new conversation within the nursing community regarding how nurses in industry experience their nursing identity and what resources, standards or other forms of support may be required from professional nursing educators and credentialing boards.

Study Design and Participants: Participants will be professional nurses possessing at least a bachelor's degree who have successfully transitioned (at least 2 years ago) from direct patient care roles to full time research positions in the biopharmaceutical or medical device industry.

Research participants will be asked to engage in three in-depth interviews over a 2 to 3 week period. Participant and employer identities will be kept confidential. The interviews will focus on questions such as "Can you describe for me the first time you became aware that there were opportunities in industry for professional nurses to engage in clinical research?" and "Can you please share with me a few defining or especially impactful experiences that you had as you transitioned to your current role in industry?" Reflections on how these experiences impacted your transition success and how you experience yourself as a nurse will be solicited.

About the Researcher: Mrs. Robin Newman is a doctoral candidate in the Executive Leadership Program of the Graduate School of Education and Human Development, The George Washington University. Robin is a Pediatric Nurse Practitioner, and transitioned full time from direct patient care to a career in clinical research working in industry more than 20 years ago. Robin hopes that this study will shine light on a previously unstudied transition experience and assist nurses and the nursing profession to better understand the challenges, opportunities, and support needed for professional nurses working in this career field.

Permission to Archive Interview Audio Recordings and Associated Transcripts

I hereby authorize Robin Newman to archive de-identified interview audio recordings, notes, and associated transcripts created as a part of my agreement to participate in the research project entitled:

From Direct Patient Care to Clinical Research:
Transitioning to an Emerging Nursing Specialty

I understand that these materials will be retained as confidential study data and will not be shared with anyone who has not signed *A Transcriber's and Reviewer's Letter of Confidentiality*.

_____
Participant (Print Name)

_____ _____
Signature Date

APPENDIX B:

INFORMED CONSENT FORM

Research Study:
From Direct Patient Care to Clinical Research:
Transitioning to an Emerging Nursing Specialty
IRB # 011535

Investigator: Robin W. Newman
Telephone Number: 484-574-9631
Electronic mail: rwnewman@gwmail.gwu.edu
Faculty Sponsor: Dr. Ellen F. Goldman
Electronic mail: egoldman@gwu.edu
Telephone Number: 202-994-1531

Introduction
You are invited to take part in a research study being conducted by Ms. Robin Newman, a doctoral candidate in the Executive Leadership Program at The George Washington University Graduate School of Education and Human Development. This study has no outside sponsor, nor funding from any source, and will be supervised by Ms. Newman's dissertation advisor, Dr. Ellen Goldman.

You are being asked to take part in this study because you have either self identified, or been identified as a professional nurse who has transitioned from a direct patient care nursing role to a full time position in clinical research employed by a biopharmaceutical or medical device manufacturer. This form has been designed to provide you with information about the study. I have also attached a Study Information Sheet that summarizes the research to be conducted. Taking part in this study is completely voluntary and, even if you decide you want to proceed, you may still withdraw from the study at any time. There are no consequences to you or your work as a professional nurse for deciding not to participate, nor will there be any consequences to you should you decide to take part at this time, and later choose to withdraw.

You are one of approximately twelve (12) professional nurses being asked to participate in this study. If you decide to talk part and then change your mind, you can stop at any time. The voluntary nature of your participation is of utmost importance.

Purpose
The purpose of this study is to understand the nature of the transition experience of professional nurses who decide to leave a traditional direct patient care role for a career in clinical research within the biopharmaceutical or medical device industry. In this study, we will explore your decision to make this career transition and how you experienced the transition itself. The goal is to understand the meaning that this experience has for you as a professional nurse, and to examine your perceptions around

any potential supports or barriers to your successful transition that you may have experienced.

Procedures
The research involves completion of three (3) interviews that I would like your permission to digitally record. You will be identified in the recording only as "Participant Number X." We can meet in your office or another location that is convenient for you as long as uninterrupted time can be assured and the interview can be recorded clearly. Each interview is expected to last approximately 90 minutes. Ideally, the three interviews will be completed within a 3-week period or less. Hence, the total amount of time you will spend in this study is 4.5 hours.

I will share the transcripts of the interviews with you so that you may review then on your own time or during our time together, and I will also share with you my summaries of the data. It is possible that you may spend time both inside as well as outside of the interview to review this material. You will have an opportunity to make any corrections or additions to the information gathered during the interviews.

The interviews will explore your formal or informal experiences that contributed to your decision and preparation to transition from direct patient care to a role in clinical research in industry. They will also explore your formal and informal experiences of the transition process itself, including opportunities and obstacles encountered, how you experienced yourself as member of the nursing profession prior, during and after the transition occurred, and any adjustments you may have been required to make. Finally, they will explore how you define success in your transition experience, what you learned about yourself from these experiences, and how the transition has impacted your work and nursing identity.

We will also explore your thoughts on the role of the professional nurse engaged in a career as a clinical research specialist in industry, and any thoughts or recommendations you may have for other nurses considering this type of transition or for the nursing profession at large.

The interview transcripts, the written dissertation as well as any publication related to it will not identify you as a participant. Data, including quotes, will only be reported in the form of "Participant 1 said . . ." or "Participant 2 said."

Possible Risks
The risks of participating in this study are no more than you would experience in everyday life.

Benefits
Taking part in this research will not help you directly; however, the process of participation may provide greater understanding and insight into your own transition experience and may be of benefit to other nurses considering a similar transition. Companies wishing to attract and retain professional nurses for clinical research roles, nurse educators, and professional nursing certification boards may also benefit from the collective insight this study provides.

Costs
There are no costs to you for participating in this study.

Compensation
You will receive no monetary compensation for participating in this study.

Right to Withdraw
You may withdraw from the study at any time with no consequences.

Confidentiality and Privacy of Research Records
The records for this study will be kept private, stored on a computer with password access, and on files that are password protected. The transcriptionist and a colleague who will assist me with limited transcript and data review will sign confidentiality statements requiring that they not share or duplicate any information transcribed or reviewed. No information will be included that will make it possible to identify you as a participant in the dissertation or any published articles or presentations. Data will be de-identified by the use of descriptors, such as Participant 1 or Participant 2, instead of using your name. The list that links research participants to numbers will be kept in a secure location, separate from the data, and will be destroyed immediately after all data have been transcribed and analyzed. The audio recording of interviews will be destroyed at that time as well. The transcripts of the interviews will be retained until the study is completed and the dissertation has been successfully defended (or withdrawn), at which time these too will be destroyed. Your records for the study may be reviewed by my dissertation advisor and by departments of the University responsible for overseeing research safety and compliance.

Questions
If you have any questions about this study, please call Robin Newman at 484-574-9631. For questions regarding your rights as a participant in human research, you may contact the GWU Office of Human Research at 202-994-2715.

Documentation of Consent
By signing this consent form, you agree that you have read this informed consent form, you understand what is involved, and you agree to take part in the study. You do not give up any of your legal rights by signing this informed consent. You will receive a copy of this consent form. Please keep it in case you want to read it again. Thank you for your agreement to participate in this study.

_____
Participant (Print Name)

_____ _____
Signature Date

Researcher Statement

I certify that the research study has been explained to the above individual by me, including the purpose, the procedures, the possible risks, and the potential benefits associate with participation in this research study. Any questions raised have been answered to my satisfaction.

_____

Investigator (Robin Newman)

_____ _____

Signature Date

APPENDIX C:

INTERVIEW GUIDES

Interview One

Note: prior to beginning the interview process, and again before each interview, the researcher will ensure that each research participant has signed the informed consent form and continues to wish to participate in the study. Permission to record each interview session will be verified.

The purpose of our first time together is to learn a little about you as a person and about the work that you currently do. As you know from our discussion about the study at the time that you signed the consent form, the overall goal is to learn about how you experienced your transition from a traditional patient-care centric nursing role to your current career focus as a clinical research specialist working for a biopharmaceutical or medical device company.

As we go through today's interview, I would like for you to reflect upon the *Career Transitions Inventory* you completed prior to my arrival. I will not be scoring or collecting this inventory from you. The goal in having you complete it was to allow you to some time to think about what motivated you to approach this transition, and what qualities or characteristics you have that may have contributed to or inhibited your transition process.

Our goal today is to learn about your background, your current work, and explore what lead you to your initial decision to consider transitioning from direct patient care to clinical research.

1. I would like to begin by exploring your background as a nurse, beginning with your decision to go to nursing school and moving through to today.
    a. Probes:
        i. How long ago did you complete your primary nursing education?
        ii. What drew you to nursing in the first place?
        iii. How would you describe the development of your identity as a nurse over time?

2. Can you describe for me the first time you became aware that there were opportunities in industry for professional nurses to engage in clinical research?
    a. Probes:
        i. What can you remember about your first reaction to this information?
        ii. From whom did you learn about this career option and what was your relationship to this individual?
        iii. Did you share this knowledge with other nurses?
            a. How did they respond?

b. Did you share the information with your nursing manger and how did he/she respond?

3. As you reflect on your education, training, and life as a nurse, what kinds of experiences did you have that you feel influenced (positively or negatively) your ability to engage in a career in clinical research? Please provide me with as much detail as possible.
   a. Probes:
      i. How did your state board of nursing respond to your decision to leave direct patient care?
      ii. Did you engage in any clinical research coursework or training along the way and who provided it?
      iii. Are there experiences or attributes of your nursing career that contribute in a special way to your role in clinical research? Any detractors?

4. Please tell me about your work here as a clinical research specialist? (Title to be adapted as appropriate.)
   a. Probes:
      i. How long have you been in your current position? With your current employer?
      ii. Is this the first role you have had? If not, can you describe your career pathway and history to me?
      iii. What types of responsibilities do you have in your current position?
      iv. What role do you play in your organization?
      v. In what way is your background as a nurse useful (or not useful) to your current position or responsibilities?

I will leave a copy of these interview questions with you today in case something occurs to you before our next meeting and you want to jot that down.

After I return to my office, I will have a transcriptionist make a paper copy of the recording we have made today and share that with you as well. I would like for you to review it at your convenience and we can discuss anything you would like to clarify or elaborate on at the time of our next visit.

Interview Two

The goal of this interview is to explore the actual transition experience itself in detail and learn as much as possible about not only what you experienced, but how that experienced impacted you as a nurse.

Picking up from our last meeting, were there any issues that you wanted to talk further about or any thoughts that you jotted down and wanted to share?

1. Can you please share with me a few defining or especially impactful experiences that you had as you transitioned to your current role in industry?
    a. Probes:
        i. What did you learn about the nursing profession from these experiences?
        ii. What is it about these experiences that made them defining or impactful, and how did they influence your transition?

2. Can you share with me a few defining or especially impactful things you experienced in terms of how you viewed yourself from the perspective of a professional nurse?
    a. Probes:
        i. What did you learn from these experiences?
        ii. Were there any longer term consequences of these experiences to you or your nursing career?
        iii. Were there any specific actions or decisions you took as a consequence of these experiences?

3. As you think about it, what most helped you to make this transition successfully?
    a. Probes:
        i. Was there anyone in particular or any specific organizational group who helped you to make the transition:
        ii. How did they help and what did they do?
        iii. What help did (or did not) the nursing profession provide to you to facilitate your transition?

4. What would you like for other nurses considering a similar transition or for the nursing profession itself to know about your experience?

As before, I will leave a copy of the study questions we explored today here for you to allow you to jot anything down that occurs to you before our next session.

After I return to my office, I will have a transcriptionist make a paper copy of the recording we have made today and share that with you as well. I would like for you to review it at your convenience and we can discuss anything you would like to clarify or elaborate on at the time of our next visit.

Interview Three

The goal of this interview is to complete our exploration of the transition experience itself in detail and learn as much as possible about not only what you experienced, but how that experienced impacted you as a nurse.

Picking up from our last meeting, were there any issues that you wanted to talk further about or any thoughts that you jotted down and wanted to share?

1. How would you describe the professional life of a nurse who has left direct patient care for a career in the biopharmaceutical device industry?
    a. Probes:
        i. Do you still consider what you do to be part of nursing? Why or why not?
        ii. How do you apply or use your nursing education and knowledge in your current career?
        iii. Do you maintain your nursing registration and/or certification?
            a. How do you obtain the necessary continuing education hours? Does your employer support and pay for this?
            b. Do you hold registrations or certifications in fields other than nursing (e.g. specific to clinical research or related industry specialties such as regulatory affairs)? Does your employer support and pay for this?

2. If you were writing an article on your transition, what would it be called? What would the major sections be?
    a. Probes:
        i. Are there any “Ah Ha!” moments that you would want to be sure to include?
        ii. Any trouble spots that you would want to emphasize.

3. I would like for you to reflect for a moment over the conversations we have had over the past few weeks. Are there any topics that you wish to revisit or any additional topics that you would like to ensure we cover?

This concludes our interview sessions. As before, after I return to my office, I will have a transcriptionist make a paper copy of the recording we have made today and share that with you. Should you have any additional comments or thoughts you wish to add, please let me know. I appreciate your willingness to participate and will be happy to share all research results with you when analysis and manuscript development are complete. Thank you.

APPENDIX D:

TRANSCRIBER'S AND REVIEWER'S LETTER OF CONFIDENTIALITY

I understand that I have been asked to listen to, transcribe, or review the content of interviews for research related to a doctoral dissertation. I agree to maintain confidentiality regarding the identity of those interviewed and the contents of the discussion.

Additionally, in preparing manuscripts, I will not identify anyone by name.

Furthermore, I will not make copies of the audio recordings I have transcribed or transcripts I have reviewed, and will return all materials to the research investigator.

_____	_____
Research Investigator	Transcriber/Reviewer
_____	_____
Date	Date

APPENDIX E:

CLINICAL RESEARCH ASSOCIATE JOB DESCRIPTION

1. Responsible for the management of designated clinical trials including investigator selection, analysis of patient recruitment potential, preparation of trial related documentation (protocol, Case Report Forms, Investigator Brochures, consent documents, letters of agreement [and study site contracts], confidentiality agreements), ongoing Ethics Committee submissions, with follow through to ensure successful outcome.
2. Organize[and manage] Investigators' start-up meeting and study initiation meetings.
3. Coordinate the movement of laboratory samples and the resulting data when central laboratory facilities are used.
4. Ensure procedures are in place for appropriate [screening and enrolling] of patients into the clinical trial.
5. Monitoring the assigned clinical trial following company SOPs and in accordance with GCP [Good Clinical Practices].
6. Planning the requirements for clinical trial material [investigational product and all associated research supplies], ordering clinical trial material (head office or local comparators), setting up and monitoring the systems whereby the Clinical Research Associate can ship CT material to the investigator[s], maintaining procedures to account for the CT material, checking the expiration of CT materials and requesting extensions if necessary.
7. Be the point of contact when Investigators/site personnel inquire about patient inclusion/exclusion criteria for ongoing trials.
8. Participate in global conference calls and meetings to review progress of ongoing clinical trials.
9. Tracking completed CRFs [Case Report Forms] and setting up systems whereby completes CRFs are rapidly entered into the database. Ensure that queries generated during [data] cleaning are responded to in a timely fashion.
10. Manage patient recruitment strategies to increase patient randomization into the trial (e.g. Investigator and research nurse meetings, update newsletters, advertising letters to GPs.).
11. Review all SAEs [Serious Adverse Events], ensure Medical Director sign-off, that sites are notified, and that all company procedures* are complied with.
12. Maintain project files including: Ethics Committee approvals, curricula vitae of Investigators and study personnel, clinical Investigator's brochure, protocols, Case Report Form instructions, consent documents, clinical trial material shipping orders, start-up meeting attendance documentation, letters of agreements, lab reference ranges, all Investigator and site correspondence, and schedules of payment.

13. Manage the Contract Research Organizations – initial identification of a suitable partner, definition of CRO responsibilities, communication plan, divisions of responsibility, milestones, contact with CRO, review monthly status reports, and the interaction management of CRO to ensure project success.
14. Participate in departmental planning sessions and SOP development.
15. Participate in product vigilance activities in both pre and post-market arenas.
16. Provide management to the clinical research assistants to ensure that their role and contribution is optimized.
17. Prepare and write clinical trial summary sections to be included in submissions for regulatory clearance and/or approval.

[*Company procedures refers to corporate Standard Procedures that are designed to ensure compliance with all applicable local, state, national, and international regulations and standards. For SAE reporting, expedited electronic reporting to a variety of global regulatory authorities and agencies applies.]

(Adapted from verbatim language located on the website of a recruiting firm: Pharmaceutical and Medical Professionals, 2014.)