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An Educational Program for Nurses on Therapeutic Misconception in the Oncology Setting

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MSN, Shenandoah University, 2005

Project Submitted in Partial Fulfillment

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Abstract

A key component of informed consent to participate in research is the understanding that research is not the same as treatment and that scientific goals have priority over therapeutic ones. However, studies have found many research participants do not understand these important differences between research and treatment, a phenomenon termed therapeutic misconception (TM). The problem addressed in this project was research nurses' lack of education regarding the existence and concepts of TM, and their struggles to assess and address research participants' TM of clinical trials. Matutina's conceptual model of TM was used to guide this project. The purpose of this project was to develop an educational program that prepares registered nurses to assess clinical trials participants for TM and correct any misunderstandings. The educational program included concepts related to TM, guidance on recognizing TM, strategies to correct participant misunderstanding, and assessments of nurses' understanding of related concepts and strategies. The products of this project include the program with an implementation plan and an evaluation plan that outlines short- intermediate- and long-term plans for evaluating effectiveness of this program. For both short and intermediate-term evaluation, outcomes will be measured using a pre and post survey. The long-term evaluation of the educational program was designed as a study to measure TM among research participants comparing data before and after nurses receive TM education. Refining the standard education of TM for registered nurses can serve both to improve protection of trial participants and to clarify the informed consent process, ultimately contributing to a more informed population of clinical trials participants.

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Dedication

This work is dedicated to the two most important men in my life: my dad and my husband. I accomplished this because they believed in me. They “knew I could.”

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Section 1: Nature of the Project

Introduction

Studies have found that some research participants do not understand important differences between research and treatment, a phenomenon called therapeutic misconception (TM) (Applebaum, Roth, & Lidz, 1982 and Barrett, 2005). TM arises from the conviction that the purpose of clinical medicine and clinical research is to benefit the patient and that a physician will always act according to what is the best medical care for the patient (Applebaum, Anatchkova, Albert, Dunn, & Lidz, 2012). When recruiting for clinical trials, healthcare providers must ensure potential participants understand that therapeutic benefit to the individual is secondary to the overriding goal of the research study. A key component of informed consent to participate in research is the understanding that research is not the same as treatment. Ethicists contend that informed consent to participate in research should explain the difference between research and treatment in language that the lay person will understand (Applebaum, Roth, & Lidz, 1982). Applebaum et al. (1982) found that many of the study participants believed they were receiving treatment in the form of a medication, based on what was most therapeutic to them personally, despite being told by the researchers that they were participating in a clinical trial in order to discover scientific knowledge and that they may not benefit from participation in the trial. Barrett (2005) stated that "although participants are explicitly told that scientific goals have priority over therapeutic ones and investigators' primary interests are in improving treatment options, participants persist in believing that they will receive benefit from their involvement in the research" (p. 752).

The Nuremburg Code clearly stated that research participation is undertaken "without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion…" (International Military Tribunal, 1949). Black et al. (2013), citing the World Medical Association (1964), stated that "the requirement of voluntariness has been confirmed universally over the years as an essential element of research participation" (p. 26). The misunderstanding of the purpose of research (TM) has the potential to compromise the voluntariness of consent by creating a risk-benefit perception by the patient that does not coincide with the reality of the trial. Barrett (2005) asserted that "as patient advocates and educators, nurses must be able to assess individuals' understanding to ensure the validity of the informed consent process" (p. 752).

Problem Statement

TM is a critical problem in research clinical trials (Applebaum et al., 2012). Research and therapeutic clinical care involves different standards with regards to the treatment of the patient or research subject. The sole purpose of medical therapy is to treat an illness or injury and to improve health. The primary purpose of medical research is to gain knowledge. The confusion of the two often leads to profound misunderstandings on the part of the research subject. The role of nursing in clinical research continues to expand and "nurses must develop strategies that provide clinical trial patients with a better understanding of the trial they are considering, identify areas of misunderstanding and correct them, and assess the outcomes of the informed consent process" (Barrett, 2005, p. 752). This project addressed the problem of the research

nurse's education regarding the existence and concepts of TM and the ability to assess and correct, if necessary, the research subject's misunderstanding of the trial. The problem addressed in the project was the lack of knowledge among registered nurses regarding TM.

Purpose Statement

Historically, research on TM has been conducted because of concern that participants may misunderstand aspects of trial care that leads them to make decisions incompatible with their true preferences and values. Obtaining informed consent, permission granted by patients for healthcare services, and knowing the possible consequences is an ethical obligation of nurses and other health care providers. Registered nurses working with clinical trial participants should (a) understand the concepts of TM as well as the potential negative impact on the informed consent process, (b) be able to assess clinical trials participants for the influence of TM, and (c) be able to correct any misunderstanding the participants may have regarding the benefits and purpose of participation in the clinical trial. The purpose of the project was to develop an educational program for registered nurses (RNs) on TM.

Goals and Outcomes

The goal of the project was to improve RNs' ability to decrease TM in clinical trials. This goal included several objectives to increase the RN's (a) knowledge of therapeutic misconception, (b) skill in assessing the participants understanding of trials, and (c) ability to correct the participants misunderstanding of the trial purpose. In

achieving the objectives, the overall goal of the project was achieved. The objectives were measured in the evaluation phase using a pre- and post-survey.

As a component of participation in the program, registered nurses were asked to complete a survey before and after the education program in order to gauge their knowledge of TM. Measures included the RNs' (a) knowledge of the existence and concepts of TM, (b) knowledge regarding the assessment of participant's understanding of trial, and (c) method of correcting the participant's misunderstanding of the trial purpose.

Definition of Terms

Clinical trial: The World Health Organization defined a clinical trial as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes" (World Health Organization, 2014, para.1).

Educational Program: A scheduled series of lessons designed to convey the knowledge and skills, related to TM, of the clinical trials experts to registered nurses inexperienced in clinical trials, through teaching, training and research.

Expert: Having, involving, or displaying special skill or knowledge derived from training or experience (Merriam-Webster on-line Dictionary).

Informed consent: Informed consent is a process designed for the protection of human subjects in research. Ensuring that subjects who participate in research are made aware of the experimental nature and that they voluntarily consented to participate is very important. Among the important consideration from the Belmont Report (1979), the

"respect-for-persons" principle is the requirement that subjects are given the opportunity to decide for themselves if they want to participate in a study after being told that they will be subjected to human experimentation. When consent is signed on the false belief that the study provides direct benefit of treatment and individual care, informed consent is not fully administered.

Registered nurse: A nurse who has graduated from an accredited school of nursing, has passed an exam, and has been registered and licensed to practice by state authority (Stedman's Medical Dictionary, 2002).

Therapeutic misconception: The definition of TM can be found in Henderson's et al. (2007) statement:

> Therapeutic misconception exists when individuals do not understand that the defining purpose of clinical research is to produce generalizable knowledge, regardless of whether the subjects enrolled in the trial may potentially benefit from the intervention under study or from other aspects of the clinical trial." (p. 3)

Assumptions and Limitations

In this project, I assumed that educating registered nurses working with clinical trials patients regarding TM had a positive impact on decreasing the existence and prevalence of TM in the research departments of adult oncology. A second assumption was that the RN recognized the value in learning about TM as a benefit not only to his or her career but more importantly as a benefit to his or her research participants.

This project was limited by the varied geographical locations of the team members, the dependence on technology, and the variance of multiple schedules. The

team consisted of clinical trials experts employed at several facilities throughout the state. Communication among the team members was accomplished via e-mail, and meetings were conducted using telephone conference lines. Conflicting schedules proved to be a challenge in scheduling meetings with all team members in attendance.

This project was further limited by the inability to test whether or not TM was actually decreased by educating RNs on the concepts and existence of TM. Because this project did not include the perceptions of research participants, the ability of the RN to decrease TM could not be measured. Therefore, the outcome of the educational intervention was measured in the evaluation stage using the nurse's perception and self-reporting.

Biases

Risks of bias for this project included program design and evaluation. By design, this project's implementation included a small sample size of registered nurses participating in the educational program. In general, the larger the sample size in a quantitative study, the more likely the sample will be representative of the population of interest (Myers & Hanson, 2002). The educational program should be expanded to include larger sample sizes before data can be considered impartial, accurate, and useful.

As a part of the participation in the educational program, in the implementation stage, registered nurses will be asked to complete a survey designed to gauge their knowledge of TM. After participating in the educational program, the nurses will be asked to complete the same survey. Before and after comparisons will be made to evaluate whether or not the program positively affects the nurses' knowledge of TM,

their ability to recognize TM, and their confidence in their ability to correct participants' misconceptions regarding the purpose of research. A pre- and post-test data collection tool offers "a measurement of the learning received during the [class] as a result of comparing what the student knew before in a pre-test and after in a post-test. The same instrument is used to collect data before and after the experience" (Diem, 2002, p. 1). The integrity of the data will depend largely on the validity and reliability of the data collection tool.

Relevance to Nursing Practice

Judkins-Cohn, Kielwasser-Withrow, Owen, and Ward (2013) stated that during the past 20 years, there has been an increase in developing policies that ensure the use of research and evidence-based practice for both nursing and medicine in the clinical setting. With the increase in research activities, more nurses are engaging in research as Principle Investigators (PIs) and members of research teams. The 2010 Institute of Medicine's *Future of Nursing* report recommended that by 2020 there will be a need for double the current number of doctoral prepared nurses. Thus, "the result is the creation of the dual role of care provider and researcher" (Judkins-Cohn et al., 2013, p. 4199). This dual nursing role demands a thorough understanding of the informed consent process. This understanding includes the difference between the goals of clinical care and research (TM), following research-specific ethics involved in the informed consent process, and understanding quality measures of the informed consent process.

The TM is a serious problem for informed consent in clinical research and conflicting desired health outcomes for healthcare providers and patients suggest

implications for nursing practice. Applebaum and Roth (1983) raised the question, "Who should have the task of explaining the therapeutic misconception to subjects?" (p. 12). Institutional policies typically require that potential participants be approached about research by someone known to them and that the consent process must be conducted by someone who fully understands the research study. The PI for a research study may also be the healthcare professional caring for a potential research participant.

The PI may be the person most knowledgeable about the research and most qualified to approach the potential participant; however, they may not be the best person to complete the informed consent process. Because of the potential for TM, there may be benefit to having a research study team member who is not the PI involved in the consent process (Pranati, 2010). The PI has a responsibility to distinguish between treatment and research and to clearly explain the implications for the potential participant. However, even when a PI clearly emphasizes that the goal of the research is not to provide care, patients sometimes continue to believe that the research will provide them with direct benefit (Pranati, 2010). Pranati (2010) also stated that a solution to this challenging situation is to have the research nurse complete the informed consent process after the PI has explained the research in detail. The study nurse can then determine whether the patient understands the research and his/her willingness to participate outside the direct influence of the PI. Clinical trial nurses must communicate information about the nature and goals of clinical research, explain the details of the specific study, and assess participants' understanding of the consent information (Ehrenberger & Lillington, 2004).

Evidence-Based Significance

Solid understanding of research ethics requires the clear distinction between research and therapeutic treatment. The first principle of The Belmont Report (1979), which is the ethical basis for the U.S. federal regulations, is "respect for persons"—persons have the right to decide for themselves whether to participate in research on the basis of information provided about the nature of the trial, potential benefits, and adverse effects, and alternative treatments. In order to decrease the incidence of TM, researchers must be judicious in their use of the term "treatment" (Banks, 2009). When a study drug, study intervention, or investigational therapy is referred to as a treatment, there is an increased chance that a potential participant will misinterpret the purpose of the trial. The patient-participant who thinks they are receiving individualized therapy when in fact they are being treated according to a research protocol cannot give informed consent (Steinke, 2004).

Kola and Landis (2004) reported that the average success rate for new drugs was 11%, ranging from 20% in cardiovascular trials to 5% in oncology trials. They found that 60% of the time, the reasons that the drugs did not make it to market were efficacy and safety. It is very likely in oncology Phase I and II trials that the patient will not benefit, and consent language must state this clearly (Kola & Landis, 2004). The mere disclosure of risks and benefits in lengthy and legalistic forms may not be sufficient in light of such evidence (Barrett, 2005). Evidence has suggested transforming the informed consent process from passive disclosure to more active education and interaction with patient participants in clinical research (Pranati, 2010). When discussing a participant's

expectations of direct benefit, only the benefits that can be "reasonably expected" should be discussed (Banks, 2009). This clarification will help participants understand the potential benefits of the research, as well as the alternatives to the research that are available.

Social Change

The societal response to ethical problems associated with clinical research has been the implementation of regulatory laws and policies, including detailed federal regulations governing research involving human subjects (Miller, Rosenstein, & DeRenzo, 1998). The application of these regulations has led to improved protection of the rights and welfare of research participants; however, there remain deficiencies that need to be addressed (Miller et al., 1998). Changes to consent procedures should be adopted to ensure that all potential participants are aware that their condition and benefit is not the priority of the clinical trial (Pranati, 2010). Diligent examination of potential research participants should expose truly altruistic reasons for participating in the trial. Potential participants should understand and accept that they may not benefit medically from participation in a clinical trial.

Summary

TM has been seen as presenting an ethical problem because failure to distinguish the aims of research treatment from those receiving standard treatment may seriously undermine the informed consent of research participants. Although TM is not considered a complete failure to obtain informed consent, health care researchers must be confident in determining the answers as to why the patient is joining the study and what health

benefit they expect to obtain. Because of the potential for TM, there may be benefit to having a research study team member who is not the PI involved in the consent process (Pranati, 2010). TM may be decreased or alleviated by educating nurses involved in research on the existence and concepts of TM, allowing participants a much clearer picture of the relative risks and benefits of participation in a clinical trial.

Section 2: Review of Literature and Conceptual Framework

Literature Review

Using the Walden Library and other appropriate databases (CINAHL Full Text, PubMed, Medline Full Text, and Ovid Nursing Journals Full Text) peer-reviewed articles were located for inclusion in this evidence-based project. Although there was an effort to use the most current information available, there was no stipulation for years searched. Key search terms included *therapeutic misconception, informed consent, oncology clinical trials*, and *nursing research communication*. The search included major authors: Applebaum, Roth, and Lidz. Inclusion criteria consisted of research ethics, medical ethics, clinical trials coordinator, and communication in research. The term therapeutic overestimation is often times confused with TM and was excluded from research criteria.

Therapeutic Misconception

In 1982, Applebaum et al. reported on findings from interviews with research patients who documented failure to appreciate the difference between research and treatment, labeling the phenomenon "therapeutic misconception." TM arises from the conviction that the purpose of both clinical treatment and clinical research is to benefit the patient and that a physician will always act according to what is the best medical care for the patient (Applebaum, 2012). In 2007, Henderson et al. reported that "for over three decades, bioethics scholarship and research ethics guidelines have identified concerns about the boundaries between research and standard clinical care" (p. 1735). Ethicists have argued that informed consent to participate in research should include clarification

of the differences between these two activities (Applebaum et al., 1982). While a research participant may receive good clinical care as a participant in research, clinical care must not be confused with clinical research, which is to generate scientific knowledge to improve therapy for future patients (Henderson et al., 2007).

Meropol et al. (2003) found that a clinical trial cannot be assigned therapeutic merit without denying the trial's scientific merit. One process instrumental in alleviating TM is the informed consent process. Informed consent is governed in clinical research by three basic elements where the participant (a) is informed about the study including risks and benefits, (b) understands the information, and (c) enrolls voluntarily (The Belmont Report, 1979). The Code of Federal Regulations (21 C.F.R. Part 50.25) requires that the consent form explicitly state that the study involves research and the purpose and procedures are experimental. This information is relevant to the current issue of the ethical implications of TM. This federal guideline reinforces the scientific focus of clinical research. Barrett (2005) claimed that "current methods of obtaining valid informed consent may be insufficient to ensure patients understanding of information of the proposed trial" (p. 751). The language used for informed consent must not promote but reduce TM.

The problem of TM may extend beyond the informed consent process and cause a lack of trust in research as a whole (deMelo-Martin & Ho, 2008). DeMelo-Martin and Ho (2008) argued that "the differences between the goals of clinical treatment and research are so significant that they ought to be governed by distinct ethical norms" (p. 202). The authors indicated that research participants trust the principle investigator in the same

way they trust their treating physician and that this trust is misplaced (de-Melo-Martin & Ho, 2008). Because the protection of patients' best interests is not a goal of an oversight agency deMelo-Martin and Ho further stated that a participant's trust in research oversight agencies is also misplaced. DeMelo-Martin and Ho concluded that under the influence of TM, research participants' trust is misplaced if they trust the researchers and oversight agencies to protect them and promote their best interests.

Lidz and Applebaum (2005) stated that patients recruited for research studies could not assume they had the same clinical goals and expected outcomes as the research investigators. The authors pointed out that the methods used in clinical research may significantly decrease clinical care. Lidz and Applebaum stated, "Patients come to the clinical research setting with expectations derived from both cultural images of the physician-patient relationship and their previous experiences with medical caregivers" (Lidz & Applebaum, 2005, p. 57). The authors acknowledged that while TM is widely recognized, little is known about affects in clinical research, including prevalence and consequences. Several studies have shown that the severity of illness affects retention of information and that the sickest patients were more likely to attribute therapeutic goals to research. Details regarding the study that researchers disclosed to participants have been identified in several previous studies as an important determinant of participants' understanding in general (Lidz & Applebaum, 2005). Lidz and Applebaum found that both the discussion between the investigator and the potential participant and the consent form should emphasize the difference between therapy and research. Specifically,

participants must be made aware that research is conducted to gain knowledge and not for therapeutic purposes (Lidz & Applebaum, 2005).

Scott et al. (2009) conducted a pilot study of subjects enrolled in a Phase I test of gene transfer for Parkinson's disease focusing on how the participants made their decision to participate. The primary goal of the pilot study was to understand how participants might fall into a misconception about the purpose of the research in which they have volunteered to participate. The approach of the study was to examine statements made by the participants that had potential implications for TM. They discovered that patients who volunteered for the gene study were highly motivated by a desire for therapeutic benefit. However, they also found that most participants with the desire for therapeutic benefit also understood the purpose of the study. Scott et al. found that there were many variations of the desire for therapeutic benefit and similar variations in the understanding of the purpose of the study. They found that most patient-participants have "styles" of reconciling their motivations with their understanding that do not compromise understanding. Their data analysis revealed potential approaches for measuring and preventing TM. (Scott et al., 2009).

Kass et al. (2009) reported that 17% of cancer patients enrolled in a Phase I cancer trial believed the trial offered a cure, 60% reported a purpose related to efficacy, and 17% related the study to dosing, safety, and side effects. The authors stated that if the reports regarding participants' beliefs about clinical trials are based on a true misconception, this causes an ethical dilemma, especially for early phase trials where the primary purpose is to determine toxicity. Their work further documented that oncologists

usually provide potential participants with brief comments regarding the limited potential for treatment benefit linked with longer encouraging statements regarding research discoveries and breakthroughs. They concluded that regardless of the patients own outlook, ensuring that the differences among Phase I, II, and II trials are described and that risk/benefit information is clear is critical to the informed consent process (Kass et al., 2009).

Prevalence

Empirical studies of clinical trials, predominantly early stage cancer trials, indicated that participants were often motivated to participate in research by expectation of direct medical benefit, and when asked, blurred the distinction between research and treatment (Weinfurt et al. 2003). Weinfurt et al. (2003) noted that

> Research and treatment are often used as interchangeable terms, surrogate endpoints (e.g., tumor shrinkage, immune response) are discussed but not distinguished from clinical endpoints (e.g., survival time, improved quality of life) and that benefit to society and inclusion benefits are not distinguished from possible medical benefits for participants. (p. 167)

Cohn, Jia, Smith, Erwin, and Larson (2008) conducted a pilot study testing the reliability and validity of an observational instrument measuring the process and quality of informed consent. The authors found that by direct observation of the informed consent process researchers were able to determine if patients suffering TM were not provided the information needed, did not remember or were confused regarding the

information provided or if the information was not explained in a language or manner that they could understand. From this study, the investigators documented a number of issues in the informed consent process, including TM.

Motivated by "genuine concern" for the welfare of cancer patients with advanced disease, Nurgat, et al. (2005) investigated the motivations and inhibitions of patients participating in cancer clinical trials, their understanding of the purpose of the research and alternative treatment options, and influences on their decision to participate in the clinical trial. Patients were surveyed after they had given informed consent and before or during the first cycle of treatment. Surveys were completed by 38 patients participating in Phase I and II cancer clinical trials: 89% listed obtaining possible health benefits as a very important factor in their decision to participate and only 17% listed helping future cancer patients as a very important factor in their decision to participate (Nurgat et al., 2005). In this survey, most patients (97%) felt that they understood the purpose of the research and had given truly informed consent. Although Phase I and II cancer clinical trials seldom offer medical benefit, the authors found that most patients volunteered for trials based on a hope for medical benefit.

In 2004, Barrett conducted a research study in order to describe clinical trials participants' knowledge and understanding of the oncology clinical trial in which they were participating. Barrett used The Quality of Informed Consent (QuIC) questionnaire, developed by Joffe (2001), to assess the adequacy of informed consent. This tool is a standardized measure for assessing informed consent in research and is based on the elements of informed consent specified in federal regulations (U.S. Department of Health

and Human Services, 2004). Barrett's findings from this study, published in 2005, offered new insight into the problem of TM. Half of the sample failed to understand that clinical trial treatment is not standard treatment and may involve additional risk. Barrett concluded that although principle investigators (PIs) have the responsibility to ensure informed consent is obtained, clinical trials nurses do not communicate information adequately to obtain valid informed consent. The use of supplemental aids and resources may contribute to the nurse's ability to communicate the information more adequately (Barrett, 2005).

Therapeutic Misconception among Researchers

In a survey of oncologists, Joffe, Cook, Cleary, Clark, and Weeks (2001) concluded that clinical investigators hold different views on the purpose of conducting clinical research. The survey found that 20% of the participants believed that main purpose of clinical research was to provide patients with "state-of-the-art" therapy. This response may explain underlying tension about the moral justification of research: that subjecting patients to potentially risky research is unethical "unless clinical benefit is a legitimate research purpose" (p. 140). However, many bioethicists and clinical investigators find this opinion problematic because the purpose of research by nature is potentially risky and may involve consequences. These consequences may be because research and clinical care procedures and activities overlap or because administration of an experimental agent is seen both as a means to learn about the safety and efficacy and as an appropriate therapeutic option (Joffe et al., 2001). This debate reveals the difficulty of applying general assessments to trials that have very different study

designs. Instone, Mueller, and Gilbert (2008) noted that TM can occur within PIs and clinical trials nurses. While conducting a study of the informed consent process at their facility, they found that many of the documents and the language of the investigators and clinical trials nurses used the terms “treatment” and “treatment trial,” which suggested that the investigators and nurses believed the trial would offer the subjects some health benefit (Instone et al., 2008).

Few researchers who are also clinicians feel comfortable acknowledging, even to themselves, that an experimental course of treatment may not be optimally therapeutic for the patient (Applebaum & Roth, 1983). Even investigators who recognize the desirability of participants making informed decisions may have trouble conveying this particular information. Researchers should be encouraged to discuss such issues with participants and to include them on consent forms. Applebaum and Roth (1983) reported that participants' perceptions of the research team as willing to "level with them," even to the point of explaining why doing so might not be in participants' interests to participate in the study, may increase their trust and cooperation. Failure to address the TM during the consent process could increase distrust of researchers and the health care system in general, especially if subjects later believe they were "deceived” (Applebaum & Roth, 1983).

Review of Evidence

Nursing Role in Research

The rapidly growing field of clinical research offers a unique and challenging role for nurses. Clinical research nurses aid in the coordination, management, and conducting

of clinical research under the supervision of a designated investigator (Pick, Liu, Drew, & McCaul, 2010). Pick and colleagues stated that "The research nurse plays a key role as patient advocate, ensuring patient safety and protection and that the patients are well supported through out the research study" (Pick et al., 2010, p. 3). The Oncology Nursing Society (ONS) addressed the role of the oncology clinical research nurse in the Oncology Clinical Trials Nurse Competencies (2010) report. Ensuring patients give fully informed consent before being enrolled to trials is fundamental to the role (ONS, 2010). Making sure patients are given all of the information they need and that they fully understand the purpose of the study, including risks and benefits and that the choice to participate is completely voluntary are responsibilities of the research nurse (ONS, 2010).

As the senior advisor for nursing for the Agency for Healthcare Research and Quality (AHRQ), Sharp, reported that while everyone's role in healthcare is changing, one major focus of change that involves interdisciplinary collaboration is patient-centered-care, which has always been a primary nursing value (AHRQ, 2012). The National Institute of Health Clinical Center delineates the responsibilities of the clinical research nurse by separating them into categories that include care coordination and continuity and human subject's protection. These responsibilities include (a) providing nursing leadership within the interdisciplinary team, (b) providing nursing expertise to community-based health care personnel related to study participation, (c) facilitating the initial and ongoing informed consent process, (d) collaborating with the interdisciplinary team to address ethical conflicts, and (e) coordinating research activities to minimize subject risk (National Cancer Institute [NCI], n.d.).

Educating Nurses on TM

In response to the enactment of the Affordable Care Act (2010) the Institute of Medicine (IOM) released a report in 2011, "The Future of Nursing: Focus on Education." This report explained that "the ways in which nurses were educated in the 20th century are no longer adequate for dealing with the realities of health care in the 21st century" (IOM, 2011). As health care settings and patient needs continue to be increasingly complex, nurses must elevate their education and competencies in order to offer high-quality care; especially in the areas of research and evidence-based practice. Despite the increased number of nurses working in the field of research there remains two major obstacles to performing this role: lack of a clear, defined job description and lack of education and training to perform the responsibilities in this occupation (Spilsbury et al., 2008). Although educating and training new clinical research nurses are important, there is no standard requirement for training and education within the research industry (Bakker & Fitch, 1998). Individual facilities are responsible for setting their own standards for educating research nurses. As nurses are expected to have education, training and licensure to practice clinically, they should also be expected to have education and training to practice in the research arena (Spilsbury et al., 2008).

Scott et al. (2013) indicated that The American Nurses Association ([ANA], 2010) Standards of Practice can assist clinical trials nurses with prevention of therapeutic misconception. The authors concluded that based on the assumption that potential research subjects do not have all of the information needed to make a participation decision or there is a misunderstanding regarding the information they do have, a

diagnosis of knowledge deficit related to lack of information or misinterpretation of information, can be made. Scott et al. reported "If research subjects continue through the informed consent process with a knowledge deficit, a therapeutic misconception may result." (p. 9). Research nurses must possess the ability to communicate clearly and give clear explanations. Clinical trial nurses should assess their ability to convey information and adjust their teaching approach to meet the patient's and family's teaching needs (Scott et al., 2013).

Having well-trained, knowledgeable staff to administer a fully comprehensive consent process is essential (Pranati, 2010). Research nurses must be trained on human research participation protection and demonstrate respect and patience during the process. After providing all of the information, to complete the communication cycle, assessing how much the patient understands is important. This will enable the nurse to realize which areas are difficult for the participant to grasp and provide the opportunity to explain those elements more carefully to the next participants (Pranati, 2010).

Ulrich stated that the knowledge and skills needed to care for patients participating in clinical trials is not included in most nursing school curricula (National Cancer Institute [NCI], 2012). She further states that the gap in nursing education can cause ethical difficulties. Ulrich (NCI, 2012) believes that every nurse should have a minimum of beginning-level competency in clinical research.

Conceptual Model

The term for the phenomenon currently known as "therapeutic misconception" originated with Applebaum et al. in 1982 after they observed psychiatric patients who

were obviously confused about research versus therapeutic treatment but consented to participate in research studies anyway. Matutina (2010) identified four elements present in TM in which patients/subjects

- Confuse research with treatment.
- Believe they will receive therapeutic benefit from research participation.
- Fail to communicate "contribution to science" as motive for their participation in research.
- Overestimate therapeutic response rates and misinterpret study purpose.

Avant (2000), referring to the Wilson Method of Concept Analysis, stated that the social context in which a concept is found can provide valuable insight (see Appendix A for a concept map of TM). Matutina identified the social context of TM as research and believes the goals and motives of the researchers should be questioned. She stated that, in the very least, one should question whether or not researchers attempt to educate subjects regarding TM as they are recruited and whether or not, while obtaining informed consent, researchers stress the positives and downplay the negatives (Matutina, 2010).

Gaps in Literature

Although there has been considerable theoretical and empirical work on TM over the past thirty years, most of the work has focused on attempts to validate measures of TM or evaluate whether and to what degree TM invalidates the informed consent process. There are two obvious gaps in the literature referencing TM. There is a lack of literature

related to the development and implementation of a tool to measure TM. The "gold standard" for the measurement has historically been an open ended interview (Henderson, et al., 2007). An interview may determine the existence of TM but does not measure the magnitude of the condition. Also, while there is much literature to determine and validate the existence of TM there is very little knowledge and research attempting to decrease or alleviate the condition. In the current literature there is very little mention of the use of nursing interventions to decrease the existence of TM.

Summary

In the past decade deficiencies in the informed consent process have become a significant priority in the clinical research arena. Researchers worldwide are exploring ways and means to strengthen the process in terms of patient comprehension and autonomy and "must be careful in the language they use to describe their studies to avoid therapeutic misconception" (Steinke, 2004, p. 91). A genuinely knowledgeable and autonomous decision to participate in research is not only an ethical obligation but will ensure the participant remains involved through out the study (Pranati, 2014). Glannon (2006) found that in many cases, the hope for direct benefit motivated people to participate in medical research. The author stated that even if clinicians and researchers carefully explained the difference between clinical care and research to patients and even if the consent process prominently stated that subjects were not likely to benefit from participation, the incidence of TM may be reduced but not eliminated. Although obtaining informed consent may be a Principle Investigator's (PIs) legal responsibility,

research nurses have an ethical responsibility to ensure patients' understanding of the entire consent process (Hubbard, 1982).

Section 3: Methodology

Project Plan

The clinical research nurse is often responsible for teaching and communicating specific details about a trial to the potential participant. Numerous opportunities to interact with research participants place the nurse in the position of being the one to discover the misconceptions regarding the purpose of the research study. Guiding patients through the consent process requires competent communication skills and specialized knowledge about human subjects' protection (NCI, 2012). The research nurse must ensure that the patient understands that the purpose of the clinical trial is to gather scientific knowledge and that the subject may not benefit from participation.

This project was accomplished by completing coordinated steps:

1. A team of clinical trials experts was established. Team members were willing to participate in the creation of an educational program to be taught at their facility. Oncology nursing backgrounds were given preference.

2. I led the project team in reviewing the relevant literature related to therapeutic misconception and nursing's role in managing therapeutic misconception.

3. The team developed an educational program for registered nurses. The educational program included concepts related to TM, guidance on recognizing TM in potential research subjects, strategies to correct potentials subject's misunderstanding, and assessments of nurses' understanding of related concepts and strategies.

4. The educational program was submitted to three scholars with expertise in nursing education and clinical trials for review and content validation.
5. I led the project team in developing an implementation plan for the program.
6. I led the project team in developing an evaluation plan for the program.

Developing the Education Program

The primary site of the project, Site A, was a small community healthcare organization in the coastal Southeastern section of the United States. The organization consists of two hospitals and two free standing community cancer centers. Clinical trials are offered through a partnership with an academic facility located 40 miles south of the primary site. Three other sites participated in the project and were chosen for the geographical location to the primary site, history of collaboration with the primary site, community setting, and participation in oncology clinical research. Site B was a community clinical oncology program that offers a center for cancer treatment and research and treats 1,300 newly diagnosed cancer patients annually. Site C was an academic facility with over 120 staff members employed in the research department that operates with 40 million dollars in funding. Site D offers a research center and cancer institute with over 70 oncology clinical trials currently open for accrual. Team members were chosen based on their expertise in oncology clinical trials, experience in the area of clinical research, and the varied training, knowledge and skills contributable to the team. Team members were chosen and responsibilities were delineated by the DNP student:

- As the project manager I (Site A) facilitated the activities of the team, organized meetings, and wrote the curriculum for the educational program.
- A Radiation Oncologist (Site A) provided a principle investigator's point of view during the development of the educational program.
- Four research nurses, one from each of the participating sites, were the primary architects of the educational program.
- The director of research for Site D assisted in the development of the educational program and in establishing the implementation plan.

All of the participating facilities had access to web-conferencing technology. The team met via web-conferencing. A recurring meeting invitation was initiated by the project manager to the team members that once accepted appeared on their calendars. Team members were encouraged to share all information they determined to be relevant, including important aspects of TM. A quality educational program was developed from the diverse backgrounds and individual expertise of team members. Meetings were scheduled weekly for 5 consecutive weeks for the duration of 1 hour each. The first meeting focused on a review of the relevant literature related to TM and nursing's role in managing TM. The second meeting established goals and a syllabus for the educational program. The third and fourth meetings were used to create the content (curriculum) of the program. Key aspects of the education program include the concepts of TM, methods to recognize TM, and strategies for correcting TM. The fifth meeting established the

duration of the educational program as five 1-hour classes as well as the design of the educational program using a classroom setting.

The Walden University IRB reviewed the project plan and determined that the project met Walden University's ethical standards. This Confirmation of Ethical Standards (CES) has an IRB record number of 12-26-14-0331603. No data were collected during the project.

Resources and Budget

Time was the most valuable as well as limited resource related to the completion of the project. Conflicting schedules proved to be a challenge in scheduling meetings with all team members in attendance. With today's healthcare employees wearing multiple hats and working within limited budgets, there was limited time available for team members to engage in the many tasks associated with the project. There were no costs associated with this project, and no budget was required.

Content Validation of Educational Program

Once the program was developed, the curriculum was shared with all members of the team for final review and approval. The approved program was then shared with three experts in the field of nursing education and research for content validation. One associate professor of nursing, one nursing instructor, and one director of clinical research (all registered nurses) examined the educational program content for validity.

Developing the Implementation Plan

Following the completion of the project, each team member agreed to teach the program to the qualified nurses within their organizations. The director of research at Site

D has vast experience in implementing new programs within the healthcare arena (specifically research) and assisted in establishing the implementation plan for the educational program developed for this project.

Developing the Evaluation Plan

Following the completion of the project and my graduation, the educational program will be implemented and then evaluated. Outcomes will be measured for each of the objectives using a pre- and post-survey. As a part of the expected participation in the educational program, registered nurses will be asked to complete a survey designed to gauge their knowledge of TM. After participating in the educational program, the nurses will be asked to complete the same survey. Before and after comparisons will be made to evaluate whether or not the program positively affects the nurses' knowledge of TM, their ability to recognize TM, and their confidence in their ability to correct participants' misconceptions regarding the purpose of research. A pre- and post-test data collection tool offers "a measurement of the learning received during the [class] as a result of comparing what the student knew before in a pre-test and after in a post-test. The same instrument is used to collect data before and after the experience" (Diem, 2002, p. 1).

Summary

Nurses have important roles as advisors and potential referral sources for patients who are volunteering for clinical research. Investigators often consult with nurses about the appropriateness of particular patients as study participants. Therefore, nurses should receive education in the fundamentals of clinical trials design and process including consent and TM. It is expected that nurses will vary considerably regarding how much

time and effort they will spend helping their patients understand and consider participation in clinical trials. To advise patients optimally, it is desirable that all nurses appreciate the general aspects of how participation in a clinical trial differs from standard clinical practice (Steinke, 2004). These issues should be incorporated into the standard and continuing nursing education processes. As nursing and other health care professional students learn to interpret research literature in the practice of evidence-based practice, how to advise patients concerning research participation could also be included in educational courses. The implications of clinical trials research are important to all health care professionals whether they choose to practice in the field of research or not.

Section 4: Findings, Discussion, and Implications

Introduction

Research and therapeutic clinical care involves different standards with regards to the treatment of the patient or research subject. The sole purpose of medical therapy is to treat an illness or injury and to improve health. The primary purpose of medical research is to gain knowledge. The confusion of the two often leads to profound misunderstandings on the part of the research subject. The purpose of this quality improvement project was to develop an educational program on therapeutic misconception for research RNs working in the oncology setting. The goal of the project was to improve RNs ability to decrease TM in clinical trials. This goal included several objectives to increase the RN's (a) knowledge of therapeutic misconception, (b) skill in assessing subject's misunderstanding of trials, and (c) ability to correct subject's misunderstanding of the trial purpose. In achieving the objectives, the overall goal of the project was achieved.

The outline for planning and designing the educational program (Appendix C: Educational Program on Therapeutic Misconception Syllabus) was adapted from Design for learning-A self paced guide by Cybela and Greer (1997). The implementation plan (Appendix D) was developed with the understanding that the educational program will be taught at several varying institutions. The program will be implemented by individual team members in a variety of organizational settings, allowing for slight adjustments to the implementation plan; however, the team has agreed that all team members will fully implement all aspects of the program. The evaluation plan (Appendix E) was created with

three time frames: short term, intermediate and long term evaluations. The Walden University Institutional Review Board (IRB) confirmed that this project meets Walden University's ethical standards. This Confirmation of Ethical Standards (CES) has an IRB record number of 12-26-14-0331603.

The Educational Program Syllabus

Assessing the Need

In order to manage time and cost, existing statistics and data were used to identify the need for educating research RNs regarding TM. Studies have found that some research participants do not understand important differences between research and treatment, a phenomenon called therapeutic misconception. Research has shown that in Phase I oncology clinical trials, subjects generally do not understand the difference between the study purpose and cancer treatment. Nearly 90% of participants stated their goals in joining a Phase I study were the same as their goals in undergoing established cancer treatments (Daugherty, 2000). Empirical studies of clinical trials, predominantly early stage cancer trials, indicated that subjects were often motivated to participate in research by expectation of direct medical benefit, and when asked, blurred the distinction between research and treatment (Weinfurt et al., 2003).

The role of nursing in clinical research continues to expand, and research nurses must be aware of the concepts of TM and its impact on the consent process. The ONS addressed the role of the oncology clinical research nurse in the *Oncology Clinical Trials Nurse Competencies* (2010) report. Ensuring patients give fully informed consent before being enrolled to trials is fundamental to the role (ONS, 2010). Making sure patients are

given all of the information they need and that they fully understand the purpose of the study including risks and benefits and that the choice to participate is completely voluntary are responsibilities of the research nurse (ONS, 2010). Despite the increased number of nurses working in the field of research, there remains two major obstacles to performing this role: lack of a clear, defined job description and lack of education and training to perform the responsibilities in this occupation (Spilsbury et al., 2008). To date, there has not been a standard education program designed or implemented to educate the clinical trial nurse regarding TM.

Plan and Design Team

Team members were invited to participate in this project on a volunteer basis, without financial compensation, based on their clinical trials experience and expertise.

Team members and responsibilities are as follows:

- The project manager and I (Site A) facilitated the activities of the team, organized meetings, and wrote the syllabus for the educational program.
- A Radiation Oncologist (Site A) provided a principle investigator's point of view during the development of the educational program.
- Four research nurses, one from each of the participating sites, were the primary architects of the educational program.
- The director of research for Site D assisted in the development of the educational program and in establishing the implementation plan.

All of the participating facilities had access to web-conferencing technology. The team met via web-conferencing twice per week beginning on January 5, 2015 (Appendix B). A recurring meeting invitation was initiated by the project manager to the team members and once accepted appeared on their calendars. Team members were encouraged to share all information they determined to be relevant including important aspects of TM. An educational program was developed using the diverse backgrounds and individual expertise of team members as a resource.

Target Audience

The target audience for this educational program is registered nurses who care for the research subject in the adult oncology setting. Their motivation to learn is based on self-efficacy as well as quality of care for the research subject.

Goals and Desired Outcomes

The goal of the educational program is to improve RNs ability to decrease TM in clinical trials. This goal includes several objectives to increase the RN's (a) knowledge of therapeutic misconception, (b) skill in assessing subject's misunderstanding of trials, and (c) ability to correct subject's misunderstanding of the trial purpose. In achieving the objectives, the overall goal of the project is achieved. Following the project completion, during the implementation and evaluation phases, the RN's knowledge will be measured using a pre- and post-survey. As a component of participation in the program registered nurses will be asked to complete a survey before and after the education program in order to gauge their knowledge of TM. Measures will include the RNs' (a) knowledge of the existence and concepts of TM, (b) knowledge regarding the assessment of subject's

understanding of trial, and (c) method of correcting the subjects misunderstanding of the trial purpose.

Content/Subject Matter

The first meeting was opened by me as a facilitator with an introduction to the purpose of the planning team and the purpose and expected outcome of the planning meetings. Each member of the team introduced themselves and gave a brief professional and educational history. This meeting focused on a review of the relevant literature related to TM and the nurses' role in managing TM. In this first meeting, the team discussed the best way to approach an introduction to TM. The team decided that a brief literature review would be best, using the Appelbaum et al. (1982) article and the Henderson et al. (2007) article. The team agreed on the use of Henderson's definition of TM. There was discussion regarding the increasing role of nurses in clinical trials and the importance of educating research nurses on the concepts of TM. A decision was made that the information from ONS (2010) on informed consent and the research of Matutina (2010) would be useful in presenting the role of the research nurse to the participants of this program. Information from Judkins-Cohn et al. (2014) will be included in the instruction on the principles of informed consent and the research nurse's role.

The second meeting established goals and discussed content for the educational program. In the second meeting, the team discussed the goals of the program, how they would be achieved, and in what order the information would be presented. The team established that the learning should be engaging and enjoyable. Content should be presented in a manner that allows learners to build upon the previous content. The team

began to establish the syllabus and time requirements for each of the covered topics. There was discussion of a format with an agreement to reevaluate this time frame and format at the fifth and final meeting. The team agreed that a Power Point presentation should be created in order to assist instructors with staying on task and within allotted time frame. A hard copy of the presentation will be made available to each of the participants with space available for taking notes.

The third and fourth meetings were used to create the content of the program. Key aspects of the education program include the concepts of TM, methods to recognize TM, and strategies for correcting TM. In the third meeting, the team discussed the history of the consent process. The team agreed that a brief review of the Belmont report and the Nuremburg Trials would be appropriate and that there should be a presentation on the impact of TM on the consent process. There was a review of information regarding strategies for recognizing TM in patients and family members and strategies to correct misunderstanding of research purpose. The team decided that the information provided by Meropol et al. (2003) would be appropriate for use in teaching this topic. There was discussion on why the QuIC (Joffe et al., 2001) was not sufficient, that determining the presence of TM does nothing to alleviate or decrease the condition and that this should be shared with participants.

In the fourth meeting, there was discussion on teaching methods of potential subjects and families designed to alleviate TM. There was discussion on the need to teach peers and physicians regarding TM and sharing suggestions to decrease TM. The team agreed that the information from deMelo-Martin and Ho (2008) as well as Glannon

(2006) would be used for teaching this topic. Further development of the syllabus was achieved.

The fifth meeting established the duration of the educational program as well as the design of the educational program. In the fifth and final meeting, the content and syllabus was completed. The team agreed five 1-hour sessions was sufficient and a classroom format was appropriate. The classroom format was chosen to ensure learner interaction and because of the severe consequence if learners were unable to adequately perform tasks. The team established that the program should be offered to groups no larger than 12 to a class to ensure active participation from the attendees. Members shared ideas for teaching the program in their respective facilities. There was brief discussion regarding the inclusion of staff development within the organizations and applications for continuing nursing education credits from nursing boards of each state.

The curriculum was shared with all members of the team for final review and approval. All team members concurred that the presentation and syllabus reflected what the team had agreed on. Following the content validation review each team member was contacted via e-mail regarding content validation results.

Content Validation

The educational program content and curriculum was shared with three experts in the field of nursing education and research for content validation. One associate professor of nursing, one nursing instructor, and one director of clinical research (all registered nurses) examined the educational program content for validity (Appendix C Educational Program Syllabus).

Training Tools/Activities

The educational program will be presented in a classroom format. Materials include scholarly articles for discussion that are available via the internet and brief lectures.

Budget

The cost of the program includes time and materials. Materials include scholarly articles for discussion that are available via the Internet. The greatest expense will be incurred in wages for the RNs participating in the educational program. According to the Bureau of Labor Statistics (2013), the medium wage for a research nurse is $35.00 per hour. The program is designed to be 5 hours long. Each participating location has an average of 12 research nurses. The cost for RN wages per location is estimated to be $2,100.00. Each organization will be responsible for the wages of their RNs. The six team members responsible for teaching the program are all salaried employees and have agreed to work the additional hours required for the program.

Implementation Plan

Following the completion of the project and my graduation, the educational program will be implemented (Appendix D). Each member of the development team has agreed to teach the program to the qualified nurses within their organization. Team members will be responsible for identifying qualified participants and securing appropriate space for the classes. It is expected that the research RN will acquire useful knowledge and skills and use them in practice, changing practice in the research department. Therefore, senior leaders and key stakeholders must be instructed about and

endorse the educational program in order to secure successful outcomes. There should be consideration and agreement on compensation of the RNs time commitment for the program, whether this will be financial compensation or take another form. The scheduling of the program is left up to the team member; however, the five classes should be scheduled no longer than 1 week apart.

Evaluation Plan

Following the completion of the project and my graduation, the educational program will be evaluated (Appendix E). Both short term and intermediate term outcomes will be measured for each of the objectives using a pre- and post-survey. Prior to participation in the educational program, registered nurses will be asked to complete a survey designed to gauge their knowledge of TM. After participating in the educational program, the nurses will be asked to complete the same survey. Before and after comparisons will be made to evaluate whether or not the education positively affects the nurses' knowledge of TM, their ability to recognize TM, and their confidence in their ability to correct subjects' misconceptions regarding the purpose of research. A test run of data entry and analysis will be performed to reduce the likelihood of unwanted surprises or wasted data. A track bar numbered 0-8 will be used to represent continuous data with a higher score corresponding to a higher level of knowledge. The main independent variable will be pre-versus-post-TM knowledge. Internal reliability will be evaluated using Cronbach's alpha. Data analysis will be performed using a paired sample student's t-test. The results of a t-test will reveal whether or not the difference between the pre and post survey is significant. The short term threshold for success will be

reached at significance levels less than .05. Results will be used to make decisions regarding the modification of the educational program.

The long term evaluation plan will be my sole responsibility. The long term goal for educating research RNs on TM is to decrease the incidence of TM among research subjects. Therefore, the long term evaluation of the educational program is designed as a study to measure TM among research subjects before and after the educational program is taught to participating research RNs.

During the five weeks that the educational program is being taught to research RNs, patients recently enrolled in clinical trials at Sites A, C, and D will be surveyed using the Quality of Informed Consent (QuIC) questionnaire (Appendix F) (Joffe et al., 2001). Twelve months later this process will be repeated at sites A, C, and D and within each institution, comparisons made using before education and after education data. Data comparisons will be made to assess the long term outcomes of the educational program and to determine whether or not there is decreased incidence of TM among the subjects enrolled in clinical trials. Success of the educational program will be determined by a lower incidence of TM among research subjects after education of the research RNs as compared to incidence of TM among research subjects before education of the research RNs.

Quality of Informed Consent Questionnaire

The QuIC is a standardized measure of assessing the quality of understanding among participants in clinical trials. The QuIC questionnaire is based on 13 independent domains derived from the eight basic elements of informed consent specified in federal

regulations. The questionnaire is written at an eighth-grade reading level and requires an estimated seven minutes to complete. The QuIC consists of three parts. Part A contains 20 questions and measures subject's knowledge of the basic elements of informed consent. Part B contains 14 questions and measures the understanding of the important elements of the specific trial in which subjects consented to participate. Part C covers subject's perception of the informed consent process, demographic characteristics, and previous participation in research. Content validity of the questionnaire was established after review by two independent panels of experts in the fields of bioethics, statistics, oncology, and clinical trial design (Joffe et al., 2001). Test re-test reliability was examined with intraclass correlation coefficients of 0.66 for tests of objective understanding and 0.77 for tests of subjective understanding (Joffe et al., 2001).

Project Completion

The most difficult portion of the development of the educational program was organizing the process. The written plan helped to make the organization slightly less difficult. Research staff from the varying organizations was pleasantly easy to work with and enthusiastic about the project however, scheduling was an issue. We managed to complete our development meetings with most of the team members in attendance at each meeting. Organizing, implementing, and evaluating new services in healthcare was not a new concept to this student however the educational piece was a new endeavor. With very little experience in teaching the knowledge and teaching background of several team members was invaluable.

Implications for Future Research

Research on TM has been motivated by concern that participants may misunderstand aspects of trial care that lead them to make decisions incompatible with their true preferences and values. Refining the standard education of TM for registered nurses can serve both to improve the protection of trial participants and clarify the informed consent process. Though participants may recognize they are in a trial, failure to understand how care received during a trial can differ from standard care, and confusion over the purpose of these distinct activities, can compromise informed consent to research participation. Progress can be made in alleviating TM by focusing on the aspects of informed consent that clearly interfere with trial participants' decision-making through failure to understand the defining nature and purpose of clinical research (Barrett, 2005). Future research efforts need to focus on the development of nursing interventions that improve the informed consent process as well as enhance patients' understanding of the research process. With education and understanding regarding TM, nurse researchers may play a key role in preventing this condition (Matutina, 2010).

Strengths and Limitations

The educational project was developed by a team of experts in the field of research nursing. It was validated by a team of experts in nursing education and research. A strong implementation plan has been developed with the ability to adjust the educational program as needed based on the evaluation. The evaluation plan is well developed and designed for both short and long term success.

This project was limited by the varied geographical locations of the team members, the dependence on technology, and the variance of multiple schedules. The team consisted of clinical trials experts employed at several facilities through-out the state. Communication among the team members was accomplished via e-mail and meetings were conducted using telephone conference lines. Conflicting schedules proved to be a challenge in scheduling meetings with all team members in attendance.

Self-Analysis

One of the greatest challenges I face today is learning to be an effective leader. I believe an effective leader possess both education and experience. My desire to learn and better myself in order to increase my leadership skills led me to pursue a DNP. With the completion of this degree and project I have increased both my education and experience. The amount of energy and dedication required to complete this doctoral program was tremendous. The fact that I am so close to accomplishing this goal tells me that I remain dedicated and committed to success in both my career and life goals. I may very well have what it takes to be successful in a leadership role within healthcare and nursing.

Summary

TM may be decreased or alleviated by educating nurses involved in research on the existence and concepts of TM, allowing subjects a much clearer picture of the relative risks and benefits of participation in a clinical trial. Diligent examination of potential research subjects should expose truly altruistic reasons for participating in the trial. Potential subjects should understand and accept that they may not benefit medically from participation in a clinical trial. Individual facilities are responsible for setting their own

standards for educating research nurses. As evidenced by research presented in this project, there is no standard education for research nurses regarding TM. It is the hope of the author that this project will change this situation and facilities will include TM in the education requirements for research RNs.

Section 5: Scholarly Product

An Educational Program for Nurses on Therapeutic Misconception in the Oncology Setting

Abstract

A key component of informed consent to participate in research is the understanding that research is not the same as treatment, that scientific goals have priority over therapeutic ones. However, studies have found that some research participants do not understand important differences between research and treatment, a phenomenon called therapeutic misconception (TM). An important element when recruiting for clinical trials is to ensure the potential subject understands that therapeutic benefit to the individual is secondary to the overriding goal of the research study. The role of nursing in clinical research continues to expand and research nurses must be aware of the concepts of TM and its impact on the consent process. The problem addressed in this project was the research nurse's education regarding the existence and concepts of TM and the ability to assess and correct if necessary, the research subject's understanding of the trial. To date there has not been a standard education program designed or implemented to educate the clinical trial nurse regarding TM. The purpose of the project was for an established team of clinical trials experts to develop an educational program for registered nurses on TM that enables them to assess clinical trials patients for the influence of TM and correct any misunderstanding the subject may have regarding the benefits and purpose of participation in the clinical trial. The educational program included concepts related to TM, guidance on recognizing TM in potential research subjects, and strategies to correct the potentials subject's misunderstanding.

Introduction

Studies have found that some research participants do not understand important differences between research and treatment, a phenomenon called *therapeutic misconception* (TM). TM arises from the conviction that the purpose of clinical medicine and clinical research is to benefit the patient, and that a physician will always act according to what is the best medical care for the patient (Applebaum, Anatchkova, Albert, Dunn, & Lidz, 2012). When recruiting for clinical trials, healthcare providers must ensure potential subjects understand that therapeutic benefit to the individual is secondary to the overriding goal of the research study. A key component of informed consent to participate in research is the understanding that research is not the same as treatment. Ethicists contend that informed consent to participate in research should explain the difference between research and treatment in language that the lay person will understand (Applebaum, Roth, & Lidz, 1982). Applebaum, Roth, & Lidz (1982) original study found that many of the study participants believed they were receiving treatment in the form of a medication, based on what was most therapeutic to them personally, despite being told by the researchers that they were participating in a clinical trial in order to discover scientific knowledge, and that they may not benefit from participation in the trial. Barrett (2005) states that "although participants are explicitly told that scientific goals have priority over therapeutic ones and investigators' primary interests are in improving treatment options, participants persist in believing that they will receive benefit from their involvement in the research" (p. 752).

The Nuremburg Code clearly states that research participation be undertaken "without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion…" (International Military Tribunal, 1949). Black, Batist, Avard, Rousseau, Diaz, and Knoppers (2013), citing the World Medical Association (1964), state that "the requirement of voluntariness has been confirmed universally over the years as an essential element of research participation" (p. 26). The misunderstanding of the purpose of research (TM) has the potential to compromise the voluntariness of consent by creating a risk-benefit perception by the patient that does not coincide with the reality of the trial. "As patient advocates and educators, nurses must be able to assess individuals' understanding to ensure the validity of the informed consent process" (Barrett, 2005, p.752).

Problem

TM is a critical problem in research clinical trials (Applebaum et al., 2012). Research and therapeutic clinical care involves different standards with regards to the treatment of the patient or research subject. The sole purpose of medical therapy is to treat an illness or injury and to improve health. The primary purpose of medical research is to gain knowledge. The confusion of the two often leads to profound misunderstandings on the part of the research subject. The role of nursing in clinical research continues to expand and "nurses must develop strategies that provide clinical trial patients with a better understanding of the trial they are considering, identify areas of misunderstanding and correct them, and assess the outcomes of the informed consent process" (Barrett, 2005, p. 752). This project addressed the problem of the research

nurse's education regarding the existence and concepts of TM and the ability to assess and correct if necessary, the research subject's understanding of the trial. The problem addressed in the project was the lack of knowledge among registered nurses regarding TM.

Purpose

Historically, research on TM has been conducted because of concern that participants may misunderstand aspects of trial care that lead them to make decisions incompatible with their true preferences and values. Obtaining informed consent, permission granted by patients for healthcare services, knowing the possible consequences, is an ethical obligation of nurses and other health care providers. Registered nurses working with clinical trial subjects should (a) understand the concepts of TM as well as the potential negative impact on the informed consent process, (b) be able to assess clinical trials patients for the influence of TM, and (c) be able to correct any misunderstanding the subject may have regarding the benefits and purpose of participation in the clinical trial. The purpose of the project was to develop an educational program for registered nurses (RNs) on TM.

Goals and Outcomes

The goal of the project was to improve RNs ability to decrease TM in clinical trials. This goal included several objectives to increase the RN's (a) knowledge of therapeutic misconception, (b) skill in assessing subject's understanding of trials, and (c) ability to correct subject's misunderstanding of the trial purpose. In achieving the

objectives, the overall goal of the project was achieved. The objectives were measured in the evaluation phase using a pre and post survey.

As a component of participation in the program registered nurses were asked to complete a survey before and after the education program in order to gauge their knowledge of TM. Measures included the RNs' (a) knowledge of the existence and concepts of TM, (b) knowledge regarding the assessment of subject's understanding of trial, and (c) method of correcting the subjects misunderstanding of the trial purpose.

Significance for Future Practice

Judkins-Cohn, Kielwasser-Withrow, Owen, and Ward (2013) state that during the past twenty years there has been an increase in developing policies that ensure the use of research and evidence-based practice for both nursing and medicine in the clinical setting. With the increase in research activities, more nurses are engaging in research as Principle Investigators (PIs) and members of research teams. The 2010 Institute of Medicine's *Future of Nursing* report recommended that by 2020 there will be a need for double the current number of doctoral prepared nurses. "The result is the creation of the dual role of care provider and researcher" (Judkins-Cohn et al, 2013, p 4199). This dual nursing role demands a thorough understanding of the informed consent process. This understanding includes the difference between the goals of clinical care and research (TM), following research-specific ethics involved in the informed consent process, and understanding quality measures of the informed consent process.

The TM is a serious problem for informed consent in clinical research and conflicting desired health outcomes for healthcare providers and patients suggest

implications for nursing practice. Applebaum and Roth (1983) raise the question, "Who should have the task of explaining the therapeutic misconception to subjects?" (p.12). Institutional policies typically require that potential subjects be approached about research by someone known to them, and that the consent process must be conducted by someone who fully understands the research study. The PI for a research study may also be the healthcare professional caring for a potential research subject.

The PI may be the person most knowledgeable about the research and most qualified to approach the potential subject, however, they may not be the best person to complete the informed consent process. Because of the potential for TM, there may be benefit to having a research study team member that is not the PI involved in the consent process (Pranati, 2010). The PI has a responsibility to distinguish between treatment and research, and to clearly explain the implications for the potential subject. However, even when a PI clearly emphasizes that the goal of the research is not to provide care, patients sometimes continue to believe that the research will provide them with direct benefit (Pranati, 2010). Pranati also states that a solution to this challenging situation is to have the research nurse complete the informed consent process after the PI has explained the research in detail. The study nurse can then determine whether the patient understands the research and his/her willingness to participate outside the direct influence of the PI. Clinical trial nurses must communicate information about the nature and goals of clinical research, explain the details of the specific study, and assess subjects' understanding of the consent information (Ehrenberger & Lillington, 2004).

Social Change

The societal response to ethical problems associated with clinical research has been the implementation of regulatory laws and policies, including detailed federal regulations governing research involving human subjects (Miller, Rosenstein, & DeRenzo, 1998). The application of these regulations has led to improved protection of the rights and welfare of research subjects; however, there remain deficiencies that need to be addressed (Miller, Rosenstein, & DeRenzo, 1998). Changes to consent procedures should be adopted to ensure that all potential subjects are aware that their condition and benefit is not the priority of the clinical trial (Pranati, 2010). Diligent examination of potential research subjects should expose truly altruistic reasons for participating in the trial. Potential subjects should understand and accept that they may not benefit medically from participation in a clinical trial.

Evidence

Solid understanding of research ethics requires the clear distinction between research and therapeutic treatment. The first principle of The Belmont Report (1979), which is the ethical basis for the U.S. federal regulations, is "respect for persons"—persons have the right to decide for themselves whether to participate in research on the basis of information provided about the nature of the trial, potential benefits and adverse effects, alternative treatments, etc. In order to decrease the incidence of TM, researchers must be judicious in their use of the term "treatment" (Banks, 2009). When a study drug, study intervention, or investigational therapy is referred to as a treatment there is an increased chance that a potential subject will misinterpret the purpose of the trial. The

patient-subject who thinks they are receiving individualized therapy when in fact they are being treated according to a research protocol cannot give informed consent (Steinke, 2004).

Kola and Landis (2004) reported that the average success rate for new drugs was 11%, ranging from 20% in cardiovascular trials to 5% in oncology trials. They found that 60% of the time, the reasons that the drugs did not make it to market were efficacy and safety. It is very likely, in oncology phase I and II trials that the patient will not benefit and consent language must state this clearly (Kola & Landis, 2004). The mere disclosure of risks and benefits in lengthy and legalistic forms may not be sufficient in light of such evidence (Barrett, 2005). Evidence suggests transforming the informed consent process from passive disclosure to more active education and interaction with patient participants in clinical research (Pranati, 2010). When discussing a subject's expectations of direct benefit, only the benefits that can be "reasonably expected" should be discussed (Banks, 2009). This clarification will help subjects understand the potential benefits of the research, as well as the alternatives to the research that are available.

Conceptual Model

The term for the phenomenon currently known as "therapeutic misconception" originated with Applebaum et al in 1982 after they observed psychiatric patients who were obviously confused about research versus therapeutic treatment but consented to participate in research studies anyway. Matutina (2010) identified four elements present in TM in which patients/subjects 1) confuse research with treatment, 2) believe they will receive therapeutic benefit from research participation, 3) fail to communicate

"contribution to science" as motive for their participation in research, and 4) overestimate therapeutic response rates and misinterpret study purpose.

Avant (2000), referring to the Wilson Method of Concept Analysis, stated that the social context in which a concept is found can provide valuable insight (see Appendix A for a concept map of TM). Matutina identified the social context of TM as research and believes the goals and motives of the researchers should be questioned. She stated that, in the very least, one should question whether or not researchers attempt to educate subjects regarding TM as they are recruited and whether or not, while obtaining informed consent, researchers stress the positives and downplay the negatives (Matutina, (2010).

Approach

This project was accomplished by completing the following steps:

1. A team of clinical trials experts was established. Team members were willing to participate in the creation of an educational program to be taught at their facility. Oncology nursing backgrounds were given preference. Team members were invited to participate in this project on a volunteer basis, without financial compensation, based on their clinical trials experience and expertise. The project manager and DNP student (site A) facilitated the activities of the team, organized meetings, and wrote the syllabus for the educational program. A Radiation Oncologist (site A) provided a principle investigator's point of view during the development of the educational program. Four research nurses, one from each of the participating sites, were the primary architects of the educational program. The director of research for site D assisted in the development of the educational program and in establishing the implementation plan.

2. All of the participating facilities had access to web-conferencing technology. The team met via web-conferencing twice per week beginning on January 5, 2015 (Appendix B). A recurring meeting invitation was initiated by the project manager to the team members and once accepted, appeared on their calendars. Team members were encouraged to share all information they determined to be relevant including important aspects of TM. An educational program was developed using the diverse backgrounds and individual expertise of team members as a resource.

3. The DNP student led the project team in reviewing the relevant literature related to therapeutic misconception and nursing's role in managing therapeutic misconception.

4. The team developed an educational program for registered nurses. The educational program included concepts related to TM, guidance on recognizing TM in potential research subjects, strategies to correct potentials subject's misunderstanding, and assessments of nurses' understanding of related concepts and strategies. The outline for planning and designing the educational program (Appendix C: Educational Program on Therapeutic Misconception Syllabus) was adapted from *Design for Learning-a self paced guide* by Cybela & Greer (1997).

5. The educational program was submitted to three scholars with expertise in nursing education and clinical trials for review and content validation.

6. The DNP student led the project team in developing an implementation plan for the program. The implementation plan (Appendix D) was developed with the understanding that the educational program will be taught at several varying institutions.

The program will be implemented by individual team members in a variety of organizational settings allowing for slight adjustments to the implementation plan however, the team has agreed that all team members will fully implement all aspects of the program.

7. The DNP student led the project team in developing an evaluation plan for the program. The evaluation plan (Appendix E) was created with three time frames; short term, intermediate, and long term evaluations.

Implementation Plan

Each member of the development team has agreed to teach the program to the qualified nurses within their organization. Team members will be responsible for identifying qualified participants and securing appropriate space for the classes. It is expected that the research RN will acquire useful knowledge and skills and use them in practice; changing practice in the research department. Therefore senior leaders and key stakeholders must be instructed about and endorse the educational program in order to secure successful outcomes. There should be consideration and agreement on compensation of the RNs time commitment for the program; whether this will be financial compensation or take another form. The scheduling of the program is left up to the team member however the five classes should be scheduled no longer than one week apart.

Evaluation Plan

Both short term and intermediate term outcomes will be measured for each of the objectives using a pre and post survey. Prior to participation in the educational program,

registered nurses will be asked to complete a survey designed to gauge their knowledge of TM. After participating in the educational program, the nurses will be asked to complete the same survey. Before and after comparisons will be made to evaluate whether or not the education positively affects the nurses' knowledge of TM, their ability to recognize TM, and their confidence in their ability to correct subjects' misconceptions regarding the purpose of research. A test run of data entry and analysis will be performed to reduce the likelihood of unwanted surprises or wasted data. A track bar numbered 0-8 will be used to represent continuous data with a higher score corresponding to a higher level of knowledge. The main independent variable will be pre-versus-post-TM knowledge. Internal reliability will be evaluated using Cronbach's alpha. Data analysis will be performed using a paired sample student's t-test. The results of a t-test will tell us if the difference between the pre and post survey is significant. The short term threshold for success will be reached at significance levels less than .05. Results will be used to make decisions regarding the modification of the educational program.

The long term evaluation plan will be the sole responsibility of the DNP graduate. The long term goal for educating research RNs on TM is to decrease the incidence of TM among research subjects. Therefore, the long term evaluation of the educational program is designed as a study to measure TM among research subjects before and after the educational program is taught to participating research RNs.

During the five weeks that the educational program is being taught to research RNs, patients recently enrolled in clinical trials at Sites A, C, and D will be surveyed using the Quality of Informed Consent (QuIC) questionnaire (Appendix F) (Joffe et al., 2001).

Twelve months later this process will be repeated at sites A, C, and D and, within each institution, comparisons made using before education and after education data. Data comparisons will be made to assess the long term outcomes of the educational program and to determine whether or not there is decreased incidence of TM among the subjects enrolled in clinical trials. Success of the educational program will be determined by a lower incidence of TM among research subjects after education of the research RNs as compared to incidence of TM among research subjects before education of the research RNs.

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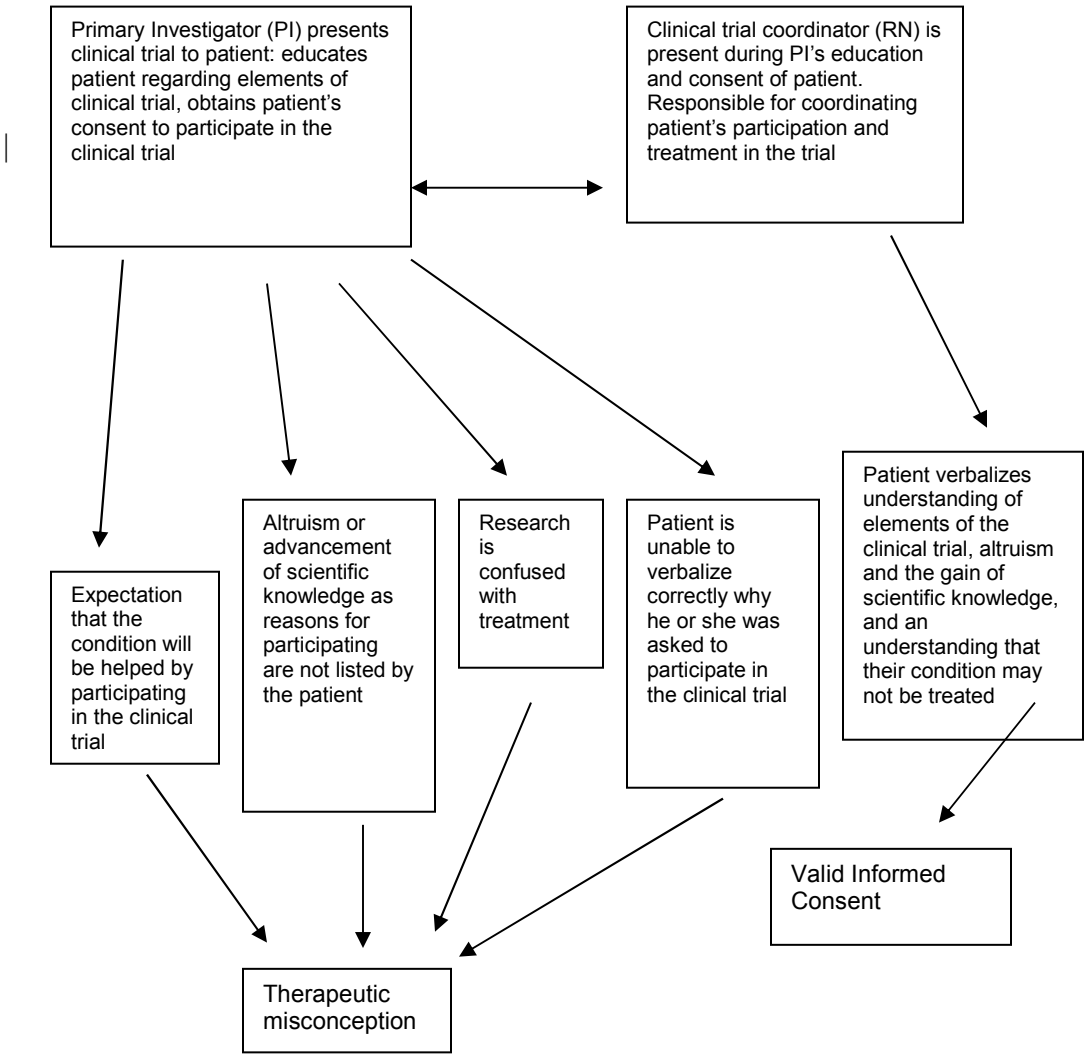
Appendix A: Conceptual Map of Therapeutic Misconception

Concept analysis: What constitutes therapeutic misconception?



Appendix B: Meeting Agendas

Agenda – Conference Call One

Objective	Educational Program on Therapeutic Misconception
Date	01/05/15
Time	**From**: 4:00p.m. **To:** 5:00p.m.
Dial-in-Number	1 (646) 558-2119
Pass code	111-384-946 audio PIN at connection
Facilitator	Debra Magnanelli

Agenda Items	Action Points	Owner	
Participants	Brief introductions	Group	
Literature Review of TM	Articles previously provided-discussion on findings	Group	
Nursing role in managing TM	Discussion	Group	

Agenda – Conference Call Two

Objective	Educational Program on Therapeutic Misconception
Date	01/12/15
Time	**From**: 4:00p.m. **To:** 5:00p.m.
Dial-in-Number	1 (646) 558-2119
Pass code	111-384-946 audio PIN at connection
Facilitator	Debra Magnanelli

Agenda Items	Action Points	Owner	
Goals of Program	Discussion, Establish and document	Group	
Syllabus	Discussion, establish, document	Group	

Agenda – Conference Call Three

Objective	Educational Program on Therapeutic Misconception	
Date	01/15/15	
Time	**From**: 4:00p.m. **To:** 5:00p.m.	
Dial-in-Number	1 (646) 558-2119	
Pass code	111-384-946 audio PIN at connection	
Facilitator	Debra Magnanelli	

Agenda Items	Action Points	Owner	
Syllabus/Content	Discussion, Establish, document	Group	
Informed Consent	History, TM's impact on	Group	

Agenda – Conference Call Four

Objective	Educational Program on Therapeutic Misconception	
Date	01/22/15	
Time	**From**: 4:00p.m. **To:** 5:00p.m.	
Dial-in-Number	1 (646) 558-2119	
Pass code	111-384-946 audio PIN at connection	
Facilitator	Debra Magnanelli	

Agenda Items	Action Points	Owner	
Content/Syllabus	Discussion, Establish, document	Group	
Teaching patients	Tips to alleviating TM	Group	

Agenda – Conference Call Five			
Objective	Educational Program on Therapeutic Misconception		
Date	01/29/15		
Time	**From**: 4:00p.m. **To:** 5:00p.m.		
Dial-in-Number	1 (646) 558-2119		
Pass code	111-384-946 audio PIN at connection		
Facilitator	Debra Magnanelli		
Agenda Items	**Action Points**	**Owner**	
Duration and Format	Discussion, establish, document	Group	
Wrap Up	Suggestions and feedback, thank you	Group	

Appendix C Educational Program Syllabus

Educational Program on Therapeutic Misconception Syllabus

Instructor and Organization TBD

Location and time TBD

Description

This five week educational program was designed to enhance nurse success in recognizing and decreasing therapeutic misconception (TM). In this program you will be offered strategies for teaching patients and family members without introducing TM, guidance in recognizing TM in potential research subjects and strategies to correct potentials subject's misunderstanding. In addition, we will explore your knowledge and skills in understanding related concepts and assessing subjects for TM.

Learning Objectives

1. You will increase your knowledge of TM and it's concepts allowing you to teach trial subjects without introducing TM
2. You will increase your skill in assessing subjects understanding of the clinical trial they are considering
3. You will increase your ability to correct subject's misunderstanding of the purpose of the clinical trial

Participation

As a component of participation in the program you will be asked to complete a survey prior to beginning the program and immediately after completing the program. This is an interactive program; questions and energetic participation are welcome through-out.

Students may vary in their learning. Obtaining competencies and achieving program goals requires work on the student's part. Absences should be discussed with the instructor; it will be the responsibility of the student to complete reading and other assignments that they miss. At the discretion of the instructor-more than one absence will likely require the student to repeat the program. Respect and courtesy for fellow students is required, the personal use of cell phones and tablets should not occur while classes are in progress.

Schedule

Week One: Introduction to TM

Instructor Introduction

- Educational and professional background
- Contact information and availability
- Institutional or departmental policies: CMEs, disabilities, diversity

Pre Survey Completion

- To be completed by each student-electronically (i.e. Survey Monkey)

Purpose and Objectives Review

- Review of program objectives and expected learning outcomes
- Review of major topics of the program
- Program information
- How the program relates to clinical trials and nursing
- Electronic access to articles and resources-hard copies provided in class

Introduction to TM

- "Discovery" and Concepts
- Operational definition

Reading Materials

Appelbaum, P., Roth, L. & Lidz, C. (1982). The therapeutic misconception: Informed consent in psychiatric research. *International Journal of Psychiatry*, *5*, 319–329.

Lidz, C.W. & Applebaum, P.S. (2002). The therapeutic misconception: Problems and solutions. *Medical Care, 40*(9), 55-63. doi: 10.1097/01.MLR.0000023956.25813.18

Matutina, R.E., (2010). The concept analysis of therapeutic misconception. *Nurse Researcher, 17*(4), 83-90. Retrieved from CINAHL Plus with Full Text

Henderson, G.E., Churchill, L.R., Davis, A.M., Easter, M.M., Grady, C., Joffe, S.,… Zimmer, C.R. (2007). Clinical trials and medical care: defining the therapeutic misconception. *Plos Medicine*, 4(11), 1735-1738. doi: 10.1371/journal.pmed.0040324 Retrieved from http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0040324

Truong, T.H., Weeks, J.C., Cook, E.F., Joffe, S. (2011). Altruism among participants in cancer clinical trials. *Clinical Trials, 8*, 616-623. doi: 10.1177/174077451141444

Week Two: Nursing Role and Teaching

Increased role of nursing in clinical trials

- History of clinical research nursing
- Role description and evaluation-pivotal and complex
- Increased emphasis on clinical research
- Structure, function and management of research-fluid
- Contributions and obligations of research nurse

Importance of research RN's understanding of TM

- Scientific and Ethical Integrity
- Motives and welfare of individual patients
- Prevention, Recognition, Correcting Misunderstanding

Strategies for teaching patients and families

- Examine your own views-potential to influence subject's opinions
- Avoid mixed messages, use clear explanation, care with use of terms (treatment and therapy)
- Interview patient regarding desired goals and expectations
- Potential benefits, potential harms, right to withdraw
- Tools and mixed methods of providing information

Reading Materials

Agency for Healthcare Research and Quality (2012). The changing role of nurses. Retrieved from http://www.ahrq.gov/news/newsletter/research-activities/12dec/1212RA1.html

Gibbs, C.L. & Lowton, K. (2012). The role of the clinical research nurse. *Nursing Standard, 26*, 37-40. Retrieved from: www.nursing-standard.co.uk

Ocker, B.M. & Pawlik, D.P. (2000). The research nurse role in a clinic-based oncology research setting. *Cancer Nursing, 23*(4), 286-292. Retrieved from: http://ovidsp.tx.ovid.com.ezp.waldenulibrary.org/sp-3.13.1a/ovidweb.cgi

Spilsbury, K., Petherick, E., Cullum, N., Nelson, A., Nixon, J., Mason, S. (2008). The

role and potential contribution of clinical research nurses to clinical trials. *Journal of Clinical Nursing, 17*(4), 549-557. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/17419791

National Cancer Institute (2012). A balancing act: nursing and ethics in clinical trials. *NCI Cancer Bulletin, 9*(15). Retrieved from: http://www.cancer.gov/ncicancerbulletin/072412

Week Three: Informed Consent and TM

History of Informed consent

- The Belmont Report
- Ethical principles
- Fully informed and voluntary
- Transparent, language that is understandable
- Written and verbal-complete disclosure

TM's potential impact on consent

- Autonomy, beneficence, and justice
- Dual role-provider and researcher

TM and the consent process

- Participant-centered quality measures
- Assessing individual's understanding
- Strategies for improving consent process
- Case scenarios

Reading Materials

Barrett, R. (2005). Quality of informed consent: Measuring understanding among participants in oncology clinical trials. *Oncology Nursing Forum, 32*(4), 751-755. doi: 10.1188/05.ONF.751-755.

Pranati, B. (2010). Informed Consent: Are we doing enough? *Perspectives in Clinical Research, 1*(4), 124-127. doi: 10.4103/22229-3485.71769

World Medical Association Declaration of Helsinki-Ethical Principles for Medical research Involving Human Subjects (1964). Retrieved from http://www.wma.net/en/30publications/10policies/b3/

U.S. Department of Health and Human Services (2004). Code of federal regulations: Title 21, section 50.25: Elements of informed consent. Washington, D.C.: U.S. Government Printing Office.

Week Four: Recognition and Guidance

Recognizing TM

- Vulnerability to TM
- Motivation, perception, understanding of science
- Decision making process of subject
- Interview guide- understanding the subject

Strategies for correcting misunderstanding

- Motivation-desire for therapeutic benefit
- Purpose of clinical trials-gather scientific knowledge
- Juxtaposing subject's motivation with scientific aim
- Integrate "neutral party" in consent process
- Specific accountability

Educating peers regarding TM

- Clinical and research norms
- TM not just among subjects
- Clinical Equipoise

Reading Materials

Scott, Y.H.K., Schrock, L., Wilson, R., Frank, S.A., Holloway, R.G., Kieburtz, K., DeVries, R.G. (2009). An approach to evaluating therapeutic misconception. *IRB, 31*(5), 7-14. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3360887/

Weinfurt, K.P., Castel, L.D., Li, Y., Sulmasy, D.P., Balshem, A.M., Benson, A.B., … Meropol NJ. (2003). The correlation between patient characteristics and expectations of benefit from Phase I clinical trials. *Cancer: American Cancer Society, 98*(1), 166-75. doi: 10.1002/cncr.11483. Retrieved from: http://www.ncbi.nlm.nih.gov/pubmed/12833469

Kass, N., Taylor, H., Fogarty, L., Sugarman, J., Goodman, S.N., Goodwin- Landher, A. …Hurwitz, H. (2008). Purpose and benefits of early phase cancer trials: What do oncologists say? What do patients hear? *Journal of Empirical Research on Human Research Ethics: An International Journal, 3*(3), 57-68.

Miller, F.G., Rosenstein, D.L., DeRenzo, E.G. (1998). Professional integrity in clinical research. *Journal of American Medical Association, 280*(16), 1449-1454. doi: 10.100/jama.280.16.1449

Glannon, W. (2006). Phase I oncology trials: Why the therapeutic misconception will not go away. *Journal of Medical Ethics, 32*(5), 252-255.

Week Five: Review and Completion

Summary Review of Information

- Q & A
- Comments and overview of program and learning

Role Play

- Teaching about a clinical trial
- Assessing for TM
- Correcting misunderstanding

Self evaluation

- Knowledge and concepts of TM
- Ability to assess potential subjects

Post Survey Completion

- To be completed by each student-electronically (i.e. Survey Monkey)

Appendix D Implementation Plan

Educational Program for RNs on Therapeutic Misconception

Following the completion of the project and graduation of the DNP student, the educational program will be implemented and then evaluated. Each member of the development team has agreed to teach the program to the qualified nurses within their organization. Studies have found that how educational programs are implemented is extremely important and that minor changes in implementation can often make a major difference in the size of the programs effects (Gorman-Smith, 2006). The program will be implemented by individual team members in a variety of organizational settings allowing for slight adjustments to the implementation plan however, the team has agreed that all team members will fully implement all aspects of the program. The steps for implementation are as follows:

1. Team members will be responsible for identifying qualified participants within their organization and soliciting participation in the education program. RNs working in the adult oncology research setting will be invited to participate and made aware of the goals of the program and benefits to participation.

2. The team member is responsible for securing appropriate space for the program; the learning environment should be safe and supportive.

3. Full institutional support is mandatory to the success of the program. Together, the DNP and the team member will present to the administration of the organization the importance of the education, program plan and syllabus, expected outcomes, and costs associated with the program (to be incurred by the institution). It is

expected that the research RN will acquire useful knowledge and skills and use them in practice; changing practice in the research department. In order to secure successful outcomes it is imperative that to garner support from senior leaders and those responsible for bringing about the organizational change.

4. There should be consideration and agreement on compensation of the RNs time commitment for the program; whether this will be financial compensation or take another form is at the discretion of each organization. Team members, along with the DNP, will negotiate and determine the compensation through collaboration with administration, clinical leaders, human resources and staff development. Many organizations budget for continuing educational activities such as conferences and courses and may be willing to provide the compensation for the education.

5. Employee development and training is the shared responsibility of the management and the individual employee. Staff development departments should be involved in the understanding of the knowledge and skill that nurses in the oncology research department will need in the future. Staff development will assist in the long-term goals of the organization regarding TM and the implication of these goals on employee development. The pre and post surveys for the TM educational program will be used as performance appraisal documents that include descriptions of the areas of knowledge and skills that must be learned in order to improve performance. The staff development department will be responsible for applying for continuing nurse education credit through the state board of nursing.

6. The scheduling of the program will be the responsibility of the team member and will be achieved through collaboration with the research department and staff development.

7. The cost of the program includes time and materials. Materials include scholarly articles for discussion that are available electronically at no cost. The greatest expense will be incurred in wages for the RNs participating in the educational program. According to the Bureau of Labor Statistics (2013) the medium wage for a research nurse is $35.00 per hour. The program is designed to be five hours long. Each participating location has an average of twelve research nurses. The cost for RN wages per location is estimated to be $2,100.00. Each organization will be responsible for the wages of their RNs. The six team members responsible for teaching the program are all salaried employees and have agreed to work the additional hours required for the program.

8. Classroom training will be the responsibility of the team member. Strict adherence to the syllabus is required. It is important to remain resolute to the original program's structure and intent. To standardize the educational program, the DNP graduate will act as the coordinating principle, communicating with team members before and after each scheduled class.

9. The DNP graduate will monitor sessions to ensure the program's content is being delivered fully and as designed. Problems will be identified and prioritized and solutions provided. Content and materials will be revised and logistical issues addressed. Monitoring will include a) number of individuals or percent of the eligible population who received the education b) number of classroom sessions delivered, how often and

over what period of time c) setting in which the education was provided d) extent to which sites closely adhere to the program syllabus and e) extent to which deviation from the program syllabus is corrected.

Table D1

Program Implementation

Activity	Responsibility of team member	Responsibility of DNP
Identify participants	yes	
Secure appropriate space	yes	
Secure administrative support	yes	yes
Determine RN compensation	yes	
Staff development support	yes	
Schedule program	yes	
Securing cost coverage	yes	yes
Classroom training	yes	
Monitor sessions for problems or concerns		yes
Program revision		yes

Appendix E Evaluation Plan

Short and Intermediate Evaluation Plans

Following the completion of the project and graduation of the DNP student, the educational program will be implemented and then evaluated. The purpose of the evaluation is to improve the educational effort by improving the program and to measure whether the educational program met the stated objectives. For both short term and intermediate evaluation of the educational program outcomes will be measured using a pre and post survey. A pre and post data collection tool offers a measurement of the learning received during the class as a result of comparing what the student knew before in a pre-test and after in a post-test (Diem, 2003). The same instrument is used to collect data before and after the experience.

Short Term Evaluation

At the beginning of the first class, prior to participation in the educational program, registered nurses will be asked to complete a survey designed to gauge their knowledge of TM. After participating in the educational program, at the completion of the final class, the participating nurses will be asked to complete the same survey. Pre and post data are collected and analyzed to evaluate whether or not the education positively affects the nurses' knowledge of TM, their ability to recognize TM, and their confidence in their ability to correct subjects' misconceptions regarding the purpose of research.

Surveys will be offered through an on-line domain (such as Survey Monkey). It has been determined that use of a previously validated instrument is not possible because

no instrument specific to TM education exists. Furthermore, research nurse participation in this study necessitates that research nurses have a say in the development and approval of the survey instrument. The survey instrument will be developed and vetted through a focus group made up of the educational program creators (original team members) and research nurses. Whenever possible, items from previously validated and reported surveys will be used, modified if necessary and vetted by the focus group. Data will be collected and analyzed by the DNP graduate using the SPSS version 17.0 (SPSS Inc., Chicago, IL). A test run of data entry and analysis will be performed to reduce the likelihood of unwanted surprises or wasted data. A track bar numbered 0-8 will be used to represent continuous data with a higher score corresponding to a higher level of knowledge. The main independent variable will be pre-versus-post-TM knowledge. Internal reliability will be evaluated using Cronbach's alpha. Data analysis will be performed using a paired sample student's t-test. The results of a t-test will tell us if the difference between the pre and post survey is significant. The short term threshold for success will be reached at significance levels less than .05. Results will be disseminated to the team members who may then share them with participating RNs and senior leaders from the organizations. Results will be used to make decisions regarding the modification of the educational program.

Intermediate Evaluation

It is anticipated that the short term evaluation will document evidence that the educational program regarding TM for RNs in the adult oncology setting made a positive difference. Modifications will be made to the program as needed. Demonstrating that the

educational program was affected does not tell us how or why or the role the education played. Approximately six months following the implementation of the initial educational program, the educational program will be expanded and taught at other institutions. The evaluation planning will follow the steps in Table 1. Using the pre and post survey the intermediate plan for evaluation will continue to assess whether or not the education program made a difference but will also focus on what led to the change. The focus group will be responsible for adding questions to the original survey designed to collect additional data asking how or why the change came about and what role the education played. For example, additional data may answer the questions, "What contribution did the educational program make?" or "What factors in the implementation process affected the outcome?" Whenever possible, items from previously validated and reported surveys will be used, modified if necessary and vetted by the focus group. Data will be collected and analyzed by the DNP graduate using the SPSS version 17.0. Internal reliability and data analysis will be performed using the same methods as the short term evaluation. The intermediate threshold for success will be reached at significance levels less than .05.

Long Term Evaluation Plan

The long term evaluation plan will be the sole responsibility of the DNP graduate. The long term goal for educating research RNs on TM is to decrease the incidence of TM among research subjects. Therefore, the long term evaluation of the educational program is designed as a study to measure TM among research subjects before and after the educational program is taught to participating research RNs.

Method

During the five weeks that the educational program is being taught to research RNs, patients recently enrolled in clinical trials at Sites A, C, and D will be surveyed using the Quality of Informed Consent (QuIC) questionnaire (Joffe et al., 2001). The data collected will be analyzed. Twelve months later this process will be repeated at sites A, C, and D and, within each institution, comparisons made using before education and after education data. Data comparisons will be made to assess the long term outcomes of the educational program and to determine whether or not there is decreased incidence of TM among the subjects enrolled in clinical trials. Success of the educational program will be determined by a lower incidence of TM among research subjects after education of the research RNs as compared to incidence of TM among research subjects before education of the research RNs.

Sample

Potential participants in this study will be identified by the affiliated institutions, responsible for registering all patients enrolled in clinical trials. Patients 18 years or older, enrolled in the previous 14 days, in phase I, II, and III cancer treatment trials, with a signed informed consent will be eligible for this study. The QuIC will be mailed to adult patients with cancer who recently enrolled in a clinical trial at one of three affiliated institutions.

Instrument

The QuIC is a standardized measure of assessing the quality of understanding among participants in clinical trials. The QuIC questionnaire is based on 13 independent

domains derived from the eight basic elements of informed consent specified in federal regulations. The questionnaire is written at an eighth-grade reading level and requires an estimated seven minutes to complete. The QuIC consists of three parts. Part A contains 20 questions and measures subject's knowledge of the basic elements of informed consent. Part B contains 14 questions and measures the understanding of the important elements of the specific trial in which subjects consented to participate. Part C covers subject's perception of the informed consent process, demographic characteristics, and previous participation in research. Content validity of the questionnaire was established after review by two independent panels of experts in the fields of bioethics, statistics, oncology, and clinical trial design (Joffe, et al., 2001). Test re-test reliability was examined with intraclass correlation coefficients of 0.66 for tests of objective understanding and 0.77 for tests of subjective understanding (Joffe, et al., 2001).

Variable

The primary objective of this study is to measure how well newly enrolled trial subjects understand the trial in which they agreed to participate. This variable will be measured before and after research RNs participate in an educational program with comparisons of before and after data made within each institution.

Data Analysis

QuIC Data Analysis

Returned questionnaires will be examined for eligibility and completeness before being included in the study. Data will be analyzed using SPSS version 17.0 (SPSS Inc., Chicago, IL). The data will be summarized using descriptive statistics, including

frequency distribution, measures of central tendency, and dispersion. The QuIC questionnaire will be scored in two steps. Responses to individual questions in Part A will be combined in a knowledge score, ranging from 0 (least) to 100. Responses to Part B will be averaged and normalized for a possible range of 0-100, generating a self-assessment score. Bivariate correlations will be performed to determine the direction and magnitude of any relationships.

Study phase one (pre) and phase two (post) Comparison Analysis

Data will be analyzed using SPSS version 17.0 (SPSS Inc., Chicago, IL). The main independent variable will be pre-versus-post- scores from Part B of the QuIC- the understanding of the important elements of the specific trial in which subjects consented to participate. Data analysis will be performed using a t-test to compare the two means within each institution. The long term threshold for success will be reached at a significance level of $\alpha < 0.05$.

Results will be disseminated to the original team members who may then share them with participating RNs and senior leaders from the organizations. Results will be used to make decisions regarding the modification of the educational program.

Appendix F: Quality of Informed Consent Survey (QuIC)

Part A

INSTRUCTIONS: Below you will find several statements about cancer clinical trials (otherwise known as cancer research studies). Thinking about your clinical trial, please read each statement carefully. Then tell us whether you agree with the statement, you disagree with the statement, or you are unsure about the statement by circling the appropriate response. Please respond to each statement as best you can. We are interested in your opinions.

A1.	When I signed the consent form for my current cancer therapy, I knew that I was agreeing to participate in a clinical trial.	Disagree$_1$	Unsure$_2$	Agree$_3$*
A2.	The main reason cancer clinical trials are done is to improve the treatment of future cancer patients.	Disagree$_1$	Unsure$_2$	Agree$_3$*
A3.	I have been informed how long my participation in this clinical trial is likely to last.	Disagree$_1$	Unsure$_2$	Agree$_3$*
A4.	All the treatments and procedures in my clinical trial are standard for my type of cancer.	Disagree$_1$*	Unsure$_2$	Agree$_3$
A5.	In my clinical trial, one of the researchers' major purposes is to compare the effects (good and bad) of two or more different ways of treating patients with my type of cancer, in order to see which is better.†	Disagree$_1$	Unsure$_2$	Agree$_3$*
A6.	In my clinical trial, one of the researchers' major purposes is to test the safety of a new drug or treatment.‡	Disagree$_1$	Unsure$_2$	Agree$_3$*
A7.	In my clinical trial, one of the researchers' major purposes is to find the highest dose of a new drug or treatment that can be given without causing severe side effects.‡	Disagree$_1$	Unsure$_2$	Agree$_3$*

Part B

When you signed the consent form to participate in your clinical trial, how well did you understand the following aspects of your clinical trial? *If you didn't understand the item at all, please circle 1. If you understood it very well, please circle 5. If you understand it somewhat, please circle a number between 1 and 5.*

		I Didn't Understand This at All		⟹		I Understood This Very Well
B1.	The fact that your treatment involves research	1	2	3	4	5
B2.	What the researchers are trying to find out in the clinical trial	1	2	3	4	5
B3.	How long you will be in the clinical trial	1	2	3	4	5
B4.	The treatments and procedures you will undergo	1	2	3	4	5
B5.	Which of these treatments and procedures are experimental	1	2	3	4	5
B6.	The possible risks and discomforts of participating in the clinical trial	1	2	3	4	5
B7.	The possible benefits to you of participating in the clinical trial	1	2	3	4	5
B8.	How your participation in this clinical trial may benefit future patients	1	2	3	4	5
B9.	The alternatives to participation in the clinical trial	1	2	3	4	5
B10.	The effect of the clinical trial on the confidentiality of your medical records	1	2	3	4	5
B11.	Who will pay for treatment if you are injured or become ill because of participation in this clinical trial	1	2	3	4	5
B12.	Whom you should contact if you have questions or concerns about the clinical trial	1	2	3	4	5
B13.	The fact that participation in the clinical trial is voluntary	1	2	3	4	5
B14.	Overall, how well did you understand your clinical trial when you signed the consent form?	1	2	3	4	5