2017

Sexuality and Healthcare: the Perceptions of Providers Regarding Role Delineation: Are Occupational Therapists Overlooked?

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Sexuality and Healthcare: The Perceptions of Providers Regarding Role Delineation. Are Occupational Therapists Overlooked?

by

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An Independent Study

Submitted to the Occupational Therapy Department

of the

University of North Dakota

In partial fulfillment of the requirements

for the degree of

Master of Occupational Therapy

Grand Forks, North Dakota
May
2017
This Independent Study, submitted by Brooke Friederichs, MOTS and Olivia Isaacson, MOTS in partial fulfillment of the requirement for the Degree of Master of Occupational Therapy from the University of North Dakota, has been read by the Faculty Advisor under whom the work has been done and is hereby approved.

[Brea C. Lamborn]
Signature of Faculty Advisor

[April 21, 2017]
Date
PERMISSION

Title       Sexuality and Healthcare: The Perceptions of Providers Regarding Role Delineation. Are Occupational Therapists Overlooked?

Department  Occupational Therapy

Degree      Master of Occupational Therapy

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Brooke Friederichs, MOTS  04-18-2017

Olivia Isaacson, MOTS  04-18-2017
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ACKNOWLEDGEMENTS

We would like to extend an immense thank you to our family and friends who have served as a steady support system throughout this study's successes and frustrations. We also wish to acknowledge those who took the time to respond to our survey; this study would not have been possible without you. Furthermore, we would like to express our thanks to Dr. Klug for her assistance during data analysis with SPSS®. Most importantly, thank you to our advisor, Breann Lamborn, for being our constant cheerleader and voice of reason—even from 780 miles away! She has been continuously encouraging of our vision and end goal; we could not have accomplished this without her guidance.
ABSTRACT

INTRODUCTION: The responsibility to address sexual activity is not clearly delineated to one certain healthcare profession, and therefore it often goes unaddressed (Rimmer et al., 2010). In addition, there is an overall lack of literature regarding the extent to which healthcare providers understand the role of occupational therapy in addressing sexual activity.

OBJECTIVES: The purpose of the study was to explore 1) how healthcare providers (physical therapists, occupational therapists, and registered nurses) perceive role delineation when addressing patient concerns about sexual activity 2) the level to which physical therapists and registered nurses believe sexual activity is outlined in the scope of occupational therapy.

METHODS: A nonexperimental, prospective, 20-question quantitative survey was distributed to 126 healthcare providers (physical therapists, occupational therapists, and registered nurses). Statistical analysis was performed using SPSS 24® to determine significant relationships.

RESULTS: There was a response rate of 30.2% (n=38). The results indicated that occupational therapists and registered nurses considered sexual activity to be outlined in their own scope of practice to some degree, while physical therapists did not. Professions outside of occupational therapy are uncertain about occupational therapy’s role in addressing sexual activity.
Identifying which professions feel sexual activity is a part of their scope of practice may lead to increased inclusion of sexual activity in treatment, clearer referral pathways, and a better understanding of interdisciplinary role delineation.
CHAPTER I
INTRODUCTION

Sexual changes are often experienced by individuals with a wide range of diagnoses including traumatic brain injury (TBI), spinal cord injury (SCI), burns, cancer, cardiac conditions, and neuromuscular disorders (Byrne, Doherty, Murphy, McGee & Jaarsma, 2013; Fitch, Beaudoin, & Johnson, 2013; O’Dea, Shuttleworth, & Wedgwood, 2012; Rimmer et al., 2010; Stein, Hillinger, Clancy, & Bishop, 2013). According to O’Dea et al. (2012), the effects of not addressing sexuality concerns with patients can negatively impact the quality of life of individuals. Although sexuality is an integral part of a person, the sexuality issues that people experience are largely unaddressed in the healthcare system (Dyer & das Nair, 2014; Fritz, Dillaway, & Lysack, 2015; Olsson, Berglund, Larsson, & Athlin, 2012; Simpson, Anwar, Wilson, & Bertapelle, 2006; Stein et al., 2013). Failing to address sexuality when working with patients with any diagnosis can hinder the outcome of therapy (Sakellariou & Algado, 2006).

If a specific profession were to be responsible for addressing sexuality, there are several interpretations of which provider would be the best equipped. Rimmer et al., (2010) found that healthcare providers view nurses as having the most education and necessary curriculum about human sexuality to address the topic. However, Rimmer et al., (2010) also suggested that professions such as physicians, physical therapists, occupational therapists, psychologists, and social workers may also be appropriate to introduce discussions regarding sexuality and intimacy concerns. Dyer and das Nair,
(2014) found that without delegating a specific profession to address sexuality, healthcare providers are less likely to introduce the topic of sexuality at all and assume that someone else will cover it.

Before specific protocols or guidelines regarding sexual activity or intimacy can be created, the researchers of this study thought it would be beneficial to further explore several healthcare roles regarding confidence in addressing this issue with patients, including physical therapists (PT), occupational therapists (OT), and registered nurses (RN). These professions were chosen based on their appearance in many studies discussed in the literature review. They were also selected due to the researchers’ accessibility to rehabilitation departments versus access to physicians or psychologists.

In addition, researchers wanted to specifically explore how the role of occupational therapy is perceived by these other professions, as sexual activity is directly identified in the profession’s framework and has been an emerging area of discussion and research in occupational therapy. Despite this, there is a lack of literature supporting occupational therapy’s role in addressing sexual activity when compared to other healthcare professions. There is also a lack of literature relating to healthcare professionals’ knowledge of occupational therapy’s role in this topic. Lastly, from student and clinical experience, the researchers have noted that occupational therapists, physical therapists, and registered nurses have frequent encounters in the healthcare setting and are often viewed as an interdisciplinary team. With these objectives in mind, the researchers aimed to facilitate further discussion about clients’ sexual activity concerns and gain a better understanding of workplace roles and perceptions regarding the responsibility for sexual activity discussions with patients.
Theory

The PLISSIT model served as the theoretical framework for the creation of the survey. The acronym PLISSIT stands for permission, limited information, specific suggestions, and intensive therapy (Ayaz, 2009). The PLISSIT model is a dynamic process of consultation, and its steps can be revisited or skipped as necessary (Rutte et al., 2015). In comparison with other sexual counseling models, the PLISSIT model has shown effectiveness across various patient groups (Rutte et al., 2015). Its implementation has been used in interdisciplinary settings in order to serve as a framework that acknowledges individual differences in skill or knowledge among clinicians when addressing sexuality (Booth, Kendall, Fronek, Miller, & Geraghty, 2003; Dyer & das Nair, 2014).

By implementing the first level, permission, it is believed that 70% of all patients’ sexual concerns can be resolved (Ayaz, 2009). When healthcare providers grant patients “permission”, they are allowing the patient to discuss sexual activity or intimacy concerns without judgment on the part of the provider. The healthcare provider is initiating a comfortable and open platform by assuring the patient that sexual activity concerns regarding injury, illness, or disability are normal, valid, and can be revisited as the patient wishes. Survey questions related to the concept of permission included inquiring about healthcare providers’ preferred time to address sexual activity, how many patients per month they discuss sexual activity concerns with, healthcare providers’ preparedness to discuss sexual activity, whether or not sexual activity is addressed during the initial evaluation, and the level of provider comfort regarding their feelings about revisiting the opportunity to discuss sexual activity during multiple points of treatment.
Limited information, the second phase of the PLISSIT model, refers to general education involving sexual activity concerns that healthcare providers may give to patients (Ayaz, 2009). This could include precautions, side effects, common symptoms, and the general impact that these aspects will all have on sexual activity or intimacy. Factual information in the form of handouts or resource lists may be provided. Survey questions related to limited information included inquiring about healthcare providers’ preparedness to discuss sexual activity, providers’ education experience with sexual activity issues and how to address them, knowledge of general interventions/treatments for sexual dysfunction, and services/resources offered by their facility in regard to sexual activity concerns.

The third phase of the PLISSIT model is specific suggestions. This level requires the healthcare provider to have advanced knowledge on the topic and comfortably collaborate with the patient on problem areas and potential strategies (Luchterhand, n.d.). Specific suggestions may include proposing lifestyle changes, medication adjustments, positioning equipment, or referral to a provider with more expertise. The intention of specific suggestions is to directly help the patient within a relatively short time frame (Rutte et al., 2015). Survey questions related to this stage included asking healthcare providers whether or not they provide specific suggestions within their professional scope of practice, and what disciplines they are most likely to refer a client to for sexual activity concerns.

Intensive therapy is the last level of the PLISSIT model. Intervention at this level is needed for patients whose areas of concern are outside of the healthcare provider’s knowledge and require more detailed consultation, such as a sex therapist or specialty...
area physician (Luchterhand, n.d.). This level has the fewest patients out of any PLISSIT model phase (Luchterhand, n.d.). The survey did not address intensive therapy, aside from gauging an understanding for referral suggestions.

While occupational therapists, physical therapists, and nurses may not always be knowledgeable or comfortable enough to provide intensive therapy, specific suggestions, limited information, and granting permission for the patient to express sexual activity or intimacy concerns would facilitate more holistic care. Identifying sexual activity or intimacy as a valid and normal concern by granting the patient permission to discuss concerns can lead to correctly identifying resources and needed referrals that may otherwise be overlooked.

By using the PLISSIT model to guide the creation of the survey, researchers were able to gain an understanding of healthcare providers’ current comfort and education levels with the topic, what they perceive to be appropriate timing to address sexual activity concerns, and explore how each profession views healthcare roles and responsibilities regarding sexual activity intervention. If the perceived roles of healthcare providers can be better understood, the PLISSIT model could be utilized more consistently and thoroughly across all healthcare providers. An emphasis can be placed on its dynamic structure and ability to grant the patient permission to freely discuss sexual activity concerns at any point in the therapy process with providers who are knowledgeable about their profession’s scope of practice. By doing so, concerns can be readily identified and directed to an appropriate resource despite the provider’s current knowledge level of specific interventions.
Purpose

The purpose of the study was to explore 1) how healthcare providers (physical therapists, occupational therapists, and registered nurses) perceive role delineation when addressing patient concerns about sexual activity, and 2) the level to which physical therapists and registered nurses believe sexual activity is outlined in the scope of practice for occupational therapy.

Problem Statement

Sexual activity is under-addressed by healthcare providers. It is unclear which profession is expected to address sexual activity in physical disability inpatient rehabilitation settings. It is also unclear as to how other professions perceive the role of occupational therapy in regard to addressing sexual activity concerns.

Hypothesis

The researchers hypothesized that there will be inconsistent responses when healthcare providers are asked which profession is most appropriate or likely to address sexual activity concerns, demonstrating insignificant results \( (p > 0.05) \). It is also anticipated that physical therapists and nurses will be uncertain as to occupational therapy’s role in addressing sexual activity concerns, demonstrating significant results \( (p < 0.05) \).

Assumptions

It was assumed that the participants would provide truthful responses to the survey questions as the survey was designed to be anonymous and voluntary. The validity of the participant’s responses cannot be guaranteed.
Scope and Delimitation

Limitations of the study include the use of gatekeepers to access participants, possibly decreasing response rates. In addition, the validity and reliability of the survey used in this study was not established. Lastly, specific variables and constants were condensed in order to increase significance during data analysis.

The location of the researchers, the study advisor, and the participants necessitated the use of an online survey. The researchers were located at the University of North Dakota Occupational Therapy Department in Grand Forks, ND and their advisor was located at the University of North Dakota Occupational Therapy Department Wyoming Site in Casper, Wyoming. The participants were located at Sanford Health facilities in Fargo, ND, Bemidji, MN, Bismarck, ND, and Sioux Falls, SD. The survey was available for a total of four weeks (January 18, 2017-February 15, 2017).

Importance of the Study

Sexual activity concerns is an important area to address with patients, although the literature base indicated that it often goes unaddressed. Understanding how healthcare providers perceive their own and other professions’ roles when addressing sexual activity can provide a baseline for establishing future guidelines and protocols when confronted with this area of concern by patients. Awareness of knowledge and comfort levels among professions may increase collaboration, teamwork, and consistent application of aspects of the PLISSIT model.
Definition of Terms

Sexual activity: “Engaging in activities that result in sexual satisfaction and and/or meet relational or reproductive needs” (American Occupational Therapy Association, 2014, p. S19).
CHAPTER II
LITERATURE REVIEW

Current Concerns

Often times, people only think of the physical loss and permanent disability associated with certain diagnoses or illnesses, however, the underlying psychosocial and emotional disruptions that include sexuality, though not seen as clearly, are just as important. Specifically, research shows that 50-60% of individuals who have suffered a TBI experience sexual functioning changes (Sakellariou & Algado, 2006). With the large percentage of individuals experiencing sexual challenges, it is discouraging to find that sexual activity concerns often go unaddressed.

In a qualitative study about women with SCI, the women reported challenges with understanding what sexual positions would be possible for their level of injury and how to make adaptations in order to engage in sexual activity (Fritz et al., 2015). These challenges were largely due to the women reporting that they did not receive support or education regarding sexuality (Fritz et al., 2015). One woman with limited sensation from her SCI, reported that since she did not receive any sexual information throughout her rehabilitation, she was unsure if engaging in sexual intercourse was even safe. In addition to SCI, sexual activity concerns are important to discuss with any diagnosis. According to Jaarsma et al. (2010), patients with cardiac problems were also concerned about their ability to resume sexual activity and reported needing sexual education as well. It is
important that healthcare providers are aware of the concerns of their patients wanting
sexual education as part of their treatment so that providers can increase their skills,
knowledge, and comfort in this area.

Knowledge of the definition and philosophies of rehabilitation can help healthcare
providers understand why it is so important to include sexual education in their treatment.
According to Booth et al. (2003), “Philosophies of rehabilitation have expanded to
encompass all life domains and therefore a holistic rehabilitation service should include
opportunities to address sexuality issues” (p. 249). The World Health Organization
(2017) defines rehabilitation as, “a process aimed at enabling them to reach and maintain
their optimal physical, sensory, intellectual, psychological and social functional levels”
(para. 1). In order to provide patients with holistic rehabilitation, every aspect that may be
affected by their injury or illness, should be addressed. However, sexuality concerns are
often neglected during the rehabilitation process (Fritz et al., 2015; Olsson et al., 2012;
Simpson et al., 2006; Stein et al., 2013). When 23 staff and 180 patients from a
rehabilitation center in New Zealand were surveyed about sexuality in a rehabilitation
setting, both groups reported that sexuality is not adequately addressed during the process
(Simpson et al., 2006).

Healthcare providers go into their respective fields to help others, not to
intentionally neglect areas of their patients’ health. Therefore, many studies have been
conducted to identify barriers of healthcare providers addressing sexual issues with
patients. Researchers have found that health professionals did not initiate the topic;
instead they preferred to wait until the patient introduced it (Dyer & das Nair, 2014; Fitch
et al., 2013). The main concern with this approach is that many patients believe it is the
professional’s role to initiate the conversation (Fitch et al., 2013). The result is that neither the professional nor patient initiates the conversation, and the topic of sexuality, though highly important, goes unaddressed.

One of the most highly cited barriers for all healthcare professionals reported in the literature is the lack of training and knowledge about sexuality (Byrne et al., 2013; Fitch et al., 2013; Olsson et al., 2012; Rimmer et al., 2010). Specifically, nurses reported that they avoid the topic of sexuality due to having insufficient skills and knowledge for specific recommendations (Olsson et al., 2012). Additionally, healthcare providers have acknowledged that if they open up the discussion about sexuality, there may be questions they will be unable to answer (Rimmer et al., 2010). Increasing the confidence of all healthcare professionals when addressing sexuality, by making it a regular aspect of assessment, having materials to hand out, or just understanding who the patient should be referred to would decrease this barrier. With a more thorough understanding of the PLISSIT model, healthcare professionals would understand that it is okay to not have all the answers (Dyer & das Nair, 2014). Rather, they could open the door by providing patients with permission to discuss their sexuality concerns. At that point, the healthcare provider could make a referral to a more appropriate profession depending on the needs.

From both the client's and healthcare professional’s points of view, a barrier to initiating the topic of sexuality was not having an opportunity to discuss the issues privately (Byrne et al., 2013; Olsson et al., 2012). This can be due to patients sharing hospital rooms or receiving therapy in a therapy room versus a private room. According to Jaarsma et al. (2010), a patient-identified barrier to asking questions about sexual concerns was that their perception of the healthcare providers’ knowledge on the topic...
may be limited. Also, some patients feel that the provider might not understand the
difficulty for the patient to bring up sexuality, as it is a sensitive topic (Jaarsma et al.,
2010). Furthermore, clients do not always want to discuss sexuality, not because of
decreased sexual desire, but due to chronic fatigue, hormonal changes, or body image
alterations (Rimmer et al., 2010). This implies that it may be important for a healthcare
provider to briefly introduce the topic by giving them permission to discuss it, but let the
client know that it can be reintroduced when he or she feels ready. Overall, Byrne et al.,
(2013) found that patients perceive less barriers to communicating about sexual health
than professionals do, and many said that they would not find it embarrassing to discuss
their sexuality concerns.

As with any sensitive topic, unfortunately the barriers often outweigh the
opportunities for discussion. It is a recurring theme that healthcare providers believe that
sexual issues are considered important and should be addressed (Anderson, Borisoff,
Johnson, Stiens, & Elliott, 2007; Fritz et al., 2015; Helland, Garratt, Kjeken, Kvien &
Dagfinrud, 2013; Stein et al., 2013). However, the majority of providers do not address
sexuality due to fear of an embarrassing situation, lack of training and knowledge, limited
private space, or thinking that it is someone else’s responsibility (Byrne et al., 2013; Dyer
& das Nair, 2014; Fitch et al., 2013; Rimmer et al., 2010). Since occupational therapy,
physical therapy, and nursing are all considered part of the interdisciplinary team, each
profession was independently researched to determine their role when addressing sexual
activity concerns.
Role of Occupational Therapy

To outline occupational therapy’s role in addressing sexuality, the American Occupational Therapy Association (AOTA) published a consumer fact sheet titled, “Sexuality and the Role of Occupational Therapy” (MacRae, 2013). Although the fact sheet acknowledges that sexual activity is in the scope of OT practice, and it is there to help facilitate sexual activity intervention, the evidence shows that OTs are rarely addressing clients’ concerns in this area (Fritz et al., 2015; Stein et al., 2013). Fritz et al. (2015) found that patients with a SCI reported receiving OT, though intervention did not include the topic of sexuality. Similarly, in a cross-sectional survey of 38 post-stroke patients intending to explore preferences when receiving counseling or information for sexuality post-stroke, occupational therapy did not rank among the top three preferred professionals to discuss sexual concerns as it followed behind physician, nursing staff, and physical therapy (Stein et al., 2013).

Evidence indicates that OTs rarely address sexuality, but that they understand clients are sexual beings who may require sexual intervention after an injury, diagnosis, or life changing events (Anderson et al., 2007; Fritz et al., 2015; Stein et al., 2013). The issue is that few OTs pursue the topic of sexual activity concerns with their clients. Sexuality is an important aspect of human identity (Isaksson, Josephsson, Lexell, & Ska¨r, 2007; Sakellariou & Algado, 2006). It is much more than a basic drive, and it can be expressed in many different ways to be considered an occupation. Therefore, OTs have a responsibility to address it in order to incorporate all meaningful occupations and treat the client holistically. People who suffer from life changing events, like a SCI for example, change their occupational identity and their need for participation in desired or
needed occupations (Isaksson et al., 2007). One aspect of the change in occupational identity and desired occupations is sexual identity and sexual intimacy, for which OTs can play an important role (AOTA, 2014; Fritz et al., 2015).

**Role of Nursing**

Much of the research regarding treating patient sexual concerns includes nurses. According to Duldt and Pokorny (1999) nurses hold an ethical responsibility to provide patients with coping and understanding of their future needs related to their diagnosis, which may include sexual activity concerns. Similar to occupational therapists, nurses are expected to deliver care using a holistic approach that encompasses social, physical, psychological, and spiritual aspects of well-being (Olsson et al., 2012). Using this approach, sexuality should be part of nursing dialogue when assessing overall patient concerns. When considering the spiritual and emotional well-being of their patients, nurses reported that they indeed, should be there to support the patient and initiate the conversation (Saunamaki & Engstrom, 2012). In a study where 15 healthcare professionals were surveyed in order to determine which providers were most likely to initiate a conversation about sexuality, nurses were ranked the highest (Helland et al., 2013).

Across the literature, most nurses report that sexuality falls under their responsibility (Jaarsma et al., 2010; Olsson et al., 2012; Saunamaki & Engstrom, 2012). In one particular study, 87% of the 157 participants reported nursing to have a responsibility for addressing sexuality (Jaarsma et al., 2010). However, the nurses in a study by Olsson et al. (2012) reported that they were unsure how to initiate the conversation, exactly who should initiate it, and when the most appropriate timing would
be. Additionally, they did not report discussing sexual issues as part of their daily routine (Olsson et al., 2012). Conflicting research shows that avoidance and excluding sexuality from daily discussion is not the case for every nurse. Saunamaki & Engstrom (2012) found that a few nurses reported the topic of sexuality to be no different to them than any other topic, and reported discussing it with their patients daily. The results of that study indicated that the nurses who routinely discuss sexual issues did so because they had a strong desire to treat their patients in every way possible (Saunamaki & Engstrom, 2012).

Nurses often spend the most time with patients and are present through all phases of rehabilitation. Therefore, it is vital that nurses have skills that either facilitate discussion on sexuality, or offer proper referral pathways if patients would like further information. The challenge is that the majority of the nurses in a study by Jaarsma et al. (2010) reported having minimal to no post-education on how to treat or deal with patients’ sexuality concerns.

**Role of Physical Therapy**

In a study among PT, OT, and nursing students, Areskoug-Josefsson, Larsson, Gard, Rolander & Juuso (2016) indicated that physical therapy students were unsure if sexual health was apart of their scope of practice. The physical therapy students were more concerned about the embarrassment of their patients when addressing sexuality than the issue itself, and therefore did not predict that they would allot time to discuss sexual health issues with their patients in their future careers. The physical therapy students felt significantly less comfortable than OT and nursing students when initiating conversation about sexual health. Although both the PT and OT students reported significantly less experiences of sexual health education in their academic programs, PT alone identified a
lower need for basic sexual health knowledge and training in comparison to OT and nursing students (Areskoug-Josefsson et al., 2016). In addition, PT students rated the need to increase their sexual health knowledge as less important than OT and nursing students (Areskoug-Josefsson et al., 2016). Although PT students rated the importance of sexual health education lower, it does not discount their importance in the overall role of addressing sexuality. With a more clear understanding of who addresses sexuality and to what extent, physical therapists can play an important role on the interdisciplinary team by referring patients to a profession with more knowledge and understanding of sexuality.

**Role Delineation**

In many healthcare settings, PTs, OTs, nurses, and additional professionals are expected to collaborate in order to provide the most well-rounded patient care. Interestingly enough, a team approach may not necessarily be the most efficient or effective when it comes to raising the topic of sexuality with a patient. Dyer and das Nair, (2014) found that without delegating a specific profession to address sexuality, healthcare providers are less likely to introduce the topic of sexuality at all and assume that someone else will cover it. This view on a team approach is also supported by (Rimmer et al., 2010), who found that if a particular topic or area is not assigned as one person’s responsibility, it may be viewed as nobody’s responsibility. Olsson et al. (2012) reported that similar issues arose when nurses expressed discomfort about addressing patient sexuality, hoping that “somebody else” would take on the responsibility of initiating sexuality concerns with patients. Furthermore, findings from Fitch et al. (2013) support the need to clarify role expectations for cancer nurses, as well as other professionals on
the team, about patient care in terms of addressing sexuality.

As previously mentioned, several barriers have been identified in literature that prevent healthcare providers and patients from addressing sexuality concerns. Across the board of providers, one of these barriers includes a reported lack of education about specific interventions or communication skills (Byrne et al., 2013; Fitch et al., 2013; Rimmer et al., 2010). Byrne et al., (2013) found that the overwhelming majority of cardiac rehabilitation staff members agreed that there were no particular service guidelines in regards to assessment or counseling for addressing patient sexuality concerns succeeding coronary heart disease. Furthermore, almost half of the participants stated that more staff should be required in order to build referral pathways (Byrne et al., 2013). In a study by Ivarsson, Fridlund, & Sjoberg (2010), it was found that 80% of hospitals did not have developed protocols for collaboration with specialties for sexual problems. Fitch et al. (2013) found that along with clarifying role expectations of all team members, a provision of education to support the anticipated role should be in place. Participants in a study by Rimmer et al., (2010) also reported a lack of education, with 62% of participants stating they did not have specialized training regarding sexuality and intimacy.

If a specific profession were to be responsible for addressing sexuality, there are several interpretations of which provider would be the best equipped. Rimmer et al., (2010) found that providers view nurses as having the most education and necessary curriculum about human sexuality needed to address the topic. However, Rimmer et al., (2010) also suggested that professions such as physicians, PTs, OTs, psychologists, and social workers may also be appropriate to introduce discussion regarding sexuality and
intimacy concerns. In contrast, Helland et al., (2013) found that the rheumatologist was most frequently reported to address sexuality, followed by nurse, general practitioner, and psychologist. Trailing those professions included OT, PT, family relative, and social worker (Helland et al., 2013).

According to Dyer and das Nair (2014), many participants were still hesitant to delegate a specific professional responsible for addressing sexuality, agreeing that the patient should be able to choose whom to introduce his or her concerns to. Although it is important for a patient to feel comfortable with his or her provider when discussing sexuality concerns, this does create several potential limitations. First, this may put the responsibility to initiate discussion on the patient. It also creates the potential for healthcare providers to leave the discussion dormant and assume another team member will address it. This contraindicates findings that state patients should not be solely responsible for initiating discussion about sexuality, while supporting the trend of inadequate coverage of sexuality and intimacy concerns by healthcare providers (Rimmer et al., 2010).

Teamwork and Solutions

While clearly identifying a healthcare professional to address sexuality may be an option to successfully decrease role confusion and increase provider responsibility (Dyer & das Nair, 2014; Fitch et al., 2013; Rimmer et al., 2010), there are additional measures that can be considered and implemented. For example, all healthcare providers can create an opportunity to discuss sexuality concerns. Although this may not end in specific suggestions, it could open the door to referral pathways and emotional support (Dyer & Niar, 2014). This requires professionals to utilize interpersonal communication skills and
counteract avoidance by routinely asking about sexuality until it is no longer a source of anxiety (Dyer & das Nair, 2014). Rimmer et al. (2010) also supports this concept of normalizing discussion in order to increase overall quality of care and communication. Utilizing a patient-report needs assessment tool may help providers address sexuality and intimacy more routinely (Helland et al., 2013).

In order to combat the lack of education that health providers feel regarding sexuality, it is necessary for health organizations and associations to recognize the joint responsibility they have to develop training courses and specific materials about sexuality and intimacy issues (Helland et al., 2013; Ivarsson et al., 2010). It is also noted that the way healthcare providers present information about sexuality may not always match patient preferences (Stein et al., 2013). Recognizing this may further encourage rehabilitation programs to develop training sessions, which will appropriately prepare healthcare providers to discuss the sensitive topic (Stein et al., 2013). Fitch et al. (2013) found that healthcare providers and patients reported that having a list of available services with details as to what those services offer, along with an individual with specialized knowledge on staff would be advantageous. Establishing clearer referral pathways to an individual with specific knowledge about sexuality and intimacy issues is suggested in additional literature (Byrne et al., 2013; Rimmer et al., 2010).

Along with assuming responsibility and building education, the inherent value of teamwork has been noted as important to healthcare providers when it comes to consulting with other professionals in order to assist with gaps of experience or knowledge (Dyer & das Nair, 2014; Helland et al., 2013). Although there may not be a designated professional at every facility to address patient sexuality concerns, it is
important that each team member is aware of their scope of practice, increases their knowledge in areas they may lack, employ interpersonal communication skills, and seek further team input when necessary. By avoiding these duties, an unfortunately common attitude to avoid discussing sexuality is being created across healthcare providers (Saunamaki & Engstrom, 2012).

**Timing**

When it comes to raising the topic of sexuality with a client, timing is a key factor in the delivery of information. Although timing is important, conflicting research exists as to what point in the treatment course sexuality should be addressed. Dyer and das Nair (2014) found that professionals were apprehensive about introducing the topic of sexuality too early in the rehabilitation process, with a perceived notion that they would offend the patient. In contrast, research demonstrates that most consumers are not offended by the discussion and do anticipate professionals to ask questions about sexuality (Dyer & das Nair, 2014). It can also be important to raise the topic of sexuality as early as possible due to the increase in shorter hospital stays. There is a risk that the patient will not receive all necessary precaution information regarding sexual activity that follows after health concerns such as myocardial infarctions (Ivasrsson et al., 2010). In addition, by raising the topic of sexuality early on, healthcare professionals are better able to understand the client’s values, beliefs, and apprehensions, therefore setting the scene for a more therapeutic relationship throughout the rehabilitation process (Sakellariou & Algado, 2006).

Although some service-users may prefer that sexuality be introduced early, Stein et al. (2013) suggests that physicians should raise the topic periodically throughout
treatment due to the initial overwhelming amount of information and concerns that often come along with the acute phase of rehabilitation. Regular discussions about sexuality are also supported by Helland et al. (2013), as well as upon initiation of new medications or general information of the disease. When looking at the inpatient rehabilitation setting for patients post-spinal cord injury, Fisher et al. (2002) found that it was a pinnacle time for changes in patients’ awareness about sexuality, but they may not have had the life experiences necessary in which questions could arise from, especially when conflicted by accompanying symptoms. Therefore, it was concluded that the best form of patient education would be ongoing sexuality counseling and resources (Fisher et al., 2002).

The preference for timing may also be dependent on the client’s current status, developmental stage, prior experience engaging in sexual activity, and their overall level of adjustment (Fritz et al., 2015). For example, Fisher et al. (2002) reported that most individuals show little interest in sexual activity in the first months after a spinal cord injury. However, sexuality can be addressed in other ways, such as coming to terms with one’s new body after injury. In some cases, sexuality concerns are looked at specifically in context to a body part (i.e., radiation treatment to breast) and not raised again (Fitch et al., 2013). Fitch et al. (2013) reported that if sexuality was going to be a concern for patients, it was not expressed until after treatment.

It appears that the best time to address sexuality is dictated by client preferences and their contextual health situation. Although some points in a patient’s recovery process may be more appropriate than others to discuss sexuality, the important consideration is that it is introduced and not entirely disregarded.
Addressing Sexuality in the Future

Initial recognition of how under-addressed the topic of sexuality with clients has been established. Barriers for both practitioners and clients have been explored. The importance of addressing sexuality at some point in the client’s rehabilitation process has been validated. Regardless of these advances, there are still improvements to be made and responsibilities to uphold when it comes to the practitioner’s role in addressing sexuality.

Along with explicit knowledge about interventions for sexuality, interpersonal skills are needed as well. Specific training in how to introduce the conversation to a client, discuss the best route for intervention or referral, and listen and respond appropriately to patient concerns could all be of focus (Fitch et al., 2013). Healthcare providers may also need to expand their definition of “sexuality”. Sexuality may not mean the engagement in sexual intercourse for every client. Expanding this term to include sexual health, intimacy such as closeness (kissing, holding hands, expressing emotion), and self-esteem are important aspects of sexuality as well (Fritz et al., 2015).

The way in which educational materials are constructed and presented to clients is another vital step in delivery of information. Fritz et al. (2015) suggested that the use of scripts, role playing, and didactic techniques may be helpful to address social challenges and difficulties initiating relationships which may surface after injury. In order to do this, healthcare providers must feel confident and knowledgeable about the topic themselves. Training programs focusing on sexuality could be approached from an interdisciplinary standpoint in order to ensure team competence in general areas and gain a better understanding of who would be appropriate for further referral (Booth et al., 2003).
According to Simpson et al. (2006), using a workshop format to deliver sexuality training has led to increased staff knowledge, comfort, and more sexuality discussions with patients. Establishing more opportunities for healthcare providers to educate themselves and practice these skills could play a large role in how clients’ sexuality concerns are addressed. Fisher et al. (2002) found that more intervention in support of sexual health after spinal cord injury leads to increased satisfaction with not only patient sex life, but overall function.

There is also a need to determine clearer guidelines and increase the understanding of each healthcare professional’s role. Although it may not be one person’s sole responsibility to address sexuality with patients, it is important to establish how much knowledge each profession on the team possesses and practices. Saunamaki & Engstrom, (2012) suggested that those in charge should encourage nursing staff to discuss sexuality as a valid topic with patients by utilizing verbal support and written guidelines.
CHAPTER III

METHODOLOGY

A nonexperimental prospective quantitative study was conducted with inpatient rehabilitation occupational therapists, physical therapists, and registered nurses employed by Sanford Health. Data was collected utilizing a survey that was designed by the researchers and was distributed electronically via Qualtrics®. The study was approved by the University of North Dakota Institutional Review Board (IRB) (see Appendix D) and Sanford Health IRB (see Appendix F).

Locale of the Study

The location of the researchers, advisor, and the participants necessitated the use of an online survey. The researchers were located at the University of North Dakota Occupational Therapy Department in Grand Forks, ND and their advisor was located at the University of North Dakota Occupational Therapy Department Wyoming Site in Casper, Wyoming. The participants were located at Sanford Health facilities in Fargo, ND, Bemidji, MN, Bismarck, ND, and Sioux Falls, SD, and were asked to complete the survey online at their convenience. The survey results were confidential and anonymous, therefore, information was not obtained that connected a participant to a specific location.

Participants

Purposive sampling was used based on the purpose of the study, which was to explore occupational therapists’, physical therapists’, and registered nurses’ perceptions about their role delineation when addressing client sexual activity concerns in an
inpatient rehabilitation setting. The researchers also explored physical therapists’ and registered nurses’ perceptions regarding occupational therapy’s scope of practice pertaining to sexual activity intervention. The researchers did not have direct contact with the participants. Following the Sanford IRB protocol, the researchers contacted the Sanford human resources department in order to be directed to the directors/managers of the occupational therapy, physical therapy, and registered nursing departments; these individuals were identified by Sanford Health and became the gatekeepers for survey distribution. The researchers then contacted the gatekeepers, who agreed to send the survey link to their staff via email. The survey link was sent to 8 gatekeepers who collectively agreed to contact 41 occupational therapists, 22 physical therapists, and 63 registered nurses working in the Sanford Health system.

The inclusion criteria included the following: participant must be an inpatient rehabilitation occupational therapist, physical therapist, or registered nurse employed by Sanford Health and be at least 20 years of age. The exclusion criteria included the following: no occupational therapy, physical therapy, or registered nursing inpatient rehabilitation work experience, under 20 years old, and not employed by Sanford Health.

The informed consent form preceded the survey (see Appendix B). Participants were informed that by completing the survey, they had provided consent.

**Survey Development**

The development of the survey was based on an extensive literature review, application of the PLISSIT model, and development of the research question that the researchers sought to answer. The survey content was reviewed by two researchers and the faculty advisor during development. Additional review was provided by a statistician.
working in the School of Medicine and Health Sciences.

The final survey included twenty questions consisting of multiple choice and ranking order responses. In order to better understand the target population and to increase the ability to generalize the results, demographics including gender, age range, profession, and years of experience range of the participants were included in the survey. The survey also included questions related to how participants perceived their profession’s role in addressing sexual activity, their preparedness to discuss sexual activity, and their perceptions regarding sexual activity as outlined in occupational therapy’s scope of practice. The implemented survey can be found in Appendix A.

Procedure

All participants were given a brief introduction to the survey via a forwarded invitational email from the researchers to the gatekeepers on January 18, 2017. The email included the purpose of the study, the link to complete the survey, and informed the participants of their expectations regarding confidentiality. A reminder email was sent to the gatekeepers to forward onto their staff on February 1, 2017. The survey was available for a total of four weeks (January 18, 2017-February 15, 2017). Responses to the survey questions were kept confidential in a password protected Qualtrics® account and were gathered anonymously. By enabling the options of “Anonymize Response” and “Anonymous Link” on Qualtrics®, respondents’ IP address and location were removed from the results. Participation was voluntary and could be discontinued at any time.

Tools for Data Analysis

The quantitative data from the survey was analyzed using the Statistical Package for the Social Sciences® (SPSS) version 24.0 software program. Descriptive statistics
were completed using frequencies, chi squares, crosstabulations, independent t-tests, and one-way ANOVAs to test for statistical significance using (p<.05). The results of the analysis are presented in Chapter IV.
CHAPTER IV

PRESENTATION, ANALYSIS, INTERPRETATION OF DATA

SPSS 24® was utilized to calculate frequencies of demographic information. A total of 36 healthcare providers, representing three professions employed through Sanford Health, participated in the survey. The three professions surveyed were registered nurses, RN=6 (16.7%), occupational therapists, OT=23 (63.9%), and physical therapists, PT=7 (19.4%).

Demographics

Healthcare providers who reported to be between the ages of 26-35 made up 36.1% of respondents. The majority of respondents (63.9%) reported to be 45 years or older. It was hypothesized that age may show a significant relationship with role understanding and higher comfort levels regarding sexual activity concerns with patients, which showed to be insignificant through data analysis.

An overwhelming majority of respondents were female (91.7%), while 1 male OT and 1 male RN made up 5.6% of respondents. One respondent, an OT, chose not to answer the question. There were not enough male respondents to test for significant relationships analyzing gender.
Figure 1. Overall, RNs showed to have the most years of work experience, with 66.7% of respondents having 10 or more years of experience. PT practitioners followed, with 51% of respondents reporting 10 or more years of experience. Lastly, 47.8% of OTs reported to have over 10 years of experience. No RNs reported to have less than one year of experience, while 8.7% of OTs reported less than one year of experience, and 14.3% of PTs reported having less than one year of experience. It was hypothesized that more experience would correlate with better role understanding and higher comfort levels regarding sexual activity concerns in patients, which showed to be insignificant.
In order to obtain a better understanding of each profession, respondents were asked how well they felt sexual activity is outlined in their scope of practice. Results indicated that occupational therapists and registered nurses consider knowledge regarding sexual activity to be outlined in their own profession to some degree. In contrast, physical therapy was the only profession to report uncertainty or disagree that sexual activity is within their scope of practice ($p = 0.005$). Similar results were found in the literature in a study conducted with PT, OT, and nursing students, where PT students indicated that they were unsure if sexual health was a part of their scope of practice (Areskoug-Josefsson et al., 2016).
In addition, it is important to acknowledge that out of the seven PT respondents, two reported that sexual activity is clearly outlined in their scope of practice. This shows that there is potential role confusion inside this profession to some degree. Regardless of how each healthcare provider perceives their role in addressing sexual concerns, it is important to understand how using the PLISSIT model could be incorporated into practice. By implementing the first level, permission, it is believed that 70% of all patients’ sexual concerns can be resolved (Ayaz, 2009). Any profession on the interdisciplinary team can grant permission to their patients to ask questions or discuss concerns they may have regarding sexual activity.
When asked to identify how clearly sexual activity is outlined in occupational therapy, all physical therapists (7/7) and over half of registered nurses (4/6) answered “uncertain”. In contrast, only one occupational therapist (1/23) answered “uncertain” (p = 0.00). This shows that registered nurses and physical therapists demonstrated an overall lack of understanding of how sexual activity is outlined in the occupational therapy scope of practice. Recognizing this outcome indicates the need to educate other professions on occupational therapy’s scope of practice in order to enhance role understanding.

The need for interdisciplinary role understanding and collaboration is supported by the PLISSIT model (Dyer & das Nair, 2014). Increasing awareness of occupational therapy’s scope of practice and its inclusion of sexual activity assistance with patients may allow registered nurses and physical therapists to seek additional knowledge from
occupational therapists on this topic. By doing so, registered nurses and physical therapists would be able to give the patient “permission” to voice concerns while suggesting occupational therapy resources as “limited information”, or referrals.
OT Rank

Figure 4. There is a lack of literature exploring how interdisciplinary professionals perceive OT’s role, in specific, when addressing sexual activity concerns in patients. To better understand this perception, all respondents were asked to rank occupational therapists among registered nurses, psychologists, physicians, and physical therapists in terms of who is most appropriate to address the topic. In a 2-tailed t-test, there was a significant difference in how OTs responded compared to the responses of PTs and RNs (p=0.037). Results demonstrated that OTs were more likely to report OT as the first or second most appropriate choice for professional referral.

In comparison, RN respondents ranked OT either 3rd or 4th, and the PT respondents had varied responses ranking OT 1st through 4th. Overall, 60.6% of respondents ranked occupational therapists as 3rd or 4th out of 5 for most appropriate to address sexual activity concerns.
Overall Ranking

Physicians (54.5%) and psychologists (24.2%) were ranked as the most appropriate professions to address sexual activity concerns in patients. Following this, 15.2% respondents ranked OT first, 6.1% of respondents ranked RN first, and no respondents ranked PT first. It should be noted that most respondents who ranked OT as most appropriate were OTs themselves. Although it is important to understand who is most likely to be ranked the highest, it is more important to understand what each profession's role is on the healthcare team. Rimmer et al., (2010) suggested that professions such as nurses, physicians, PTs, OTs, psychologists, and social workers may be appropriate to introduce discussion regarding sexual activity and intimacy concerns in patients. Using the PLISSIT model, each healthcare provider has a vital role which should start with granting permission to the patient to discuss sexual concerns (Ayaz, 2009). From there, the healthcare provider can use limited information, if they have the appropriate knowledge, or refer the patient onto the appropriate profession depending on the area of concern.

Most Likely to Address

Corresponding with the previous question, 60% of respondents reported physicians or psychologists as the most likely profession to address sexual activity concerns in patients at their facility. Occupational therapists followed as the most likely to address sexual activity concerns with 22.9% of respondents reporting OT to be the most likely. However, it is important to note that those who reported OT as most likely to address sexual activity, were all OTs. This demonstrates that OTs understand their scope of practice in relation to sexual activity, but other professions do not consider this topic to
be within OT’s role.

Regardless, if professionals more clearly understand the responsibilities within healthcare roles and have awareness of their capabilities, they may be more likely to uphold role duties. Upholding role duties does not necessarily entail direct intervention on behalf of one provider, but it is important for the initial provider to grant the patient “permission” to discuss sexual activity and seek collaboration with the interdisciplinary team when appropriate.

**Services/Resources**

Respondents were asked what services and resources they offer at their facility with the choices being pamphlets, patient education courses, referrals, or specific suggestions (positioning, compensatory techniques, adaptive equipment). The results indicated that 63.9% of respondents reported to provide pamphlets, and 55.6% of respondents reported that they provide referrals. This means that over half of the respondents have the opportunity to provide some sort of service or resource to their patients. Providing general information in the form of a pamphlet is the second stage of the PLISSIT model, limited information (Ayaz, 2009). Furthermore, delving into the third stage of the PLISSIT model, specific suggestions, the results from this survey indicated that 60% of OTs, 42.9% of PTs, and 16.7% of RNs reported to provide specific suggestions related to positioning, compensatory techniques, and adaptive equipment.

The overall responses to this question are interesting when compared with how many patients per month providers reported to discuss sexual activity concerns with. The majority of respondents (91.4%) reported to address sexual activity with only 0-1 patients per month. Therefore a conclusion is drawn that although over half of the facilities have
the resources and services to do so, these resources are not being utilized to the degree they could be. In addition, if 91.4% of respondents reported that they are only addressing sexual activity with 0-1 patients per month, the number of healthcare providers initiating the first stage of the PLISSIT model, permission, is limited.

The majority of respondents (77.8%) reported that their profession, at the facility they work at, does not provide patient education courses. This statistic corresponds with the research in a study addressing sexuality by Rimmer et al., (2010), who found that 62% of participants reported a lack of education or specialized training regarding sexuality and intimacy in their academic program. This suggests that a lack of education on sexuality/intimacy training results in poorly utilized resources and services for clients.

**Most Appropriate Timing**

When asked the most appropriate timing for sexual activity intervention, 85.7% of respondents reported “during intervention” with the other choices including initial evaluation, upon discharge, or post-discharge. There is conflicting research as to what point in the treatment course would be most appropriate to discuss sexual activity. It has been reported that professionals are hesitant to introduce the topic of sexuality initially for fear that they may offend the patient (Dyer & das Nair, 2014). However, research also demonstrates that most consumers are not offended by the discussion and do anticipate professionals will ask questions about sexuality (Dyer & das Nair, 2014).

Although there is not a definite answer as to when sexual activity should be addressed, offering “permission” to the patient to openly discuss their concerns in the initial evaluation would be beneficial. This way, the patient understands that sexual activity can be a topic of discussion at any point in the rehabilitation process.
Interest in Attending a Workshop

When asked if respondents would be interested in attending a workshop on how to address patients’ sexual activity concerns, 21/34 (62%) reported an interest to attend to some extent. This information is promising for the future of healthcare as it shows over half of the respondents are interested in gaining knowledge in an area of health that often goes unaddressed (Dyer & das Nair, 2014; Fritz et al., 2015; Olsson et al., 2012; Simpson et al., 2006; Stein et al., 2013). Therefore, a workshop to increase healthcare providers’ understanding of sexual activity may be well-received. Workshops have the potential to cover a wide array of PLISSIT components including interdisciplinary and patient communication skills (permission), general precautions and impact related to diagnoses (limited information), and intervention strategies (specific suggestions).

Reasons for Not Addressing Sexual Activity

When providers were asked why they did not address sexual activity, the most common response was a reported lack of knowledge (70.9%). This has been supported in multiple literature findings, as lack of education or knowledge is one of the most highly cited barriers for all healthcare professionals (Byrne et al., 2013; Fitch et al., 2013; Olsson et al., 2012; Rimmer et al., 2010). This is important to note, because the PLISSIT model emphasizes that a lack of personal knowledge does not constitute as an excuse to avoid addressing sexual activity; the topic can still be acknowledged, but information outside of the provider’s scope of knowledge can be directed elsewhere (Booth et al., 2003; Dyer & das Nair, 2014). Although patient concerns may not be immediately addressed, at least they are made known and can be acted on.

Occupational therapists reported to be more likely to initiate discussion with their
patients (54.5%) in comparison to physical therapists (28.6%) and registered nurses (0%). In terms of nursing, these results contradict the findings of Hellend et al. (2013), who found nurses to be ranked the highest among healthcare professionals when determining who would be most likely to initiate a conversation about sexuality.

This shows that most providers are not following the first step in the PLISSIT model to grant patients “permission” to discuss sexual activity concerns. By implementing the first level, permission, it is believed that 70% of all patients’ sexual concerns can be resolved (Ayaz, 2009).

Three crosstabulation and chi-square tests were conducted for the following relationships:

1. Significance among profession, comfort levels, and profession’s perceived outline of sexual activity.
2. Significance among profession, years of experience, and profession’s perceived outline of sexual activity.
3. Significance among profession, years of experience, and perception of how sexual activity is outlined in occupational therapy.

All crosstabulation and chi-squares tests were found to be insignificant, showing no clear difference or pattern among the relationships listed above. However, those who reported higher comfort levels also reported a more clear idea of how sexual activity is outlined in their profession. This relationship was not statistically significant, but still slightly present.

Other variables including previous education in respective educational programs, feelings of preparedness, understanding of appropriate treatments and interventions, and
feeling comfortable about revisiting the topic of sexual activity were explored by conducting a cross tabulation using SPSS 24®. None of these variables demonstrated significant relationships among professions.

Insignificant and “split” responses may suggest role confusion, differing knowledge bases, and a wide variety of comfort levels. This is supported by literature findings that discuss the lack of clarity in role expectations and how this lack can lead to providers tendency to overlook sexual activity concerns in patients (Fitch et al., 2013; Dyer & das Nair, 2014; & Rimmer et al., 2010).

Because of this lack, it is important to incorporate the PLISSIT model, which will still allow patients to initially voice concerns about sexual activity while being referred to healthcare providers with proper knowledge. This also shows the importance of an interdisciplinary approach, as it is imperative to seek knowledge and expertise of other professions or individuals. Lastly, this may indicate a need for further education such as a workshop or communication skills training in order to increase personal knowledge and comfort levels that will allow healthcare providers to fulfill role duties.
CHAPTER V

CONCLUSIONS

Upon completion of this research study, the principal investigators have identified a summary of the research findings, limitations of the current research study, recommendations for further research, and conclusions drawn from the study.

Summary of Findings

A prospective, quantitative study was conducted to determine how OTs, PTs, and RNs, employed in inpatient rehabilitation at Sanford Health facility locations, perceived their profession’s role in addressing sexual activity concerns in patients, their preparedness to discuss sexual activity concerns, and their perceptions regarding sexual activity as outlined in occupational therapy’s scope of practice. To guide the research, the interdisciplinary PLISSIT model was used. The non-experimental prospective study was carried out through the utilization of a 20 question, online Qualtrics® survey. Although, the survey’s validity and reliability had not been established, important information was obtained.

According to the results from this research study, occupational therapists and registered nurses considered sexual activity to be outlined in their own scope of practice to some degree. In contrast, physical therapy was the only profession to report uncertainty or disagree that sexual activity is within their scope of practice. While utilizing the PLISSIT model, it is important to understand that although sexual activity may not be clearly outlined in a profession’s scope of practice, any healthcare
professional is still able to open the discussion with patients. By doing so, the healthcare professional can refer the patient to the most appropriate profession to address the sexual activity concerns.

Additionally, the participants were asked to identify how sexual activity is outlined in occupational therapy in order to gain an understanding of how other healthcare professionals perceive OT’s role. The results indicated that all the physical therapists and over half of the registered nurses answered “uncertain” regarding OT’s role with this topic. In contrast, only one occupational therapist answered “uncertain”. PTs, RNs, and OTs work closely on an interdisciplinary team in inpatient rehabilitation settings. In some cases, a patient’s sexual activity concerns may be appropriately addressed by an OT. Therefore, it is important for PTs and RNs to have a more clear understanding of OT’s role.

The survey also included questions related to overall comfort level for addressing patient sexual activity concerns. While the results of this data demonstrated insignificance, there was a slight correlation with those healthcare providers who reported higher comfort levels and those who reported a more clear idea of how sexual activity is outlined in their profession. One way to potentially increase comfort level, knowledge, and skills for addressing patient sexual activity concerns, would be to implement a workshop or in-service through the Sanford Health system. This may be well-received as over half of the respondents in this study reported interest in attending a workshop.

Overall, the varied responses in this research demonstrate the need to further investigate how patient sexual activity concerns are addressed in healthcare. No matter where healthcare providers feel their place is in the PLISSIT model, incorporating this
approach will allow patients to initially voice their sexual activity concerns and be referred to the appropriate healthcare provider with proper knowledge. This may increase the possibility of all areas of health to be addressed, while working as an efficient and effective interdisciplinary team that provides holistic care.

**Limitations**

Throughout the course of this research, limitations were identified that contributed to the results of the study. The validity and reliability of the survey, which was created by the researchers, was not established. Additionally, using online surveys poses a risk of response set error which may have impacted the results.

Following Sanford Health protocol, the researchers were required to use a gatekeeper, rather than be in direct contact with the OTs, PTs, and RNs working in inpatient rehabilitation. Although the researchers received confirmation from the gatekeepers that they would email the survey link to their staff, researchers cannot be certain that it was sent to all rehabilitation staff.

Furthermore, the small sample size and geographic region limits the ability to generalize the results of this study. Over half of the respondents were OTs (n=23) which may have caused some of the data to be skewed. To increase statistical significance, some of the variables and constants were analyzed by condensing the PTs and RNs into one response group.

**Recommendations**

Based on the limitations of this study, there are recommendations to further expand this research. The validity and reliability of the survey should be established to ensure the survey questions measure what they are intended to measure and that they are
written using language applicable to all professions. It would also be beneficial to conduct this study with a larger pool of participants, including OTs, PTs, and RNs from all geographic regions, to increase the ability to generalize the results. Furthermore, using randomization and an equal number of respondents from each profession would increase the validity and reliability of the study.

Due to the respondents’ interest in attending a workshop on addressing patients’ sexual activity concerns, it would be beneficial to create a workshop that incorporates the interdisciplinary PLISSIT model. The survey could be used as a pretest, posttest, and 6-month follow up for the workshop in order to measure increased knowledge, comfort level, and the number of patients that professionals address sexual activity with each month.

Conclusions

In conclusion, OTs and RNs considered sexual activity to be outlined to some extent in their own scope of practice, while PTs had varied responses. There was uncertainty reported among RNs and PTs regarding how sexual activity is outlined in the scope of practice for occupational therapy. While it is important to understand one’s own role when addressing sexual activity, it is also important to understand the role of those whom one works closely on an interdisciplinary healthcare team. Increased understanding of interdisciplinary role delineation may lead to increased inclusion of sexual activity patient concerns in treatment and clearer referral pathways.

Using the PLISSIT model for guidance, occupational therapists are qualified to address patients’ sexual activity concerns. To continue enhancing the profession of OT, it is imperative that OTs advocate for themselves in every area of occupation to increase
healthcare providers’ understanding of the OT role.
REFERENCES


APPENDICES
APPENDIX A

Survey

Q1 Please choose your profession

- Registered nurse (1)
- Occupational therapist (2)
- Physical therapist (3)

Q2 Please indicate years of experience working in inpatient rehabilitation

- No experience (1)
- Less than 1 year (2)
- 1 to 3 years (3)
- 4 to 6 years (4)
- 7 to 10 years (5)
- Over 10 years (6)

Q3 Please select your age range

- 20 to 25 years (1)
- 26 to 35 years (2)
- 36 to 45 years (3)
- 46 to 55 years (4)
- Age 56 or older (5)

Q4 Please select the gender which you identify with most

- Male (1)
- Female (2)
- I prefer not to answer (3)

Q5 How well do you feel your profession outlines its role in addressing patients’ sexual activity concerns?

- My profession’s scope of practice clearly outlines addressing patients’ sexual activity concerns (1)
- My profession’s scope of practice outlines addressing patients' sexual activity concerns (2)
- My profession’s scope of practice briefly outlines addressing patients' sexual activity concerns (3)
- My profession’s scope of practice does not outline addressing patients' sexual activity concerns (4)
- I am uncertain if my profession’s scope of practice outlines addressing patients' sexual activity concerns (5)
Q6 Rank the following in order from 1-5 of who you think would be the most appropriate to address sexual activity (1= most appropriate). Drag responses in desired order.
   ______ Registered nurse (1)
   ______ Psychologist (2)
   ______ Occupational therapist (3)
   ______ Physician (4)
   ______ Physical therapist (5)

Q7 Who would be the most likely profession at your facility to address sexual activity?
   ☑ Physical therapist (1)
   ☑ Registered nurse (2)
   ☑ Physician (3)
   ☑ Occupational therapist (4)
   ☑ Psychologist (5)

Q8 Which profession are you most likely to refer a patient to who has sexual activity concerns?
   ☑ Occupational therapist (1)
   ☑ Physician (2)
   ☑ Physical therapist (3)
   ☑ Psychologist (4)
   ☑ Registered nurse (5)

Q9 At your facility, what services/resources does your profession offer in regards to addressing patients' sexual activity concerns? Choose all that apply.
   ☐ Pamphlets (1)
   ☐ Patient education courses (2)
   ☐ Referrals (3)
   ☐ Specific suggestions (positioning, compensatory techniques, adaptive equipment) (4)

Q10 When is the most appropriate timing for sexual activity intervention in an inpatient rehabilitation setting?
   ☑ Initial evaluation (1)
   ☑ During intervention (2)
   ☑ Upon discharge (3)
   ☑ Post-discharge (4)

Q11 On average, how many patients per month do you discuss sexual activity concerns with?
   ☑ 0-1 (1)
   ☑ 2-6 (2)
   ☑ 7-11 (3)
   ☑ 12 or more (4)
Q12 If I do not address sexual activity with a patient, it is most likely because
✓ It is due to fear of creating an uncomfortable situation for either myself or client (1)
✓ It is due to lack of time (2)
✓ It is due to lack of knowledge or appropriate resources (3)
✓ It is not my profession’s place to address sexual health/intimacy (4)

Q13 I am unprepared to talk about sexual activity with patients
✓ Strongly agree (1)
✓ Agree (2)
✓ Somewhat agree (3)
✓ Neither agree nor disagree (4)
✓ Somewhat disagree (5)
✓ Disagree (6)
✓ Strongly disagree (7)

Q14 I received thorough education on sexual activity issues and how to address them with patients during my respective schooling
✓ Strongly agree (1)
✓ Agree (2)
✓ Somewhat agree (3)
✓ Neither agree nor disagree (4)
✓ Somewhat disagree (5)
✓ Disagree (6)
✓ Strongly disagree (7)

Q15 I have a good understanding of what treatments/interventions would be appropriate for a variety of sexual activity patient concerns
✓ Strongly agree (1)
✓ Agree (2)
✓ Somewhat agree (3)
✓ Neither agree nor disagree (4)
✓ Somewhat disagree (5)
✓ Disagree (6)
✓ Strongly disagree (7)

Q16 I would be interested in attending a workshop on how to address patients’ sexual activity concerns
✓ Strongly agree (1)
✓ Agree (2)
✓ Somewhat agree (3)
✓ Neither agree nor disagree (4)
✓ Somewhat disagree (5)
✓ Disagree (6)
✓ Strongly disagree (7)
Q17 My profession (at my facility) addresses sexual activity during the patient’s initial evaluation
- Strongly agree (1)
- Agree (2)
- Somewhat agree (3)
- Neither agree nor disagree (4)
- Somewhat disagree (5)
- Disagree (6)
- Strongly disagree (7)

Q18 If sexual activity is not initially discussed with a patient, I can comfortably present the opportunity to revisit it in the future
- Strongly agree (1)
- Agree (2)
- Somewhat agree (3)
- Neither agree nor disagree (4)
- Somewhat disagree (5)
- Disagree (6)
- Strongly disagree (7)

Q19 I am more likely than my patient to initiate discussion or raise concerns regarding sexual activity
- Strongly agree (1)
- Agree (2)
- Somewhat agree (3)
- Neither agree nor disagree (4)
- Somewhat disagree (5)
- Disagree (6)
- Strongly disagree (7)

Q20 How do you feel sexual activity is outlined in the scope of occupational therapy?
- Sexual activity is clearly outlined in the scope of occupational therapy (1)
- Sexual activity is outlined in the scope of occupational therapy (2)
- Sexual activity is briefly outlined in the scope of occupational therapy (3)
- Sexual activity is not outlined in the scope of occupational therapy (4)
- I am uncertain if sexual activity is outlined in the scope of occupational therapy (5)
Appendix B

Informed Consent

Sanford Health
Consent to Participate in a Research Study

Title: Sexuality and healthcare: The perceptions of providers regarding role delineation. Are occupational therapists overlooked?

Principal Investigator: Brooke Friederichs OTS, Olivia Isaacson OTS, Breann Lamborn

What is the purpose of this study?
The purpose of this research study is to gain understanding of what each healthcare provider’s role is in addressing sexual activity. According to the American Occupational Therapy Association’s (2014) practice framework, sexual activity is defined as, “Engaging in activities that result in sexual satisfaction and/or meet relational or reproductive needs.” In addition, researchers are interested in gaining insight as to how, in specific, the occupational therapy role is perceived and understood by other healthcare professionals.


What will happen during this study?
You will be asked to complete a short, anonymous online survey through Qualtrics®. You are free to skip any questions that you prefer not to answer. If you agree to take part in this study, your participation in the study will last approximately five to ten minutes. This study can be completed on a computer at your convenience.

What are the risks of the study?
There may be some risk from being in this study, but any risk for participating is not expected to be more than risk experienced in everyday life. You may experience frustration that is often experienced when completing surveys. Some questions may be of a sensitive nature, and you may therefore become upset as a result. However, such risks are not viewed as being in excess of “minimal risk.” If, however, you become upset by questions, you may stop at any time or choose not to answer a question.
What are the benefits of this study?
Researchers hope that this survey will allow participants to reflect on the importance of including sexuality when providing patient care. This has the potential to increase overall patient satisfaction. There will be no compensation for involvement in this study.

What are the alternatives to participating in this study?
The alternative is to not participate in this study.

Are my records confidential?
While we cannot guarantee absolute confidentiality, we will use all available security measures to minimize the risk that this information would be given to someone outside of the study. Your study record may be reviewed by the University of North Dakota Institutional Review Board (IRB), Sanford IRB, and Sanford Research Compliance.

If we write a report or article about this study, we will describe the study results in a summarized manner so that you cannot be identified. Confidentiality will be maintained through a password protected Qualtrics® account that only the researchers have access to. You will not be asked to provide any personal identifiers such as name, date of birth, city of employment, or contact information.

All survey responses that we receive will be treated confidentially. However, given that the online surveys can be completed from any computer (e.g., personal, work, library), we are unable to guarantee the security of the computer on which you choose to enter your responses. As a participant in our study, we want you to be aware that certain "key logging" software programs exist that can be used to track or capture data that you enter and/or websites that you visit. We will be using the "Anonymous Response" and "Anonymize Link" option on Qualtrics® to ensure that no location data or IP addresses will be affiliated with your response. No personal identifiers including name, date of birth, or city of employment will be asked of you.

Is this study voluntary?
Your participation is voluntary. You can choose not to participate or you may stop your participation at any time without penalty or loss of benefits to which you are otherwise entitled.

If you choose to exit the survey early, know that data is collected immediately after each response is submitted and will be unable to be retracted from the study.

Your decision whether or not to participate will not affect your current or future relations with Sanford Health.

Who can I talk to?
You may ask any questions you have now or later.

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (307)-268-2223.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). An Institutional Review Board is a group of people who protect the rights and welfare of
people who participate in research. You may talk to them at (605) 312-6430 or eIRB@sanfordhealth.org if:

* Your questions, concerns, or complaints are not being answered by the research team.
* You cannot reach the research team.
* You want to talk to someone besides the research team.
* You have questions about your rights as a research subject.
* You want to get information or provide input about this research.

For this study you must be 18 years of age older to consent to participate in this research study.

**Beginning this survey implies that you have read the information in this form and consent to participate in the research.**
Appendix C

UND Letter of Approval
January 12, 2017

Principal Investigator(s): Brooke Friederichs; Olivia Isaacson
Project Title: Sexuality and Healthcare: The Perceptions of Providers Regarding Role Delineation. Are Occupational Therapists being Overlooked?
IRB Project Number: IRB-201701-158
Project Review Level: Exempt 2
Date of IRB Approval: 01/12/2017
Expiration Date of This Approval: 01/11/2020

The application form and all included documentation for the above-referenced project have been reviewed and approved via the procedures of the University of North Dakota Institutional Review Board.

If you need to make changes to your research, you must submit a Protocol Change Request Form to the IRB for approval. No changes to approved research may take place without prior IRB approval.

This project has been approved for 3 years, as permitted by UND IRB policies for exempt research. You have approval for this project through the above-listed expiration date. When this research is completed, please submit a Termination Form to the IRB.

The forms to assist you in filing your project termination, adverse event/unanticipated problem, protocol change, etc. may be accessed on the IRB website: http://und.edu/research/resources/human-subjects/

Sincerely,

[Signature]
Michelle L. Bowles, M.P.A., CIP
IRB Coordinator
MLB/sb
Cc: Breann Lamborn, M.P.A.
Appendix D

UND IRB
University of North Dakota Exempt Certification Form – JANUARY 2015 VERSION
Research Involving the Use of Survey, Interview, Observational Procedures or Educational Tests

Complete this form if you are requesting permission to use survey, interview, or observational procedures, or educational tests.

All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University’s policies and procedures governing the use of human subjects. No activities are to be initiated without prior review and approval by the Institutional Review Board.

Please answer the following questions regarding your research. Handwritten forms are not accepted – responses must be typed.

1. Are prisoners included in the research? □ Yes ☒ No
If you answered “Yes” to the above question, this research does not qualify as exempt. Please fill out and submit a “Human Subjects Review Form.” If you answered “No”, continue to question 2a.

2a. Are children included in the research? □ Yes ☒ No
If you answered “No” to the above question, please skip question 2b and continue to question 3. If you answered “Yes”, continue to question 2b:

2b. Does the research include survey or interview procedures? Does the research involve the observation of public behavior with researcher interaction with the subjects? ☐ Yes ☒ No
If you answered “Yes” to questions 2a and 2b, this research does not qualify as exempt. Please fill out and submit a “Human Subjects Review Form.” If you answered “No”, continue to question 3.

3a. Will the data be documented in such a manner that subjects cannot be identified, either directly or through identifiers linked to the subjects (subject name, social security number, birth date, coding, etc.)? ☒ Yes □ No
If you answered “Yes” to the above question, please skip question 3b and continue with the rest of the form. If you answered “No”, continue to question 3b.

3b. Will the disclosure of the subjects’ responses outside of the research reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation? ☐ Yes ☒ No
If you answered “Yes” to the above question, this research does not qualify as exempt. Please fill out and submit a “Human Subjects Review Form.”

4. Will the research involve the use of audio, video, digital or image recordings of subjects? ☐ Yes ☒ No
If you answered “Yes” to the above question, this research does not qualify as exempt. Please fill out and submit a “Human Subjects Review Form.” Provide the information requested below:

Principal Investigator: Brooke Friederichs, MOTS & Olivia Isaacson, MOTS
Telephone: (701) 403-9832, (763) 218-6667  E-mail Address: brooke.friederichs@unm.edu, olivia.isaacson@unm.edu
Complete Mailing Address: 8267 Yuma Way N, Maple Grove, MN, 55311
School/College: University of North Dakota  Department: Occupational Therapy

Student Advisor (if applicable): Breana Lamborn, MPA
Telephone: (307) 268-2223  E-mail Address: breana.lamborn@med.unm.edu
Address or Box #: 125 College Drive, Casper, WY, 82601
School/College: University of North Dakota  Department: Occupational Therapy

*** All IRB applications must include a Key Personnel Listing

Project Title: Sexuality and healthcare: The perceptions of providers regarding role delineation. Are occupational therapists being overlooked?

Proposed Research Beginning Date: 12/20/2016  Exempt research will be approved for 3 years from the original approval date.

Revised 1/9/2015  1
Funding agencies supporting this research: NA

(A copy of the funding proposal for each agency identified above MUST be attached to this proposal when submitted.)

Does any researcher associated with this project have a financial interest in the results of this project? If yes, submit a separate piece of paper an additional explanation of the financial interest. The Principal Investigator and any researcher associated with this project should have a Financial Interests Disclosure Document on file with their department.

☐ YES or ☒ NO Will any research participants be obtained from another organization outside the University of North Dakota (e.g., hospitals, schools, public agencies, American Indian tribes/reservations)?

☐ YES or ☒ NO Will any data be collected at or obtained from another organization outside the University of North Dakota?

If yes to either of the previous two questions, list all institutions: Sanford Health

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands its involvement and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and should be printed on organizational letterhead.

Does any external site where the research will be conducted have its own IRB? ☒ YES or ☐ NO

If yes, does the external site plan to rely on UND’s IRB for approval of this study? ☒ YES or ☐ NO

(If yes, contact the UND IRB at 701-777-4279 for additional requirements)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

<table>
<thead>
<tr>
<th>Sanford Health</th>
<th>Date submitted</th>
<th>Status</th>
<th>Approved</th>
<th>Pending</th>
</tr>
</thead>
</table>

(include the name and address of the IRB, a contact person at the IRB, and a phone number for that person)

Type of Project: Check "Yes" or "No" for each of the following.

☒ YES or ☐ NO New Project ☒ YES or ☐ NO Dissertation/Thesis/Independent Study

☒ YES or ☐ NO Continuation/Renewal ☒ YES or ☐ NO Student Research Project

Is this a Protocol Change for previously approved project? If yes, submit a signed Protocol Change Form, along with a signed copy of this form with the changes bolded or highlighted.

Please provide additional information regarding your research by responding to questions 5-11 on a separate sheet of paper.

5. In non-technical language, describe the purpose of the study and state the rationale for this research.

6. In non-technical language, describe the study procedures.

   How will subjects be informed of the research? If you will be having subjects sign a consent form justifiy why. How will instrument(s) be distributed/collected? Will compensation be provided? What is the expected duration of subject participation? Etc.

7. Where will the research be conducted?

8. Describe what data will be recorded.

9. How will data be recorded and stored (that is will it be coded, anonymous, etc.)?

   Note: Must state that data will be stored for a minimum of three years after data analysis is complete, or for a period of time sufficient to meet federal, state, and local regulations, sponsor requirements, and organizational policies and procedures.

10. Describe procedures you will implement to protect confidentiality of data collected from participants and privacy of participants when participating in research activities.

Revised 1/9/2015 2
11. Describe the nature of the subject population and the estimated number of subjects.

Participants who are likely to be vulnerable to coercion and unequal influence are to be included in the research. Define procedures to protect the privacy and interests of these participants and additional safeguards implemented to protect the rights and welfare of these participants.

12. Include a copy of the study information sheet to be given to participants (either in person or online, depending on the nature of the research) that describes research information. A template is available under 'Research Certification Forms' on the IRB Forms page of the IRB website: https://www.iu.edu/researchinstitute/research/certification/forms.

**Necessary attachments**

- Signed Student Consent
- Informed Consent Form (students and parents, if applicable)
- Researcher Letter of Assumption of Responsibility
- Barco Emanuel Clinician
- Surveys: Informed consent, or statement and contract
- Participants' ages and their consent is over the internet,
- Advertising, including new hires, communities, and social networks, websites, and
- Index:

**NOTE:** The UND IRB requires that all key personnel involved in the research document human subject selection before IRB approval to conduct research can be granted.

By checking this item, I certify that the above information is accurate and that this research will be conducted in agreement with the statement provided above, that research does not involve minors. If a subject becomes a prisoner, I will notify the IRB.

[Signature of Investigator]

Date: 12/15/14

[Signature of Student]

Date: 12/15/14

**All students and medical residents must list a faculty member as a student advisor on the first page of the application and must have that person sign the application.**

Submit the signed application form and any necessary supplements to the Institutional Review Board, 254 O'Shaughnessy Drive, Sapp 712, Grand Forks, ND 58202-7230; or by fax to the Regulatory Office, 1805 Kittredge Hall, Room 110.

**Revised 7/2015**
5. In non-technical language, describe the purpose of the study and state the rationale for this research.

The purpose of this research study is to gain understanding of what registered nurses’, occupational therapists’, and physical therapists’ roles are in addressing patients’ sexual activity concerns. In addition, researchers are interested in gaining insight as to how, in specific, the occupational therapy role is perceived and understood by other healthcare professionals.

6. In non-technical language, describe the study procedures.

Sanford Health IRB must be obtained before researchers can implement the electronic survey, which will be sent to occupational therapists, physical therapists, and registered nurses in the inpatient rehabilitation setting employed by Sanford Health. The researchers obtained Sanford IRB contact information from www.sanfordhealth.org. Once in contact, researchers received necessary paperwork to fulfill Sanford IRB requirements. Researchers have no direct contact with participants, however, the director/manager of each Sanford site’s physical therapy, occupational therapy, and nursing departments were contacted. Researchers contacted human resources/operator by phone (phone numbers found on www.sanfordhealth.org). In some cases, human resources provided researchers with the director/manager’s email address. If this was not the case, researchers were connected with the corresponding departments. Voicemails, providing a brief description of the study and researcher contact information, were left for managers/directors.

Once an email was received from the director/manager, researchers provided additional information and obtained director approval. The managers/directors agreed to email the survey to their staff members granted Sanford and UND IRB approve of the study.

Upon Sanford and UND IRB approval, the researchers will email the anonymous survey link to the managers/directors who will then forward onto their staff. An additional reminder will be emailed two weeks later. The survey will close after 4 weeks. Purposive sampling was used based on the study’s purpose to explore physical therapists’, occupational therapists’, and registered nurses’ perceptions about client sexuality in an inpatient rehabilitation setting. All information will be kept confidential and responses will be anonymous. The study’s purpose is to collect knowledge and attitudes, therefore it poses minimal risk and minimal to no safety concerns.

The survey is 20 questions long, consisting of multiple choice and likert-scale style questions. It is estimated to take 5-10 minutes to complete.

When all responses have been collected via Qualtrics® after 4 weeks, descriptive analyses including central tendencies, variance, ranges, and standard deviation will be utilized using SPSS®.
7. Where will the research be conducted?

Surveys will be e-mailed to department directors via an anonymous Qualtrics® survey link. Participants will be able to complete the survey on any computer where they can access their email. Data will be compiled through a password protected Qualtrics® account, which only the researchers and advisor have access to. The analysis of the data will be conducted at the University of North Dakota.

8. Describe what data will be recorded.

See attached survey screen shots. The electronic survey consists of 20 multiple choice or likert-scale questions, estimated to take 5-10 minutes to complete. There will be no follow up studies.

9. How will data be recorded and stored (that is will it be coded, anonymous, etc.)?

Data will be recorded through Qualtrics® using an anonymous survey link. All responses will be anonymous and data will be stored on a password protected Qualtrics® account which only researchers and the advisor have access to. Upon completion of the study, the Qualtrics® account will be permanently deleted. Once researchers are finished working with the data, the data will be kept on a jump drive stored in a locked filing cabinet for three years and then destroyed after three years by wiping all electronic files.

10. Describe procedures you will implement to protect confidentiality of data collected from participants and privacy of participants when participating in research activities.

While we cannot guarantee absolute confidentiality, researchers will use all available security measures to minimize the risk that this information would be given to someone outside of the study. If we write a report about the study, we will describe results in a summarized manner so that participants cannot be identified. Confidentiality will be maintained through a password protected Qualtrics® account which only researchers and advisor have access to. The participants will not be asked to provide any personal identifiers such as name, date of birth, city of employment, or contact information. All survey responses will be treated confidentially. However, given that online surveys can be completed from any computer (e.g., personal, work, library), we are unable to guarantee the security of the computer on which the participants choose to enter their responses. We want participants to be aware that certain “key logging” software programs exist that can be used to track or capture data that they enter and/or websites that they visit. By enabling the options of “Anonymize Response” and “Anonymous Link” on Qualtrics®, respondents’ IP address and location data will be removed from the results.

11. Describe the nature of the subject population and the estimated number of subjects.

For the purpose of our study, the survey will be distributed to as many Sanford Health physical therapists, occupational therapists, and registered nurses working in inpatient rehabilitation as possible. The actual reach of survey participants will be determined by the availability through the gatekeeper. The sample size will be determined by number of
responses. Researchers hope for 75 returns. Proportions and sample size will determine if randomization will be utilized to equalize percentage of response rate across disciplines.

Inclusion criteria for participants includes the following: participant must be an inpatient rehabilitation registered nurse, physical therapist, or occupational therapist employed by Sanford Health and be at least 20 years of age. Exclusion criteria for participants includes the following: no registered nursing, physical therapy, or occupational therapy inpatient rehabilitation work experience, under 20 years old, and not employed by Sanford Health.
Appendix E

Sanford Health Letter of Approval
APPROVAL OF SUBMISSION

January 12, 2017

Dear Brooke Friederichs:

The IRB reviewed the following submission:

<table>
<thead>
<tr>
<th>Type of Review:</th>
<th>Modification via Expedited Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title of Study:</td>
<td>Sexuality and healthcare: Sexuality and healthcare: The perceptions of providers regarding role delineation. Are occupational therapists overlooked?</td>
</tr>
<tr>
<td>Investigator:</td>
<td>Brooke Friederichs, OTS</td>
</tr>
<tr>
<td>IRB ID:</td>
<td>MOD00000792</td>
</tr>
<tr>
<td>New Items This Review:</td>
<td>• Sanford Consent, Category: Consent Form</td>
</tr>
<tr>
<td>Special Determinations:</td>
<td>None</td>
</tr>
</tbody>
</table>

The IRB approved the study in its current form on 1/12/2017.

All documents previously approved by the IRB remain approved until modified or withdrawn. If this study is closed to accrual, a new consent is not approved unless required for re-consent.

In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103) and all policies relevant to human research, which can be found by navigating to the eIRB library.

For questions please contact the IRB Office: eIRB@sanfordhealth.org.
Appendix F

Sanford Health IRB

INSTRUCTIONS:

• Use “Protocol Template Investigator Initiated (HRP-503e)” to prepare an IRB submission for Sanford Investigator Initiated research when templates HRP-503a-d do not apply.

Upload this document in the eIRB “Basic Information” for this type of project.

• Depending on the nature of the project, some sections may not be applicable to your research. If so mark as “Not Applicable”.

• Read through the protocol template before completing. This should help you avoid repeating information in multiple sections.

• Mouse over / hover over the <?> graphic to view form instructions.

• When writing a protocol, always keep an electronic copy. You will need to upload this copy to eIRB. The IRB approved version in the electronic system is the master copy. You will need to modify this copy when making changes. The master copy will be available in eIRB under the documents tab.

• All referenced items can be found in the eIRB Library.

• Please submit a Project Initiation Form to researchinitiation@sanfordhealth.org Do not upload in eIRB.

PROTOCOL TITLE: <?> Sexuality and healthcare: The perceptions of providers regarding role delineation. Are occupational therapists overlooked?

Include the full protocol title.

PRINCIPAL INVESTIGATOR:

Name: Brooke Friederichs MOTS
Telephone Number: (307)-268-2223
Email Address: brooke.friederichs@und.edu

VERSION: <?> Click here to enter text.

Include the date of submission or version number.
Study Design

1.0 Objectives

1.1 Purpose- Describe the purpose of this research. The purpose of this research study is to gain understanding of what each healthcare provider’s role is in addressing sexuality. In addition, researchers are interested in gaining insight as to how, in specific, the occupational therapy role is perceived and understood by other healthcare professionals.

1.2 Hypothesis- State the hypothesis or hypotheses to be tested. The researchers anticipate that the role delineation will be unclear across all healthcare providers. Researchers predict that healthcare providers, including occupational therapists, lack initiative when addressing sexuality. It is also anticipated that the responsibilities of occupational therapists to address sexuality will be overlooked.

1.3 Treatment in Non-investigational Setting- Describe how patients would be treated in a non-investigational setting; what treatments are available outside this research. Not Applicable

1.4 Test article availability outside of Research- Indicate if the study test article(s) is available to patients without taking part in the study. Not Applicable

2.0 Background

2.1 Scientific or Scholarly Background- Provide the scientific or scholarly background for and significance of the research based on the existing literature. Describe how this research will fill gaps in existing knowledge. Describe the significance or novelty of this proposed study. Sexuality refers to not only sexual function and health, but personal relationships and sexual expression as well (WHO, 2014). Addressing sexuality in healthcare continues to be an area that is associated with provider discomfort and lack of knowledge. Dyer and das Nair (2013) found that this perceived or actual lack of knowledge prevents healthcare providers from initiating the topic of sexuality and negatively affects how providers manage client-initiated discussions about sexuality. Although sexual activity is an activity of daily living according to the occupational therapy practice framework (AOTA, 2014), the role that occupational therapists have among other healthcare professionals in regards to addressing sexuality is still unclear. In a study about burn professionals’ attitudes towards discussing sexuality, 47% of respondents said that there was no specific staff role designated to address sexuality (Rimmer et al., 2010). It is important to clarify which healthcare professionals are responsible for covering the topic of sexuality to ensure that patients are receiving holistic treatment. O’Dea, Shuttleworth, and Wedgewood (2012) found that out of 144 clients with neuromuscular disorders, 66.7% of them had an interaction with a healthcare provider related to sexuality. Only 2.1% of these interactions were with occupational therapists. Physical therapists were responsible for 4.9%, nurses for 7.6%, psychologists for 16.7%, and medical practitioners for 35.4% of interactions. This is one of the few studies that provides a breakdown of healthcare provider interactions addressing sexuality. This study will fill gaps in existing knowledge by providing a better understanding of how healthcare providers perceive the role delineation when addressing clients’ concerns about sexual
activity. It will also help to gauge healthcare providers’ self awareness of the issue. It is the researchers’ hope that these findings will allow sexuality to be addressed more effectively with patients, yielding more holistic care.

2.2 Relevant Preliminary Data

Describe any relevant internal preliminary data, such as a pilot project or previous research. Not Applicable

3.0 Procedures Involved

3.1 Study Design

Describe and explain the study design. Nonexperimental prospective quantitative survey

- Community-based Participatory Research

Describe involvement of the community in the design and conduct of the research. Note: ‘Community-based Participatory Research’ is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes, and eliminate health disparities. Click here to enter text. Not Applicable, not Community-based Participatory Research

3.2 Research Procedures

Provide a description of all research procedures performed and when they are performed, including procedures performed to monitor subjects for safety or minimize risks. The researchers obtained Sanford IRB contact information via www.sanfordhealth.org. Once in contact, researchers received paperwork to fulfill Sanford IRB requirements. Researchers have no direct contact with participants. In order to obtain letters of support, the director/manager of each Sanford site’s physical therapy, occupational therapy, and nursing departments were contacted. Researchers contacted human resources/operator by phone (phone numbers found on www.sanfordhealth.org). In some cases, human resources provided researchers with the director/manager’s email address. If this was not the case, researchers were connected with the corresponding departments. Voicemails providing a brief description of the study and researcher contact information were left for managers/directors. Once an email was received from the director/manager, researchers provided additional information and obtained director approval (see attached email threads). The managers/directors agreed to email the survey to their staff members, granted IRB approves of this study. Once IRB approves the study, the researchers will email the survey link to the managers/directors who will then forward onto their staff. An additional reminder will be emailed two weeks later. Purposive sampling was used based on the study’s purpose to explore physical therapists’, occupational therapists’, and registered nurses’ perceptions about client sexuality in an inpatient rehabilitation setting. This study will be approved by Sanford IRB and the University of North Dakota IRB before researchers proceed. All information will be kept confidential and responses will be anonymous. The study’s purpose is to collect knowledge and attitudes, therefore it poses minimal risk and minimal to no safety concerns.
3.3 **Drugs and Devices**

Describe all drugs, biologics and devices used in the research, the purpose of their use, and their regulatory approval status for the use in this study. Not Applicable

**4.0 Drugs or Devices**

Not applicable, skip this section if no drugs or device intervention/testing

Use Worksheet HRP-306 Drugs or Worksheet HRP-307 Devices to ensure the necessary information for IRB review. For drug studies, provide a brief explanation of methods used to determine dosing, expected maximum dosage, and duration of exposure to the drug.

**4.1 IND/IDE/ Abbreviated IDE**

If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information or state “Not Applicable”:

- **IND/IDE Exempt**
  - Justify claim of IND exemption 21CFR 312.2 (b) /IDE exemption 21 CFR 812.2 (c). Use Worksheet HRP-306 Drugs or Worksheet HRP-307 Devices to ensure the necessary information for IRB review. Click here to enter text. Not Applicable

- **Abbreviated IDE**
  - Justify claim of Abbreviated IDE (Nonsignificant Risk) 21 CFR 812.3(m) Review Checklist HRP-418 to ensure you have provided the necessary information. Click here to enter text. Not Applicable

- **IND/IDE Sponsor**
  - Identify the holder (sponsor) of the IND/IDE/Abbreviated IDE. Click here to enter text. Not Applicable

**4.2 Drug/ Device Plan for use only by authorized investigators**

If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators. Not Applicable

**4.3 FDA Sponsor Requirements**

Explain procedures followed to comply with FDA sponsor requirements for the following: (not required if IND/IDE exempt) Refer to regulation and worksheets HRP-332 IND Compliance or HRP-333 IDE & Abbreviated IDE to ensure the necessary information for IRB review. Click here to enter text. Not Applicable

Applicable to:

- FDA Regulation IND Studies IDE Studies Abbreviated IDE Studies
  - 21 CFR 11 Electronic Records and Signatures X X
  - 21 CFR 54 Financial Disclosure X X
  - 21 CFR 210 GMPs Manufacturing
  - 21 CFR 211 GMPs Finished Product
  - 21 CFR 312 HRP-332 Worksheet-IND Compliance X
  - 21 CFR 812 HRP-333 Worksheet-IDE & Abbrev. IDE X X
  - 21 CFR 820 GMPs for Medical Devices X

**5.0 Inclusion and Exclusion Criteria**


5.1 Inclusion Criteria-<??><??><??> Justify any inclusion or exclusion criteria specific to gender, age, racial/ethnic groups. Indicate if your employees (you have direct/indirect oversight) or your students are included. Describe the criteria that define who will be included for study enrollment (e.g., age, sex, diagnosis, etc.). List vulnerable populations included. Indicate specifically whether the study will include each of the following vulnerable populations: (You may not include members of these populations as subjects in your research unless you indicate this in your inclusion criteria.) Cognitively Impaired Adults (Adults unable to consent), Children, (specify: infants, children, teenagers), Neonates, Pregnant women, Prisoners Inclusion criteria for participants includes the following: participant must be an inpatient rehabilitation registered nurse, physical therapist, or occupational therapist employed by Sanford Health and be at least 20 years of age.

5.2 Exclusion Criteria-<??> Describe the criteria that define who will be excluded for study enrollment (e.g., age, sex, diagnosis, etc.) Exclusion criteria for participants includes the following: no registered nursing, physical therapy, or occupational therapy inpatient rehabilitation work experience, under 20 years old, and not employed by Sanford Health.

6.0 Number of Subjects

6.1 Overall Subject Numbers-<??> Indicate the total number of subjects that will participate including withdrawals and screen failures (i.e., consented and some level of participation). The survey will be distributed to as many Sanford Health physical therapists, occupational therapists, and registered nurses working in inpatient rehabilitation as possible. The actual reach of survey participants will be determined by the availability through the gatekeeper.

6.2 Sample Size Determination-<??> Specify the number of subjects needed for statistical analysis for the study. Justify this sample size; provide a power analysis. The sample size will be determined by number of responses. Researchers hope for 75 returns. Proportions and sample size will determine if randomization will be utilized to equalize percentage of response rate across disciplines.

7.0 Study Timelines

7.1 Participation Duration-<??> Describe the duration of an individual subject’s participation in the study including any follow up. The electronic survey consists of 20 multiple choice questions, estimated to take 5-10 minutes to complete. There will be no follow up studies.

7.2 Anticipated Enrollment Timeframe-<??> Describe the duration anticipated to enroll all study subjects. Once participants receive the link to the survey, they will have four weeks to complete it. Survey protection via Qualtrics® will prevent participants from taking the survey more than once.
7.3 Anticipated Completion Date-<??> Describe the estimated date for the investigators to complete this study (complete primary analyses) It is estimated that the investigators will complete the primary analyses by February 1, 2017.

8.0 Statistical Methods

8.1 Statistical Methods-<??> Describe the data analyses plan, including any statistical procedures. Descriptive analyses including central tendencies, variance, ranges, and standard deviation will be utilized.

8.2 Study Endpoints-<??> Describe the primary and secondary study endpoints. Not Applicable

8.3 Data Analysis Plan-<??> Include statistical procedures Researchers plan to use SPSS to determine descriptive statistics.

9.0 Data and Specimen Management (for this study)

9.1 Source Records-<??> Describe the source records that will be used to collect data about subjects. Ex., Billing records, Medical records, databases, public records, observation, images, quality improvement records. (Attach in eIRB “Supporting Documents” all surveys, interview scripts, etc.) If the medical record is the source of your data, remember to include a HIPAA authorization in your submission HRP-575a or b HIPAA Authorization Template Electronic survey questions will be created and distributed via Qualtrics® and attached in eIRB “Supporting Documents”.

9.2 Data Recorded-<??> Describe what data will be recorded including long term follow-up. (Attach in eIRB “Supporting Documents” any data collection forms) Responses to survey questions will be anonymously gathered via Qualtrics®. Survey responses will be recorded and analyzed through SPSS. Only researchers and advisor will have viewing access. The SPSS data analyses will be maintained through the UND IRB confidentiality guidelines. Participant records from Qualtrics® and the data analysis files from SPSS will be maintained.

9.3 Specimen Collection-<??> Describe specimen collection, list amounts/volumes, and how the specimens are obtained. (ex., left over tumor from surgery obtained from pathology up to 4 grams as available, blood collected at consent and two weeks 10 mls each collection). Not applicable Click here to enter text. Click here to enter text.

9.4 Specimen Processing-<??> Describe testing to be performed on specimens and how this relates to the study hypothesis. Not applicable Click here to enter text. Click here to enter text.
9.5 Confidentiality-<QQ> Describe the steps that will be taken to secure the data Note: Data can include paper files, computer files, audio/video files, photographs, etc.

Paper records accessible only by research personnel, locked/secured storage
Computer files accessible only by research personnel, protected by passwords and encryption
Data transfer electronically through secure e-mail, encrypted external storage
Audio / video recordings are transcribed and destroyed to eliminate audio/visual identification
Separation of identifiers and other research data Certificate of Confidentiality

Other While we cannot guarantee absolute confidentiality, we will use all available security measures to minimize the risk that this information would be given to someone outside of the study. The study record may be reviewed by the University of North Dakota Institutional Review Board (IRB), Sanford IRB, and Sanford Research Compliance. If researchers write a report or article about this study, they will describe the study results in a summarized manner so that the participants cannot be identified. Confidentiality will be maintained through a password protected Qualtrics® account that only the researchers and advisor have access to. The participants will not be asked to provide any personal identifiers such as name, date of birth, city of employment, or contact information. The researchers will be presenting the results of this survey to the University of North Dakota Occupational Therapy Department in order to fulfill capstone requirements for their Master's in Occupational Therapy (MOT). As with any potential report or article, participants' confidentiality will be maintained. All survey responses that researchers receive will be treated confidentially. However, given that the online surveys can be completed from any computer (e.g., personal, work, library), researchers are unable to guarantee the security of the computer on which the participants choose to enter their responses. Researchers want participants to be aware that certain "key logging" software programs exist that can be used to track or capture data that they enter and/or websites that they visit. By enabling the options of “Anonymize Response” and “Anonymous Link” on Qualtrics®, respondents’ IP address and location data will be removed from the results.

9.6 Use of Codes, Master List, or Key-<QQ> If identifiers will be associated with the data and/or specimens, describe whether a record or list containing a code (i.e., Subject number) will be used, where the list will be stored, who will have access to the list, and when it will be destroyed.

Describe storage, access, destruction plan: Once researchers are finished working with the data, the data will be kept on a flash drive stored in a locked filing cabinet and will be destroyed in three years. All electronic files will be wiped and all paper files will be shredded.

Anonymous – without any identifiers that could link the data to a specific subject
Coded – linked to a specific subject by a code-link rather than a direct identifier (e.g., name linked to a subject number, subject number associated with data).
Identified – linked to a specific subject by personal identifiers sufficient to identify a specific subject. (e.g., name with data)
9.7 **Identifiers Associated with the Data and/or Specimens for this Study**

Describe what identifiers will be associated with the data or associated with the specimens. (e.g., names, addresses, telephone/fax numbers, email addresses, dates (ex., dates of birth, admission/discharge dates, medical record numbers, social security numbers, health plan beneficiary numbers, and other elements of PHI.) By enabling the options of “Anonymize Response” and “Anonymous Link” on Qualtrics®, respondents’ IP address and location data will be removed from the results.

9.8 **Data and/or Specimens being Stored**

Identify what data and/or specimens will be stored and the data associated with each specimen. Participants’ anonymous responses to the survey and researchers’ data analysis will be stored in a locked cabinet.

9.9 **Location of Storage**

Identify the location where the data and/or specimens will be stored. Note: If the Sanford Biobank (SB) is used, distinguish whether subject specimens are merely stored in the SB as a service to this study or if subjects are enrolled in the SB. Discuss this use with the Sanford Biobank Director, Chunhung, chan@sanfordhealth.org (605) 312-6403. Data will be maintained in a locked cabinet under the control of the research advisor.

**If using the Sanford Biobank:** Not Applicable, not using the SB

Stored-The Sanford Biobank merely provides a storage and/or analysis service for the original study. Describe if needed: Click here to enter text.

Enrolled-The left over specimens become available for the use of the Sanford Biobank per the biobank protocol. Describe if needed: Click here to enter text.

9.10 **Duration of Storage**

Identify how long the data and/or specimens will be stored, when and how specimens will be destroyed. The data will be stored until May 1, 2020. Following the data storage protocol for UND IRB, the data will be kept for three years. After three years, the advisor will wipe the electronic files and shred any paper files. Sanford policy, "Record Retention and Destruction" will also be followed.

9.11 **Procedures for Quality Control of Collected Data**

Describe any procedures that will be used for quality control of collected data. If this is a multicenter trial, please describe that this item is addressed in section Multi-site research/Quality Control. All participants will be receiving the same survey during the same time frame.

9.12 **Access to Data and/or Specimens**

Identify how specimens will be accessed and who will have access to the data and/or specimens. Only the researchers and advisor will have access to the research data through password protected Qualtrics®.

9.13 **Transporting/Transferring Data and/or Specimens**

Describe how data and/or specimens will be transported between collaborators, locations or labs. Identify how (e.g., method, level of identifiable) the data and/or specimens will be transported/transferred. All members of the research team are affiliated with the department of occupational therapy at the University of North Dakota.

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10.0 Data and Specimen Banking (for future research)

Not Applicable, skip this section

If this study is collecting data and/or specimens that will be banked for future limited or undetermined research, please describe in this section or check Not Applicable.

10.1 Data and/or Specimens being Stored-<??>
Identify what data and/or specimens will be stored and the data associated with each specimen. Click here to enter text.

10.2 Identifiers Associated with the Data and/or Specimens-<??><??>
Describe what identifiers will be associated with the data or associated with the specimens. (e.g., names, addresses, telephone/fax numbers, email addresses, dates (dates of birth, admission/discharge dates, etc.), medical record numbers, social security numbers, health plan beneficiary numbers, and other elements of PHI.) Click here to enter text.

10.3 Location of Storage-<??><??>
Identify the location where the data and/or specimens will be stored. Note: If the Sanford Biobank (SB) is used, distinguish whether subject specimens are merely stored in the SB as a service to this study or if subjects are enrolled in the SB. Discuss this use with the Sanford Biobank Director, Chunhung, chan@sanfordhealth.org (605) 312-6403. Click here to enter text.

If using the Sanford Biobank: Not Applicable, not using the SB

Stored-The Sanford Biobank merely provides a storage and/or analysis service for the original study. Describe if needed: Click here to enter text.

Enrolled-The left over specimens become available for the use of the Sanford Biobank per the biobank protocol. Describe if needed: Click here to enter text.

10.4 Duration of Storage-<??>
Identify how long the data and/or specimens will be stored, when and how specimens will be destroyed. Click here to enter text.

10.5 Access to Data and/or Specimens-<??>
Identify how specimens will be accessed and who will have access to the data and specimens. Click here to enter text.

10.6 Procedures to Release Data or Specimens-<??>
Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens. Click here to enter text.

10.7 Transporting data and/or specimens-<??>
Describe how data and/or specimens will be transported (to and from outside collaborators, between study sites). Click here to enter text.

10.8 Process for Returning Results for Future Research-<??>
Describe the process for returning the results about the use of the data and/or specimens. Click here to enter text.
11.0 Data and Safety Monitoring Plan

Not Applicable as this research is minimal risk, optional to skip this section or include for minimal risk research.

This section is required when research involves more than Minimal Risk to subjects as defined in HRP-001. For additional help please also see Research Compliance DSMP Guidance in eIRB Library.

11.1 Periodic Evaluations Describe evaluation of data collected regarding harms/benefits to determine whether subjects remain safe. The plan might include establishing a data and safety monitoring committee and a plan for reporting committee findings to the IRB and the sponsor. Click here to enter text.

11.2 Data Reviewed What data are reviewed, including safety data, adverse events or complications, and efficacy data Click here to enter text.

11.3 Collection of Safety Data How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants). Click here to enter text.

11.4 Data Collection Frequency The frequency of data collection, including when safety data collection starts Click here to enter text.

11.5 Who/What Group will Review Data Who will review the data Click here to enter text.

11.6 Frequency of Data Review Describe when and how often evaluations of cumulative data will take place. Click here to enter text.

11.7 Safety Endpoints Describe any primary or secondary safety endpoints. Click here to enter text.

11.8 Statistical Tests for Safety The statistical tests for analyzing the safety data to determine whether harm is occurring Click here to enter text.

11.9 Conditions for Suspension Describe any conditions that trigger an immediate suspension of the research. Click here to enter text.

Subjects/Study Participants

1.0 Risks to Subjects

1.1 Risks to Subjects List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to the subjects’ participation in the research. Describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. There may be some risk from being in this study, but any risk for participating is not expected to be more than risk experienced in everyday life. Participants may experience frustration that is often experienced when completing surveys. Some questions may be of a sensitive nature, and participants may therefore
become upset as a result. However, such risks are not viewed as being in excess of "minimal risk."

1.2 Risk Mitigation Describe how the probability or magnitude of risks is mitigated. (e.g. data security, lab tests, appropriate selection of participants, safety monitoring) If participants become upset by questions, they may stop at any time or choose not to answer a question.

1.3 Unforeseeable Risks Indicate which procedures may have risks to the subjects that are currently unforeseeable. Include a statement regarding unforeseeable risk in the consent document. Click here to enter text. Not Applicable

1.4 Risk to Embryo or Fetus If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant or father a child. Click here to enter text. Not Applicable

1.5 Risks to Others If applicable, describe risks to others who are not subjects. (ex. study intervention is a live virus, identification of heritable gene) Click here to enter text. Not Applicable

2.0 Potential Benefits to Subjects and/or Others

2.1 Potential Benefits to Subjects Describe the potential direct benefits that individual subjects may experience from taking part in the research. Describe the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit. This may benefit subjects by providing them the opportunity to reflect on the importance of including sexuality when providing patient care.

2.2 Potential Benefits to Others Include benefits to society or others. We hope that, in the future, other people might benefit from this study. Researchers hope that this survey allows healthcare providers to reflect on the importance of including sexuality when providing patient care. This has the potential to increase overall patient satisfaction.

3.0 Recruitment Methods

3.1 Identification of Subjects Describe the methods used to identify potential subjects. If not recruiting subjects directly, (e.g. database, medical record query for eligible participants, records or samples) state what will be queried, how and by whom. For the purpose of this study, researchers narrowed their interest to Sanford Health inpatient rehabilitation physical therapy, occupational therapy, and nursing departments. Researchers have no direct contact with participants, however, the director/manager of each Sanford site’s physical therapy, occupational therapy, and nursing departments were contacted.

3.2 Recruitment Process Describe when, where, and how potential subjects will be recruited. (e.g., approaching or providing information to potential subjects for participation
Researchers have no direct contact with participants, however, the director/manager of each Sanford site’s physical therapy, occupational therapy, and nursing departments were contacted. Researchers contacted human resources/operator by phone (phone numbers found on www.sanfordhealth.org). In some cases, human resources provided researchers with the director/manager’s email address. If this was not the case, researchers were connected with the corresponding departments. Voicemails, providing a brief description of the study and researcher contact information, were left for managers/directors. Once an email was received from the director/manager, researchers provided additional information and obtained director approval (see attached email thread). The managers/directors agreed to email the survey to their staff members, granted IRB approves of this study. Once IRB approves the study, the researchers will email the survey link to the managers/directors who will then forward onto their staff. An additional reminder will be emailed two weeks later. Not Applicable

3.3 Eligibility/Screening of Subjects  
If potential subjects will be asked eligibility screening questions before obtaining informed consent, describe the process. Describe the plan to de-identify any data linked to screen failures. Add the screening script documents and a list of the eligibility questions that will be used to eIRB in the “Consent Forms and Recruitment Materials”. Click here to enter text. Not Applicable

3.4 Recruitment Materials  
Use Worksheet HRP-315Advertisements to provide the necessary information. Upload recruitment documents (scripts, flyers, emails, letters, advertisements, and etc.) to eIRB. IRB will only approve material submitted in final form. IRB will however conduct a preliminary review for a proposed radio/television/draft printed material to preclude retaping/reprinting because of inappropriate content, provided the IRB approves the final form.

• Mode of Communication  
Describe materials and mode of communication (e.g., television, radio, webpage URL, social networking, flyer, e-mail, SanfordConnect) that will be used to recruit subjects. Email was used to contact directors/managers of each department in order to maintain confidentiality of participants. See attached email threads for details.

• Sanford Patients or Employees  
Describe if Sanford patients or employees are a targeted subject pool. State if using settings specific to these groups (ex., SanfordConnect, flyers in hospital) Click here to enter text.

4.0 Provisions to Protect the Privacy Interests of Subjects

4.1 Study Team Access to data  
Indicate how the research team is permitted to access any sources of information about the subjects. (ex., EMR, School Records) Researchers will not have access to participants’ personal data aside from what they provide during the survey (gender, age range, profession, years of experience range). Even so, by enabling the options of “Anonymize Response” and “Anonymous Link” on Qualtrics®, respondents’ IP address and location data will be removed from the results
4.2 Privacy Measures

Describe the steps that will be taken to protect subjects’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on whom they interact or to whom they provide personal information.

Subject is informed about who has access to research information
Research discussion/treatment plan conducted with only select people chosen by subject

Other precautions: Click here to enter text.

4.3 Avoiding Sense of Intrusiveness

Describe what steps you will take to make the subjects feel at ease with the research situation. “At ease” relates to the sense of intrusiveness

Research intervention in private room
Use of drapes or other barriers
Collection of sensitive information about subjects limited to amount necessary

Other precautions: Click here to enter text.

5.0 Economic Burden to Subjects

5.1 Costs

Describe any costs subjects may be responsible for because of participation in the research. There will not be any cost to participate in this study.

5.2 Compensation for Research-related Injury

If the research involves more than minimal risk to subjects, describe the available compensation in the event of research related injury. Be sure to include this information in the consent document(s).

Use Sanford approved consent template language.

Not Applicable, research is minimal risk to subjects. The study sponsor plans to provide full coverage in the event of a research-related injury. The study sponsor plans to provide coverage for research related injury to the extent not covered by a subject’s insurance. There are no plans for the study sponsor to reimburse subjects for research-related injury. Other plan, describe here and include in consent form. Click here to enter text.

6.0 Subject Stipend and/or Travel Reimbursements

Describe the amount and timing of any subject stipend/credit/payment or travel reimbursement here. Use Worksheet HRP-316 Payments to ensure you have provided the necessary information for IRB review. Click here to enter text. Not Applicable, no subject stipend or reimbursements
7.0 Sharing of Results with Subjects

7.1 Return of Research Results

Describe whether and how results (study results, such as results of investigational diagnostic tests, genetic tests, images or incidental findings) will be shared with subjects or others. Describe any opting in/out choices. Include this information in the consent document(s). The researchers will be presenting the results of this survey to the University of North Dakota Occupational Therapy Department in order to fulfill capstone requirements for their Master’s in Occupational Therapy (MOT). As with any potential report or article, participants’ confidentiality will be maintained.

8.0 Withdrawal of Subjects

8.1 Circumstances of Withdrawal by PI

Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent. (e.g., safety reasons, failure of subject to adhere to protocol requirements, disease progression, etc.) If any participant reports that they have no experience in an inpatient rehabilitation setting, their survey results will be retracted from the study.

8.2 Orderly and Safe Termination of Study Procedures

Describe any procedures for orderly and safe termination of study procedures and/or the investigational product or treatment. Describe how to safely discontinue research intervention (i.e. drug/device). Participants will be notified when the survey is complete.

8.3 Withdrawal Procedures

Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from research procedures with continued data collection. Note: Any partial withdrawal from research procedures should be documented with a new IRB approved consent form covering the new limited study participation. Explain any data or specimen destruction/ de-identification procedures that would occur upon withdrawal of subject. Data destruction not allowed for FDA There are no risks or procedures following withdrawal. Participants can exit the survey at any time. However, answers that have already been submitted will not be able to be retracted.

8.4 Data prior to withdrawal

Describe the plan for data collected up to the point of study withdrawal. Include plan in consent document. Data is collected immediately after each response is submitted and will be unable to be retracted from the study. Participation in this study is completely voluntary.

Consent

1.0 Consent Process

Refer to HRP-090 Informed Consent Process for Research. Indicate whether you will obtain informed consent. If Consent waiver or not required for exempt research, mark Not Applicable. Not Applicable, consent process waived or not required, skip this section.
1.1 Timing and Location of Consent

Refer to HRP-502 Template Consent Document to create the consent document or script

- **Location-** Where will the consent process take place? (A private area, non-private area for presentation with private follow up discussion, self-consent)
  
  Describe whether friends or family of potential participant will be present.
  
  In a private area, subjects approached by study personnel for consent discussion.
  
  In a non-private area with private follow up; Describe: Click here to enter text.
  
  Consideration of Parental inclusion if the study involves young children
  
  Consideration of Parental absence if the study visit involves sensitive information and/or teens. Describe if needed: Click here to enter text.
  
  Online, via phone, or other process other than in person; Describe: Consent form will proceed the survey. Participants will be informed that by continuing onto the survey, participants will have provided consent.
  
  Other: Click here to enter text.

- **Time to Consider Participation-** Describe any waiting period available between informing the prospective subject and obtaining the consent.
  
  Subjects will be allowed to take home unsigned consent for consideration
  
  Subjects will be allowed a waiting period of (time) Click here to enter text. to consider their decision
  
  Other measure: Participants will receive the link to the survey via email with a description of the survey. The email will include information for the last date to take the survey (4 weeks from the time it is sent out).

1.2 Avoiding Coercion or Undue Influence

- **Ongoing Consent-** Describe ongoing consent.
  
  Inform subjects on alternative treatment options/ non-research options
  
  Continued explanation of research procedures
  
  Reminder of voluntariness
  
  Inform subjects on alternative treatment options/ non-research options
  
  Balanced presentation of risks and benefits, assurance that non participation will not result in any penalty, loss of benefit, or affect relationship with Sanford Health or other institution
  
  Other measures: Click here to enter text.

- **Subjects’ Understanding-** Steps taken to ensure subjects’ understanding
  
  Have the subject summarize key points of the study (purpose, risk, benefits, and voluntariness) Provide a copy of the consent document for subject to follow during consent discussion Provide time for questions, ongoing consent dialog
PI available to answer questions Participation in the research indicates willingness and understanding (ex. Online survey research)

Other measures: Click here to enter text.

1.3 Non-English Speaking Subjects
Not Applicable, no non-English speaking subjects anticipated

- **Non-English Speaking Participants Anticipated**

  Indicate any non-English speakers who are likely to present as prospective subjects or legally authorized representatives. Non-English speaking participants should not be systematically excluded because of language barriers; such participants can be enrolled via the short form consent process. See Consent Documentation section. Click here to enter text.

- **Written Materials**

  If non-English speakers will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in a language understandable to subjects. Indicate the language(s). Click here to enter text.

- **Consent Documentation**

  Indicate whether the consent process will be documented with the translated long form consent document or with the short form consent document. Review HRP-091, HRP-317, and the Investigator Manual to ensure that you have provided sufficient information. Click here to enter text.

1.4 Children: (viable neonates, infants, children, teenagers)

- **Parental Permission**

  Choose one:

  - One or both parents.
  - Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. The “Both Parents” option is required for research with more than minimal risk and no direct benefits to subjects.
  - One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. A waiver of parental consent (permission) is requested.

- **Guardian Permission**

  Describe whether permission will be obtained from individuals other than parents. Describe the process used to determine these
individuals’ authority to consent to each child’s general medical care. Click here to enter text.

- **Assent will be required of all, some, or none of the subjects**

  All children will assent
  Some or None of the children will assent
  Describe which children will not assent Click here to enter text.
  Describe why assent is not appropriate for these children:
  Assent waived for this group as the capability of these children (taking into account the ages, maturity, and psychological state of the children involved) is so limited that they cannot reasonably be consulted. Assent waived for this group as the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research. Assent is waived under 45 CFR 46.116(c) or (d)

  **Assent Waiver Justification**
  Review HRP-410 Waiver or Alteration of Consent Process to ensure you have provided sufficient information for IRB to make these determinations. Click here to enter text.

- **Assent documentation**

  Describe whether assent of the subjects will be documented and the process to document assent. Click here to enter text.

  Children will sign within parental consent document or on separate assent Document Investigator will document assent in the consent signature block or other study medical record
  Other: Click here to enter text.

  **1.5 Cognitively Impaired Adults**
  Review HRP-013 Legally Authorized Representatives, Children and Guardians and HRP-417 Checklist: Cognitively Impaired Adults to ensure you have provided the necessary information. Not Applicable, no cognitively impaired Adults included, skip this section.

- **Capability of Providing Consent**

  Describe the process to determine whether an individual is capable of consent. Click here to enter text.

- **Consent Process**

  Describe whether and how informed consent will be obtained from a legally authorized representative. Click here to enter text.

- **LAR Identification**

  Describe who will be allowed to provide consent.
  Describe the process used to determine these individuals’ authority to consent to research. Click here to enter text.

- **Assent of Adults Unable to Consent**

  Describe the process for assent of the adults unable to consent. Click here to enter text.

- **Assent will be required of all, some, or none of the subjects**

  Indicate whether assent will be obtained from all, some or none of the
subjects; include a rationale. If assent will be obtained from some subjects, indicate which subjects will be required to assent. Click here to enter text.

• Assent documentation-<??> Describe whether assent of the subjects will be documented and the process to document assent. Click here to enter text.

• Withdrawal of subjects <??> Describe the process for withdrawing subjects when they indicate or appear unduly distressed Click here to enter text.

2.0 Process to Document Consent in Writing / Waiver of Written Documentation of Consent

2.1 Document Consent in Writing-(Subjects sign a consent document) <??> Describe whether you will be following “SOP: Written Documentation of Consent (HRP-091)” If not, describe whether and how consent of the subject will be documented in writing.

Following SOP HRP-091 Written Documentation of Consent

Other method for documentation of consent: Click here to enter text.

Applying for Waiver or Alteration of Consent Process, skip this section

Waiver of Documentation of Consent (Subjects are not required to sign a consent document) -<??> <??> <??> <??> If your research is minimal risk and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. Review CHECKLIST: Waiver of Written Documentation of Consent (HRP-411) to ensure that you have provided sufficient information. The criteria for the waiver under 21 CFR 56.109 (c)(1) & 45 CFR 46.117.(c)(2) shown here as it is most commonly used. If requesting a waiver under 45 CFR 46.117 (c)(1) please add the information from HRP-41. Click here to enter text.

The written script of the information to be provided orally and all written information to be provided include all required and appropriate additional elements of consent disclosure per WORKSHEET: Criteria for Approval (HRP-314).

The research presents no more than Minimal Risk of harm to subjects

The research involves no procedures for which written consent is normally required outside of the research context A written statement describing the research will / will not be provided to the subject or subject’s LAR.

3.0 Waiver or Alteration of Consent Process

(consent will not be obtained, required information will not be disclosed, or the research involves deception)

Not applicable, no waiver requested, skip this section.
3.1 Waiver or Alteration Justification

Review HRP-410 Waiver or Alteration of Consent Process to ensure you have provided sufficient information for IRB to make these determinations. This waiver is not allowed for nonviable neonates if the project has HHS funding. The waiver under 45 CFR 46.116(d) shown here as it is most commonly used. See HRP-410 for other means (Public benefit programs, FDA regulated research involving anonymous tissue) Click here to enter text.

The research is NOT FDA regulated
The research does NOT involve non-viable neonates
The research involves no more than Minimal Risk.
Primary risk is a breach of confidentiality, confidentiality adequately protected
Similar privacy risk as experienced with clinical use of the medical record.
Other justification Click here to enter text.
The waiver or alteration will not adversely affect the rights and welfare of the subjects.
Similar privacy risk as experienced with clinical use of the medical record.
Other justification
The proposed study is a survey distributed by a Qualtrics® link sent in an email by designated Sanford personnel to participants. No identifying information is requested in the completion of the survey. Information received will be collated for composite responses. Study data will be maintained by the project advisor following the guidelines set by the University of North Dakota to protect study data, and will be destroyed by the advisor following the 3-year retention guideline.
The research could not practicably be carried out without the waiver or alteration.
Missing or incomplete contact information available to contact subjects for consent
Patients/subjects lost to follow up
No contact information recorded for research
Other rationale: Click here to enter text.
Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
This is not possible as no contact information is recorded.
Other justification for not providing information after participation: Click here to enter text.
Subjects will be provided with: Click here to enter text.

3.2 Waiver for Planned Emergency Research

If the research involves a waiver the consent for planned emergency research, please review the CHECKLIST: Waiver of Consent for Emergency Research (HRP-419) to ensure sufficient information for the IRB to make these determinations. Click here to enter text. Not Applicable

3.3 Deception or Incomplete Disclosure

If the alteration is because of deception or incomplete disclosure, explain whether and how subjects will be debriefed. Add any debriefing materials to eIRB in the 'Consent Forms and Recruitment Materials'. Click here to enter text. Not Applicable
4.0 HIPAA Waiver of Authorization

A waiver is used when access to medical records for research is necessary without subject HIPAA Authorization. Use Checklist: HRP-441 HIPAA Waiver of Authorization Not Applicable, skip this section.

4.1 Records Used-
Describe what records are being accessed (ex. Electronic Medical Record) Click here to enter text.

4.2 Necessary PHI-
Describe the PHI that is necessary for the research. Elements of PHI Click here to enter text.

4.3 Protection of PHI-
Describe the plan to protect the identifiers from improper use and disclosure.

No PHI is recorded
Encrypted portable electronic device storage of identifiers
Identifiers never associated with the other subject data.
Only research personnel will have access to the data

4.4 Destruction Plan for PHI-
Describe the plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

Destruction of data via shredding of paper documents, complete deletion of all electronic records
Other destruction plan: Click here to enter text.
Destruction not allowed. Describe: Click here to enter text.

4.5 Assure PHI will not be Reused or Disclosed-
PI assures that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512
Describe if needed: Click here to enter text.

4.6 Research could not practicably be conducted without the waiver-
Describe why it is not feasible for subjects to sign a HIPAA Authorization.

Missing or incomplete contact information available to contact subjects for signed Authorization Patients/subjects lost to follow up
No contact information recorded for research
Other justification: Click here to enter text.

5.0 Vulnerable Populations

Additional Safeguards-
If the research involves individuals who are vulnerable to coercion or undue influence; describe additional safeguards included to protect their rights and welfare not included previously.
Review the corresponding checklists to ensure you have provided the necessary information within this protocol so that the IRB is able to justify inclusion of these populations. Information not included elsewhere in this protocol should be addressed here.

5.1 Pregnant Women-<??> CHECKLIST: Pregnant Women (HRP-412) Click here to enter text. Not Applicable

5.2 Neonates of Uncertain Viability or Non-viable Neonates-<??> CHECKLIST: Neonates of Uncertain Viability (HRP-414) or Non-viable Neonates (HRP-413) Click here to enter text. Not Applicable

5.3 Prisoners-<??> CHECKLIST: Prisoners (HRP-415) Click here to enter text. Not Applicable

5.4 Children-<??> (viable neonates, infants, children, teenagers) CHECKLIST: Children (HRP-416) Click here to enter text. Not Applicable

5.5 Adults Unable to Consent-<??> CHECKLIST: Cognitively Impaired Adults (HRP-417) Click here to enter text. Not Applicable

Setting/Facilities/Research Site

1.0 Setting

1.1 Locations-<??> Describe the sites or locations where the research team will conduct the research. (ex., Sanford Hospital Dept., Clinic, School, non-Sanford sites) Sanford region information is recorded in eIRB; there is no need to restate. The survey will be completed through Sanford employees remotely, and the data collection and data analyses will be completed at the occupational therapy department and the University of North Dakota in Grand Forks, ND.

1.2 Location of research procedures-<??> Identify where research procedures will be performed. Indicate any specific site certifications (example: CLIA lab certification) Data collection and data analyses will be completed at the occupational therapy department at the University of North Dakota in Grand Forks, ND.

1.3 Prior Approvals-<??> Describe any approvals that will be obtained prior to commencing the research. (E.g., school, external site, funding agency, laboratory, radiation safety, or biosafety approval.) University of North Dakota IRB. Not applicable, no other approvals needed.

1.4 Community Advisory Board-<??> Describe the composition and involvement of any community advisory board. (ex., Tribal board, Community Board) Not Applicable

1.5 Non Sanford site specific considerations-<??> For research conducted outside of Sanford sites, describe: Site-specific regulations or customs affecting the research for
research outside the organization. Local scientific and ethical review structure. (ex., non-
Sanford IRB review) University of North Dakota IRB.

2.0 Multi-Site Research

If this is a multi-site study (i.e., the study will be conducted at other institutions
each with its own principal investigator) and you are the lead investigator, describe the
processes to ensure communication among sites.

Not Applicable, not multi-site research, skip this section.

2.1 Communication Plan

Describe the plan for regular communication
between the overall PI and the other sites to ensure all sites use the most current version
of the protocol, consent document, etc. initially and when modifications occur. Describe
the process to ensure that all required approvals have been obtained at each site
(including approval by the site’s IRB of record). Describe the process for
communication of problems
with the research, interim results and closure of the study. Click here to enter text.

2.2 Data Submission and Security Plan

Describe the process and schedule for
data submission and provide the data security plan for data collected from other sites.
Describe the process to ensure all engaged participating sites will safeguard data. Click
here to enter text.

2.3 Subject Enrollment

Describe the procedures for coordination of subject
enrollment and randomization for the overall project. Click here to enter text.

2.4 Reporting of Adverse Events and New Information

Describe how adverse
events and other information will be reported from the clinical sites to the overall study
director. Provide the timeframe for this reporting. Click here to enter text.

2.5 Quality Control

Describe the process to ensure all local site investigators
conduct the study appropriately. Describe any on-site auditing and monitoring plans for
the study. Click here to enter text.

3.0 Resources Available

3.1 Qualifications

Describe the overall qualifications (e.g., training, experience,
oversight) of you and your staff performing their role. Provide enough information to
convince the IRB that you have qualified staff for the proposed research. The primary
researchers are in their graduate year of the occupational therapy program at the
University of North Dakota. They have completed the Collaborative Institutional
Training Initiative and course work in quantitative and qualitative research. The advisor
holds her Masters of Public Administration and is an assistant professor at the University
of North Dakota in the occupational therapy department.
All study team members working within their scope, all study team members appropriately privileged for any medical research procedures. Explain if needed: No medical research or interventions. It is survey research.
Sanford Clinical Research Department assisting PI, established, experienced staff
Training through Sanford Clinical Research Department
All key personnel will be trained by PI relevant to their delegated duties

3.2 Feasibility of Recruiting Subjects How many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?
Researchers have access to approximately 75 participants in inpatient rehabilitation physical therapy, occupational therapy, and nursing at Sanford Health. While there is no required response rate, researchers hope for 50%-75%.

3.3 PI Time Describe the time that you will devote to conducting and completing the research. Researchers are planning to conduct the survey for four weeks with ongoing data collection. After all responses are received, data analyses and write up will be completed in two months. All research and analysis will be completed by May 1, 2017.

3.4 Facilities Describe your facilities’ ability to manage adverse events that subjects might need as a result of the research. (ex. Medical office/ Hospital with equipment and personnel, Psychological resources, Non-medical facility adequacy justified) Click here to enter text.
Medical Office/ Hospital with emergency equipment and personnel to manage serious adverse events or other consequences of the research
Non-medical facility Justify adequacy: Click here to enter text.
A need for medical or psychological services are not anticipated
Other provision: If adverse events, questions, or complaints were to occur, participants may contact the research team at (307)-268-2223.

3.5 Process for Informing Study Team Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions. Researchers will remain in close contact throughout the research process in order to stay informed about the protocol, procedures, and duties. Researchers will conduct weekly meetings with their advisor.