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Improving Research Participants' Understanding of Informed Consent

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IMPROVING RESEARCH PARTICIPANTS' UNDERSTANDING OF INFORMED CONSENT

by

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ABSTRACT

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Twenty-five to sixty percent of research participants are unable to understand important information during the research consenting process. This lack of comprehension may unintentionally expose research participants to potential harm. The purpose of this study was to test the teach back method of communication as an intervention to improve research participants' understanding of informed consent. The Shannon Weaver Communication model was the theoretical framework supporting this study. The pre-intervention sample (control group) of 18 participants enrolled in a cardiology clinical trial at a large tertiary hospital in New England completed the Quality of Informed Consent (QuIC) survey. Two cardiology research coordinators were trained in teach back communication as the intervention. A post-intervention sample (experimental group) of 5 participants completed the QuIC survey.

There was no significant difference in mean scores of objective understanding between the pre-intervention and post intervention groups. There was also no significant difference in the relationship between objective and subjective understanding in the pre-intervention group compared to the post intervention group. There was poor understanding of compensation for research-related injury where 50% of the pre-intervention group and 60% of the post intervention group were either unsure or answered questions related to this concept incorrectly.

Another poorly understood concept was with a description of the procedures to be followed. Sixty-one percent in the pre-intervention and no one in the post intervention group understood this concept. A Chi-square test for independence indicated no significant association between highest educational level obtained and understanding of compensation for research-related injury or an understanding of procedures to follow.

With the uncovering of a poor understanding of the two concepts of compensation for research-related injury and procedures to follow, not reported in the literature, more research specifically targeting these concepts and participants' understanding are warranted. Inductive and deductive approaches may yield interesting results. Institutional and national policies need to be put into place assuring participant understanding of all regulatory requirements. However, the practical application of such policies cannot be mandated until there is comprehensive science available to support its practice.

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CHAPTER 1 STATEMENT OF PROBLEM

According to the Institute of Medicine (IOM) more than 177,000 registered research studies involving human participants are currently taking place in 187 countries representing a small portion of ongoing clinical research worldwide (IOM, 2013). With every clinical trial there are inherent risks about which every individual needs to be informed before making a decision as to whether or not to participate. There is a body of knowledge demonstrating that research participants have significant misunderstandings about the potential benefits, risks and other aspects of their research study (Barrett, 2005; Bergenmar, Molin, Wilking, & Brandberg, 2008; Flory & Emanuel, 2004; Hietanen, Aro, Holli, Schreck, Peura, & Joensuu, 2007; Jefford et al., 2010; Joffe, Cook, Cleary, Clark, & Weeks, 2001; Meade, 1999; Palmer & Trott, 2013; Paris et al., 2007; Schwartz & Appelbaum, 2008). As many as 25-60% of research participants are inadequately informed and/or are unable to recall or understand important information during the research consenting process (Aaronson, et al., 1996; McCarthy, Waite, Curtis, Engel, Baker & Wolf, 2012). If research participants agree to enroll into a research study without truly understanding all aspects of the study they might unintentionally be exposed to potential harm The purpose of this study was to empirically test the teach back method of communication in research participants as a method to improve objective understanding of informed consent.

Informed Consent for Research

Obtaining informed consent for research is not just the signing of a document, but rather a process of developing a relationship between the investigator or member of the research team and the potential research participant, in order to provide the participant with the full and complete information needed to make a voluntary informed decision including time to have questions about the research study answered. Research studies may expose participants to risks

or burdens they would not normally face. It is therefore imperative that potential research participants be knowledgeable about these risks and burdens through the informed consent process (Wendler & Grady, 2008). Clear communication and an assessment of participant understanding are a critical part of the relationship between the investigator and the potential research participant. Informed consent can be said to have been given by a participant once the participant has acknowledged they have a clear appreciation and understanding of the facts, implications, and future consequences of an action.

Background

In 1932 the United States Public Health Service began a research study to investigate the clinical course and progression of syphilis. Black, African American men living in Alabama were recruited to participate by the offer of free medical care. The majority of the men recruited by the investigators were sons and grandsons of slaves, impoverished and had never seen a doctor or received medical care. Thus, the men showed up in hordes. While being screened for the study's inclusion criteria of having venereal disease, the research physicians never disclosed to the participants they had syphilis. As physicians studied the natural progression of syphilis, for further enticements, families were offered fifty dollars towards burial insurance. With the new discovery of penicillin as a powerful treatment for syphilis, the treatment was withheld to the research subjects in order for the physicians to monitor the diseases progression. The researchers justified the lack of treatment by explaining that these men would not normally be receiving medical care, so why miss the opportunity to study the natural progression of the disease. The study was originally designed to last 6 months, but continued to enroll and monitor syphilis stricken men for forty years. The study came to an abrupt halt in 1972 when it became public

knowledge after one of the former venereal disease investigators disclosed to a reporter the unethical conduct of the study (Thomas, 2000).

An institution on Staten Island, New York, named Willowbrook served the mentally retarded population from 1947-1987. A research study, partly funded by the United States Armed Forces, Department of Epidemiology, was undertaken in 1955 to study the progression of and treatment of hepatitis. Children living at Willowbrook were purposely fed fecal matter extract and given doses of the live hepatitis virus. Although parental consent was obtained, the investigators did not disclose to parents the risks of participation (Robinson & Unruh, 2008). Investigators had discovered high rates of hepatitis among the residents at Willowbrook and hypothesized that if children were deliberately given an injection of live hepatitis viral strain, they would develop immunity. The hepatitis experiments at Willowbrook are commonly cited as one of the most serious ethical breaches since the Nazi human experimentations of World War II (Robinson & Unruh, 2008).

In response to the travesties of the Nazi human experimentations during World War II, and the unethical conduct of research involving human subjects from the Tuskegee Study, and the Hepatitis study at Willowbrook, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published a landmark report, "*Ethical Principles and Guidelines for the Protection of Human Subjects for Research*" commonly referred to as the *Belmont Report* (National Commission for Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Contained within the *Belmont Report* are three ethical principles guiding research conduct with human participants. These principles include respect for persons, beneficence and justice. The focus of this paper is the principle of respect for persons, which honors individuals' right to choice and emphasizes potential research participants

must have the capacity to consent as well as comprehend any risks and benefits (Shuster, 1997). Working within this principle, investigators are required to provide a consent process to potential research participants with sufficient knowledge and understanding of research for informed decision making (Whitney, 2001).

It is common for research consent forms to contain structured and technical language to disclose participants' rights and responsibilities (Institute of Medicine, 2004). The practice has been that informed consent documents are typically written at the same reading level as papers written for medical journals (Green, Duncan, Barnes, & Oberklaid, 2003). In addition, the informed consent process is often seen as "bureaucratic form filling" rather than an important and necessary part of the research process requiring time, insight and communication skills (Banner & Zimmer, 2012). Institutional Review Boards (IRB) often provide investigators with templates for writing informed consent documents that satisfy the IRB's requirements but do not take into account the specific verbiage needed for the study's population.

For research participants to give informed consent, four conditions must be met: disclosure, comprehension, capacity to understand and voluntary nature (Iltis, 2006). For complete disclosure investigators must provide potential participants with sufficient information regarding the nature and purpose of the study, the risks and benefits, alternatives, costs and protection of confidentiality. Comprehension refers to the language used in the informed consent document and must be at a level potential research participants can understand. Capacity to understand refers to research participants being legally competent and able to appreciate the information given to them and finally, participation in research must be voluntary in nature with the option of declining to participate while not jeopardizing their clinical care or right to other resources (Iltis, 2006).

The essential elements of informed consent are defined in the United States Department of Health and Human Service's *Code of Federal Regulations* (CFR) and include: the purpose of the research, risks and benefits of participation, voluntary nature of participation, a distinction between research and clinical care, potential for compensation for a research-related injury, the opportunity to ask questions and alternatives to participation (Office of Human Research Protection, 2009). The CFR's has recently been revised and several sections on informed consent have been updated specifically in regards to "new requirements relating to the content, organization and presentation of information included in the consent form to facilitate a prospective subject's decision about whether to participate in research…" (Federal Register, 2017, p. 7210). The impetus for these changes came from arguments stating that consent forms have evolved over time to be documents more designed to protect institutions from liability rather than provide individuals with decision-making information, along with the growing length and complexity of these forms making reading and comprehension difficult (Beardsley, Jefford, & Mileshkin, 2007; Federal Register, 2017). These new regulations take effect January 2018 so it remains to be seen what if any effect there will be to participants' understanding as a result.

Obtaining informed consent for research is essential for ethical conduct and a requirement of these federal regulations (Flory & Emanuel, 2004). To make the consent process truly informed, participants must be given sufficient, understandable information to allow independent decision making (Lansimies-Antikainen, Pietila, Laitinen, Schwab, Rauramaa, & Lansimies, 2007). This honors individuals' autonomy and protects them from potential harm (Antoniou, Draper, Reed, Burls, Southwood, & Zeegers, 2011). Research participants' signing of a consent form serves as documentation of their consent and voluntary participation and satisfies

legal and ethical requirements (Armstrong, Dixon-Woods, Thomas, Rush, & Tarrant, 2012; Banner & Zimmer, 2012).

In 2007 the Food and Drug Administration (FDA) Amendment Act mandated the registration of human subjects' research involving drugs and/or medical devices approved for use in the United States (Califf, Filerman, Murray, & Rosenblatt, 2012). The National Institute of Health (NIH) developed the database (clincialtrials.gov) for the registration. Each week more than 330 research studies are registered on the database, which is the repository for more than 177,000 studies (Califf et al., 2012). The Clinical Trials Cooperative Group, which is sponsored by the National Cancer Institute (NCI) registers more than 25,000 research participants every year from more than 3,100 organizations which include more than 14,000 research investigators in the United States, Canada, and Europe (National Cancer Institute, 2009). Given the large volume of research studies currently being conducted, and the plethora of research demonstrating participants' lack of understanding of informed consent for research, it is imperative that interventions to address the issue of respect for persons, including improving comprehension of informed consent be addressed.

Problem Statement

Clear communication is an important element of healthcare quality and patient safety (Institute of Medicine, 2001), yet 47% of Americans, roughly, 90 million, have difficulties understanding health information given to them by their providers (Wilson, 2009). It has been documented that patients absorb and recall only about half of what physicians have communicated to them (Schillinger et al., 2003). In addition, approximately 40-80% of medical information is forgotten almost immediately with the greater the amount of information being given proportional to the amount of information forgotten (Kessels, 2003). Adding to these

alarming statistics is the difficult readability of informed consent documents, particularly documents for research participation. Readability is described as the person's ability to read and understand written material (Redish & Selzer, 1985). A document's readability is determined by a mathematical formula applied to written texts in order to predict how difficult the material will be for any group to read and understand. This is determined by counting the number of syllables per word and number of words per sentence (Buccini, Iverson, Caputi, & Jones, 2010). Readability scores are expressed as a grade level equivalent to the number of years of formal Western education. Nearly half of American adults read at or below an 8th grade reading level (National Center for Education Statistics, 2003). However, most informed consent documents are written at a 10th grade reading level or higher (Pfizer, 2014). Written materials for research participants must explain complex ideas and information, including the purpose of the study, in depth study procedures, and confusing privacy laws.

Buccini et al. (2010) evaluated the readability of research consents for Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS) and Type 2 Diabetes research. Ten consent forms from each group were assessed for readability using the Simple Measure of Gobbledygook (SMOG) and Gunning Fog Index (FOG). Both the SMOG and the FOG are calculated from a free online readability calculator which records readability from grade 4 up to grade 18 (post graduate education). Readability scores for both groups of documents ranged from a grade level of 9.4 to 16.6. The mean reading grade level for the HIV/AIDS consent document was 14.0 and the mean level for the Type 2 Diabetes document was 13.3. The authors recognize this does not meet the local ethics committee's recommendations for an 8th grade reading level for research consent documents.

Hopper, TenHave, and Hartzel (1995) also assessed consent documents used for radiology research. The authors evaluated 284 consent forms from 156 different institutions. The sample was taken from active members of the Association of University Radiologists. The authors used a computerized software program, Right Writer 4.0, to analyze readability based on the year of education, with a readability index of less than 6 considered simple, a readability of 6-10 considered a good document and more than 10 indicating a complex document. The mean readability score for the consent forms was 12 with a range of 8-17. The authors recognized that the readability of research consent forms used in radiology were too complex for the average person to comprehend. Sharp (2004) and Ogloff and Otto (1991) found similar results when assessing consent documents for psychology and oncology research. These studies are also supported by LoVerda, Prochazka, and Byyny (1989) who evaluated research consent documents used at the Veterans Administration Medical Center, where the authors found that the average reading level was 13. 4 and 22% of all text passages were at the post-graduate level. Grossman, Piantadosi, and Covahey (1994) and Cheung, Pond, Heslegrave, Enright, Potanina, & Siu (2010) found similar results with oncology research consent forms. Beardsley et al., (2007) show that in recent years, the average number of pages in oncology research consent forms has increased from 7 to 11. In addition, in oncology research, very long (20 letter) words are expected to be read and understood by participants who may have recently received a devastating diagnosis, and are in a fragile state of mind contributing to the difficulties of their understanding (Griffith, Wright, Hackworth, & Gilheart, 2012). Terminally ill patients may be eager to enroll into a research study believing it their last chance for a "cure" and thus negate the potential for risks. Of particular consideration to investigators is the fact that people with chronic mental and/or physical health conditions are among several vulnerable populations whose reading level is

below the 8th grade national average (Plain Language and Action Information Network, 2014). Given what is currently known about the length and complexity of the language used in research consent forms, it is important for investigators to assign enough time to adequately discuss all the elements within the consent form and to assess potential research participants' understanding during the consenting process. Kemp, Floyd, McCord-Duncan, & Lang (2008) believe that asking simple yes/no questions is not adequate to assess understanding. The authors' state there may be times when patients did not understand instructions well enough to formulate a question and therefore simply respond "no" when asked if they have any questions (Kemp et al., 2008). Despite the plethora of research on patients' misunderstanding of medical information, physicians still do not routinely check for understanding during clinical encounters with patients (Kemp et al., 2008). The potential for harm may increase significantly when enrolling into a research study without fully understanding the risks.

Despite 25 years of research describing the problem with informed consent processes, empirical evidence testing interventions to improve communication and participant understanding during the informed consent process have primarily been conducted with Oncology patients. This may be due to the potential high risk to participants when testing new cancer treating pharmaceuticals as well as initiatives from the National Cancer Institute (NCI) for improving informed consent for research participants (National Cancer Institute, 2009). Other studies have tested interventions at improving informed consent understanding among HIV patients, healthy volunteers or asthmatic patients (Coletti, Heagerty, Sheon, Gross, Koblin, Metzger, & Seage, 2003; Dresden & Levitt, 2001; Paris et al., 2007; Sengupta, Lo, Strauss, Eron, & Gifford, 2011; Stunkel et al., 2010). Only a few studies were found that enrolled Cardiology patients (Bjorn, Rossel & Holm, 1999; Kripalani, Bengtzen, Henderson & Jacobson, 2008). All

of these studies have mixed results or lack a theoretical framework. Given the potential risks involved in research participation, it is imperative that interventions to improve the research consenting process be empirically tested, thereby enhancing communication, participant understanding and ensuring true voluntary participation.

With increasingly complex and sophisticated research protocols, high-risk treatment options, an aging population at risk of cognitive impairment and an increased awareness of the overwhelming problem of low health literacy, there is an urgent need to ensure that participants truly understand all aspects of their research study prior to consenting. To make sure that research participants are truly informed, information must be communicated in a manner they can understand (Lansimies-Antikainen et al., 2007). One place to start would be to look toward communication theories as a possible framework to guide studies specifically testing interventions to improve research participants' understanding of informed consent.

The overarching concept of this dissertation is communication as it pertains to informed consent for research. Although the current state of the science informs us of participants' misunderstandings of the research study in which they participate, and poor health literacy in this country, empirical studies testing specific interventions that influence the degree to which participants understand or misunderstand research participation information have limitations.

Many of the interventions that have been empirically tested have focused on simplifying the language in the informed consent document or providing potential research participants with other consenting methods such as the use of videos. When conducting an extensive literature search on this topic, only one study was found that tested the teach back method of communication in this cohort (Kripalani et al., 2008). No studies were guided by a theoretical framework. Additionally, the majority of studies testing interventions to improve research

participants' understanding have been conducted with Oncology patients. No studies were found that addressed interventions improving understanding for patients enrolled in cardiology clinical trials. Therefore, this study will address these gaps in the literature and add to the body of science for this potentially vulnerable population.

Theoretical Framework

Communication is a complex behavior, combining physical and mental events, with the aim of exchanging messages between two or more individuals (Schindler, Ruoppolo, & Barillari, 2010). The field of communication is very broad and encompasses many forms of communication from interpersonal communication to public broadcasting to the masses, to speech and language development. Communication theory may be used to understand, explain and predict health beliefs, attitudes, intentions, and behaviors of individuals, dyads, or groups (Bylund, Peterson, & Cameron, 2012). "An interesting and novel focus for improving consent could be creating interventions designed explicitly on improving communication skills" (Nishimura, Carey, Erwin, Tilburt, Murad, & McCormick, 2013, p. 12). The following section will describe the communication model used to support this research.

Shannon Weaver Model of Communication

The Shannon Weaver model of communication (Figure 1) was first developed in 1948 by engineers from Bell Laboratories who felt the need to develop a framework around signal transmissions with telephone line capacities and distortions. Weaver then extended the framework to other kinds of communication and developed the philosophical aspects of the framework as it applies to communication in general (Shannon & Weaver, 1948). The Shannon Weaver model contains the following elements required for communication: information source (sender), transmitter (encoder), channel, reception (decoder), and the destination (receiver). The

sender is the person who starts the conversation with a message he/she wishes to convey. The sender encodes the concept of what he/she wants to communicate by putting it into an understandable format for the receiver to be able to interpret. Decoding occurs by the receiver as he/she interprets the message. The message is the idea or concept with a distinct meaning. The channel is the route the message is sent and can be verbal or written, on paper, or electronic. The authors further explain that the communication or message is effected by noise that may occur within the channel. Level A noise is referred to as any interference or distortion that may lead to changes in the initial message such as the static one hears on the telephone line or the physical noise in the room. Level B noise is the semantic noise such as the vocabulary the source has chosen to use that may potentially contribute to misunderstanding of the message. The vocabulary used by the sender is problematic when it contains medical terminology that the receiver may not understand. This "noise" leads to misunderstanding of the message. Shannon and Weaver (1948) state that in order for communication to be clear, the noise must be reduced. The next step in the model is the feedback loop. This is where the sender asks the receiver to state back in their own words what they heard as the message. If the message is inaccurate the sender has the opportunity to provide clarification of any miscommunication and an opportunity for the sender and receiver to ask questions as necessary.

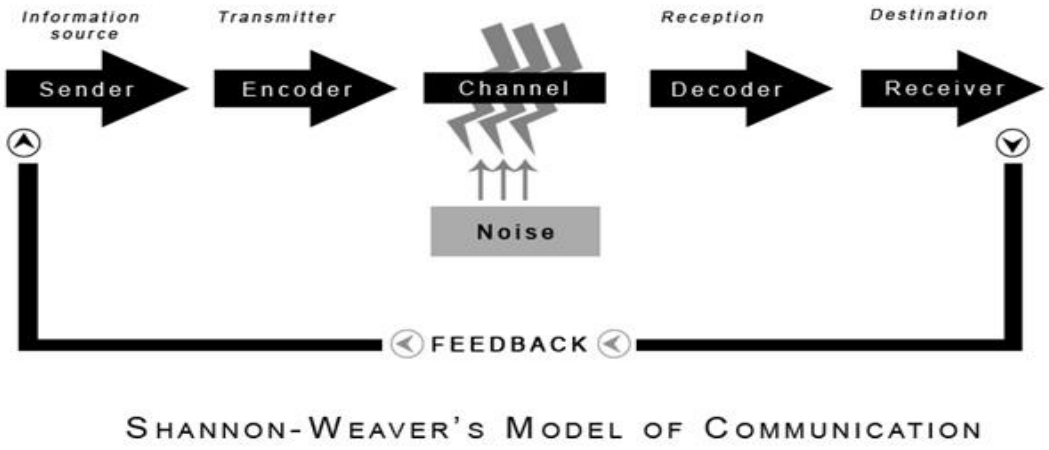

Figure 1. Shannon-Weaver Communication Model

The Shannon Weaver Model of Communication was applied to empirically test the communication intervention of "teach back" to determine whether or not this communication method improved research participants' understanding of the informed consent process, including specific required elements of informed consent as required by federal regulations (Figure 2). It was hypothesized that the teach back method of communication would improve research participants' understanding of informed consent in the following ways: provide new skills to the sender (research coordinator) to encode complex medical and scientific concepts into lay language which would decrease the noise by avoiding the over use of medical terminology, along a verbal channel during the initial informed consent process. The feedback loop (teach back) is where the receiver (potential research participant) states back in his/her own words what it is he/she heard/understood the sender to say. By applying the principles of teach back it was hypothesized that there would be a reduction of Level B noise thereby leading to an improvement of the receiver's (potential research participant) interpretation and understanding of the complex information provided at the time of obtaining informed consent for research.

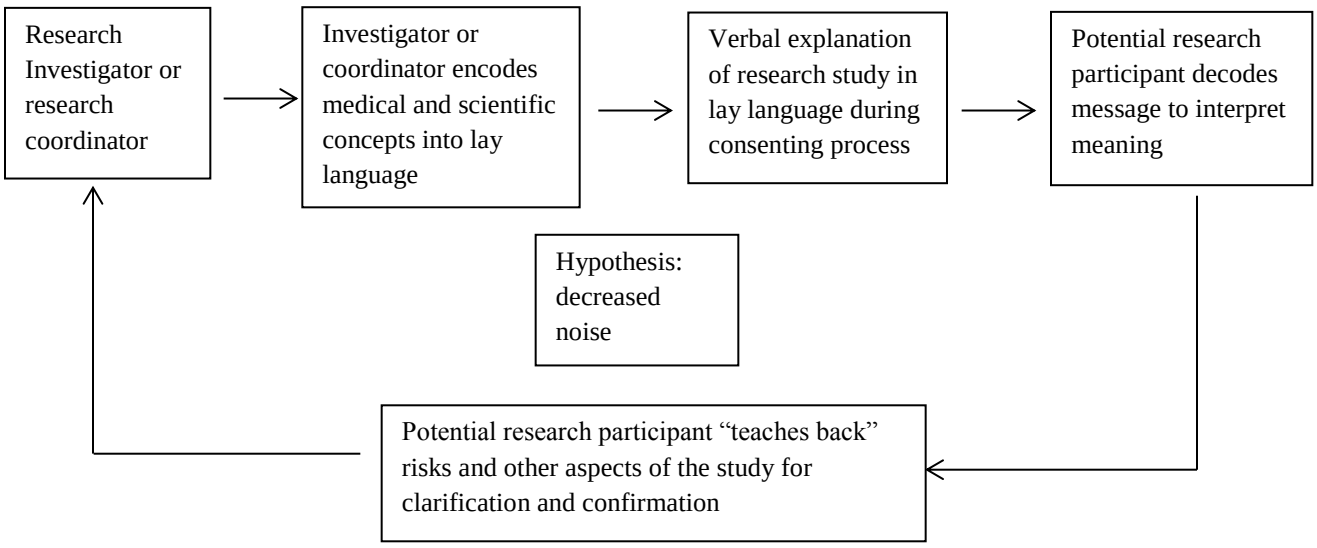

Figure 2. Modified Shannon Weaver Model as Applied to Research Consenting

Interpersonal communication is a key component of the research investigator and potential research participant relationship. The teach back method of communication has been described as when the patient is asked to state back in their own words, to the educator, what they have learned (Negarandeh, Mahmoodi, Noktehdan, Heshmat, & Shakibazadeh, 2012). Teach back was developed to allow the educator to determine if the communicated message was received correctly, thus allowing for the message to be tailored to each individual's literacy level. This relatively simple and quick method allows the educator to evaluate the patient's level of understanding. Teach-back has demonstrated increased patient comprehension leading to improvements in clinical outcomes (Kornburger, Gibson, Sandowski, Maletta, & Klingbeil, 2013; Negarandeha, et al., 2012). Yet this simple communication strategy has not been widely tested as a method of communication when obtaining informed consent for research participation.

In a study by Kemp et al., (2008) patients viewed three physician-patient scenarios of teaching: a yes/no conversation, a Tell-back Directive method and a Tell-back Collaborative

(teach back) method for inquiring about patient understanding of new medical information. The yes/no method was used as it is frequently applied in practice and allows for only closed-ended responses when patients are asked if they understand their instructions. The Tell-back Directive used an authoritative, paternalistic approach to assessing patient understanding and the Tell-back Collaborative approach asked patients to tell back in their own words what the physician had said in order for the physician to assess his/her own communication. This method creates an environment where patients do not need to feel embarrassed if they do not understand their instructions and is the recommended approach (Weiss, 2003). The Tell-back Collaborative method was preferred by patients when compared to the Tell-back Directive and the yes/no method (Kemp et al., 2008).

Nishimura et al. (2013) conducted a meta-analysis of randomized clinical trials testing interventions to improve participant understanding of informed consent for research. The meta-analysis was conducted on 22 interventions which included the use of multi-media, enhancing the informed consent document and extended discussion. There were no significant increase in participants' understanding with the use of multi-media, but there were significant increases in understanding among research participants when alterations were made to the informed consent document (shorter and lower reading level) and having an extended discussion. The authors concluded that when using extended discussion approaches there was an increase in participants' understanding when compared with a controlled consent discussion and state there is no substitute for personal communication where there is the opportunity for questions and answers (Nishimura et al., 2013). Dunn and Jeste (2001) had similar conclusions from their systematic review of participants' understanding of informed consent for research and state one effective intervention is that of corrected feedback. "Learning to develop communication skills to obtain

feedback and verify successful communication is critical to working competently with others, and contributes to addressing the problem of health literacy" (Institute of Medicine, 2004, p.118). These systematic reviews as well as the IOM's report suggest the teach back process of communication may be one possible intervention to improve research participants' understanding. Given the plethora of research demonstrating research participants' misconceptions during and after the informed consent process, more studies examining the communication between the investigator and the potential research participant are needed.

Purpose

The purpose of the current study was to empirically test the teach back process of communication when obtaining informed consent for research participation.

Research Questions and Hypotheses

The research questions for this study were expressed using the Patient, Intervention, Comparison, and Outcome (PICO) method (Stillwell, Fineout-Overholt, Melnyk, & Williamson, 2010). The research questions driving this study were 1. In research participants, will the use of the teach back process of communication compared to standard language, improve objective understanding of informed consent? 2. In research participants, is the relationship between objective and subjective understanding different in the control group (standard communication) compared to the experimental group (teach back communication)?

The following hypotheses were proposed for testing in this study: participants will have a greater understanding of the risks, benefits and other key elements of their research study after receiving the teach back process of communication. A secondary hypothesis is that there will be less of a difference between objective and subjective understanding within the experimental group.

Independent and Dependent Variables

The independent variable was the teach back process of communication (the intervention) and the dependent variables were participants' objective and subjective understanding as measured by scores on the Quality of Informed Consent (QuIC) Instrument developed by Joffe, Cook, Cleary, Clark and Weeks (2001).

Significance to Nursing

According to Carper (1978) a profession will determine the kind of knowledge it aims to develop by organized, tested and applied means. Carper (1978) challenges the nursing profession to develop an empirical body of knowledge specific to nursing yet this scientific quest has been slow. Knowledge and the scientific foundation of any profession is developed using strict methodological rigor involving the conduct of human subjects' research. Traditionally, clinical nurses have had very little involvement in nursing research. While an introductory course in research may be offered at the Baccalaureate educational level, once graduated, those research concepts have not been applied to practice. Nurses' involvement with research has evolved over the past thirty years as the profession has undergone a paradigm shift from technical and task oriented to a more autonomous, science-based profession (Smirnoff, Ramariz, Kooplimae, Gibney, & McEvoy, 2007). With this shift has come an expectation that the nursing profession, including clinical nurses will embark upon scientific inquiry to define its practice.

In recent years the evidence-based practice (EBP) paradigm has gained momentum within the nursing profession with clinicians and administrators embracing EBP to make practice changes for improvements in patient outcomes. With the EBP paradigm comes the expectation that clinical nurses will lead practice changes. This requires the ability to not only be an evidence consumer, but an evidence creator as well. When there is an area of clinical practice that does

not have an evidence base, nurses, with appropriate preparation and guidance from doctorally prepared nurses need to design and conduct research studies. Bedside clinicians conducting research is a relatively new phenomenon with many nurses not having the specific knowledge and skill set. Additionally, nurses working in the role of research coordinator have little formal education and training for that role, yet are often required to obtain informed consent from potential research participants. Particularly important is the knowledge of regulatory requirements when obtaining informed consent for research as well as the roles and responsibilities of the Principal Investigator.

Although there is a plethora of research studies addressing the issue of poor comprehension among research participants, few studies have been published in nursing journals, those typically read by nurses. Additionally, many recently published books on the conduct of nursing research do not address the regulatory requirements and other issues for obtaining informed consent for research participation.

Although there are many research translation models currently adopted by organizations none specifically address how to enroll participants into a research study. Informed consent and the communication skills needed to obtain and assess participant understanding are currently not a part of the national nursing dialogue.

In 1994 the American Nurses Association (ANA) published a position statement, *Education for Participation in Nursing Research* which outlines nurses' involvement in the conduct of research from the Associate degree through the Doctoral degree educational level. Although the Associate Degree prepared nurse may be involved in research by identifying clinical issues and data collection, it is at the Baccalaureate educational level where the ANA describes nurses' involvement with human subject and potential research participation. "Ethical

principles are a big part of the baccalaureate education, not the least of which is the protection of human subjects" (American Nurses Association, 1994).

The American Nurses Credentialing Center's (ANCC) Magnet Recognition Program requires hospitals to document how clinical nurses are evaluating and incorporating research into their professional practice. ANCC also expects clinical nurses to take the lead on process improvement changes and to disseminate results internally and externally (Weierbach, Glick, Fletcher, Rowlands, & Lyder, 2010).

This paradigm shift in nursing practice will require doctorally prepared nurse scientists working in the clinical arena to serve as research mentors to clinical nurses. According to Aaronson et al. (1996) "remarkably little attention has been paid to the potential contribution of nurses to the informed consent process" (p 985). Given the amount of time nurses spend with patients, both in the inpatient and outpatient settings, and their role in education, nurses are better positioned to provide and reinforce information patients have heard during the informed consent process. In order to be able to assist with this education and clarify any misunderstandings research participants may have, nurses need the knowledge of the federally mandated consent required in each research consent document.

Although one may agree clinical nurses' involvement in evidence-based practice a good thing, obtaining informed consent from potential research participants takes an additional skill set not traditionally provided in primary nursing education. Doctorally prepared nurse scientists have the analytic abilities to design research studies around clinical questions and the knowledge of regulatory requirements when conducting research. As more and more hospitals are seeking ANCC's Magnet recognition, with its research requirements, more and more hospitals are hiring doctorally prepared nurses to serve as mentors to staff. When these nurse scientists conduct their

own research studies and/or are mentoring others they must incorporate these best practices when obtaining informed consent.

Finally, this study will advance the science on what is currently known about teach back, empirically test the teach back communication process in the understudied cohort of Cardiology research participants and test the use of the Shannon Weaver Communication Theory. Breakdown in communication most often occurs during the decoding of the message by the receiver (Odell, 1996). Schramm (1954) points out that the more commonalities there are between the sender and the receiver the more likely the chance of the message being interpreted as intended. One way to enhance the commonalities is to avoid the use of medical terminology and jargon. Decreasing the use of medical terminology is one of the steps in the teach back training process.

Chapter Summary

Meade (1999) recognized the absence of underlying theoretical frameworks supporting empirical research on informed consent and suggests scholars look towards the discipline of communication. Despite the plethora of research on participants' understanding of informed consent, most studies do not propose a specific theory for conducting or improving the informed consent process (Sankar, 2004). According to Conn, Rantz, Wipke-Tevis, & Maas (2001) an intervention is more likely to be effective if based on a model or theory and in particular reflect key constructs within the conceptual framework. Without relating the intervention to a theory or framework, the results are likely to be misinterpreted. Furthermore, innovative communication interventions need to be developed and tested to assist informed consent for research (Meade, 1999). This research study will add to the body of the science by incorporating a communication theoretical framework.

Structure to Dissertation

This dissertation is organized in the following manner: Chapter 1 provided a brief overview of the topic. Chapter 2 is divided into Parts A and B and includes two manuscripts. Part A is a critique of the theoretical framework supporting this dissertation and Part B is a systematic review of the literature to describe the current state of the science. In Chapter 3 the research methods including design, sample, research questions, hypotheses, intervention and data analyses are described. Chapter 4 presents the results of this study and includes the third manuscript. In Chapter 5 the study is summarized, limitations addressed and a discussion of implications for nursing, policy and future research are provided.

CHAPTER 2 REVIEW OF LITERATURE

This chapter consists of two manuscripts. The first manuscript is a critique of the Shannon Weaver Communication theory. The second manuscript is a systematic review of the literature.

Teach Back has been published by the Joint Commission as one of its top patient safety goals (The Joint Commission, 2007). The National Quality Forum also endorses teach back as part of best practice (Wu, Nishimi, Page-Lopez, & Kizer, 2005). Additionally, teach back is a requirement for the American Nurses Credentialing Center's (ANCC) Magnet Recognition program. This has led to teach back being implemented in many healthcare organizations. With more and more hospitals implementing teach back and more literature being published on its empirical use, an article critiquing a communication theory to support teach back is timely. The Journal *Research and Theory for Nursing Practice* was chosen as the journal for submission for this manuscript. This journal was chosen because it is a peer-reviewed journal that primarily publishes knowledge development in a broad sense to include issues relevant to making improvements in nursing education and practice. Formatting per the journal's requirements will be completed prior to submission.

Manuscript One: Critique of the Theory

TITLE PAGE

A Critique of the Shannon Weaver Theory of Communication and its Implications for Teach Back

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Abstract

With the Joint Commission's revelation that as much as 65-70% of the time miscommunication has been discovered to be the root cause of many sentinel events, it may be timely to examine a communication theory to support practice improvement efforts. Effective communication has been shown to decrease medical errors, improve patient satisfaction, and increase adherence to treatment plans leading to better health outcomes yet very few studies have examined communication theories and their applicability to practice. This article will examine the Shannon Weaver Communication Theory as one theory that may support future studies examining the teach back communication method as a means to improving patient health literacy leading to improvements in clinical practice.

Keywords theory, communication, teach back

Introduction

A theory is a coherent and non-contradictory set of statements, concepts or ideas that organizes, predicts and explains phenomena, events, and behavior (Bem & Looren-de-Jong, 1997). Theories are common in the social sciences such as psychology, sociology and nursing to develop an understanding of basic and clinical sciences. "Theoretical thinking in nursing uses concepts and their relationships to organize and critique existing knowledge and guide new discoveries to advance practice" (Higgins & Moore, 2000 p. 179). A formal method for theoretical analysis is important in order to determine if the theory has the potential to be useful in the educational, clinical or research arena. By analyzing a theory, the theory's attributes maybe optimized to guide clinical practice. The following six steps of theory analysis as outlined by Walker & Avant (2010) were employed as the Shannon Weaver Communication theory (Figure 1.) was critiqued: 1. identify the origins of the theory 2. examine the meaning of the theory 3. analyze the logical adequacy of the theory 4. determine the usefulness of the theory 5, define the degree of generalizability and the parsimony of the theory and 6. determine the testability of the theory(Walker & Avant, 2010).

The Origins of the Shannon Weaver Communication Theory

In 1947, Shannon, a research mathematician at Bell Laboratories developed a communication theory to explain data transmitted over telephone lines. The purpose of the theory was to describe signal transmissions with maximum capacity and minimal distortions (Shannon & Weaver, 1948). This theory describes technical problems with the accuracy of both the signal and the speech being transferred from sender to receiver. The Shannon Weaver model was based on information theory to describe the predictability of messages being received accurately. Although the theory first described telephone signal transmissions, the original linear

model was later adapted to describe the flow of information with a feedback loop from the receiver to the sender added to the model to better describe inter-personal communication (Shannon & Weaver, 1948). The authors recognize that certain characteristics distort, or change the way a message was intended. For example, static on the telephone line or medical terminology used by healthcare professionals to lay persons may contribute to the message being misinterpreted by the receiver.

The Shannon Weaver Communication theory is historically significant as it was described at the time telephone and computer technologies were being developed post World War II. Many people working in the field of human communication had difficulties understanding the formulas used in Shannon's mathematical theory, but the pictorial model is easy to understand. The source-channel-receiver diagram quickly became the standard description of interpersonal communication during conversations between two people. The terminology used in the model is still the basis for the description of interpersonal dialogue (Griffin, 1997).

The Meaning of the Theory

According to Walker & Avant, (2010) the meaning of the theory refers to its concepts and the relationship among them. The Shannon Weaver model contains the following concepts required for communication: information source (sender), transmitter (encoder), channel, reception (decoder), and the destination (receiver). The sender is the person who starts the conversation with a message he/she wishes to convey. The sender encodes the concept of what he/she wants to communicate by putting it into an understandable format for the receiver. The channel is the route the message is sent and can be verbal or written, on paper, or electronic. Decoding occurs by the receiver as he/she interprets the message. The message is the idea or

concept with a distinct meaning. The authors further explain that the message may be distorted by noise that occurs within the channel. Level A noise is any interference that may lead to changes in the initial message such as the static one hears on the telephone line or music playing in the room. Level B noise is the semantic noise such as the vocabulary the source has chosen to use that may potentially contribute to misunderstanding of the message. For example, the vocabulary used by the sender is problematic when it contains medical terminology that the receiver may not understand. This "noise" leads to misunderstanding of the message. Shannon and Weaver (1948) state that in order for communication to be clear, both level A and level B noise need to be reduced. The final step is the feedback loop. It is during the feedback loop that the sender asks the receiver to state what he/she heard as the message, provide clarification of any miscommunication and an opportunity for the receiver to ask questions. This feedback loop takes the model from its original linear conception to reflect what is more consistent of dialogue. Frandsen and Millis (1993) recognize the feedback loop has been absent in many other communication theories. Schillinger et al. (2003) describe feedback as the "communication loop."

The Logical Adequacy of the Theory

To understand the logical adequacy of a theory the analyst must examine the outcomes the theory is able to predict. For the Shannon Weaver Communication theory, the concept of noise predicts whether or not communicated messages are received as intended. When analyzing the theory we need to ask ourselves if the flow of the relationship among the concepts makes sense, seems logical and is able to make predictions. When viewing the diagram of the Shannon Weaver Communication theory, the reader can quickly assess the relationships among the concepts by the use of the arrows denoting messages from the sender, through a communication

channel and to the receiver. Likewise, the reader is able to understand by the arrow from the receiver back to the sender that this part of the theory explains the concept of feedback. This structure is logical and able to make the predictions of communicated messages received both accurately and inaccurately, depending upon the level of noise. The model does not predict when or where noise will occur, but make suggestions for decreasing the level A and level B noise to improve upon the probability of the sender's message being accurately received.

The Usefulness of the Theory

A theory is considered useful if researchers are able to use it to explain phenomenon, offers new insights into a phenomenon, and make predictions based upon the theory (Walker & Avant, 2010). The theory should identify which clinical issues may support its use, and if the theory has the potential to influence practice, education or research (Walker & Avant, 2010). If the theory is new then it should make significant contributions to the field in which it was developed. The time in history immediately after World War II saw an explosion in information technology with further development of the telephone and the television. The Shannon Weaver Communication theory first described at this time, made significant contributions that helped explain how communication was sent, received and interpreted over telephone lines and was later adapted to include a description of interpersonal communication. The Shannon Weaver Communication theory is one of the most widely used inter-personal communication models. Part of its success is in its ability to explain how communication works, and how communication fails (Foulger, 2004).The body of research conducted on healthcare communication has primarily focused on physician patient communication, specifically from the perspective of the physician giving the patient bad news (Sheldon, Barrett, & Ellington, 2006). For nurses working in a busy and complex healthcare environment, communication may often become hurried and medically

oriented yet very few studies have focused on the nurse patient communication (Sheldon et al., 2006). By using a theoretical framework, such as the Shannon Weaver Communication theory, more studies may be conducted that might provide insight into the breakdown of communication and the introduction of "noise" between the nurse and the patient.

For many hospitals today, patient satisfaction data are captured by the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) scores and are publicly reported. This survey instrument was developed in partnership with the Center for Medicare and Medicaid Services (CMS) and the Agency for Healthcare Research and Quality (AHRQ) and endorsed by the National Quality Forum (NQF) (hcahpsonline.org, 2014). The public reporting of the HCAHPS scores is designed to increase transparency and stimulate hospital incentives to improve practices. One of the many questions posed to patients after discharge from the hospital are their perceptions of the communication between the nurses and themselves. If scores are low, it is difficult for hospitals to create quality improvement processes without first identifying the areas of communication failures. Applying a communication theory to practice will help to identify areas of "noise" leading to communication failures which may then lead to appropriate quality initiatives.

One major criticism of the Shannon Weaver Communication model is that it was originally designed for data transmission which has no meaning attached to it as opposed to information sharing where the receiver attached meaning and emotion to the message (Stewart, Malayan, & Roberts, 2001). This thought is echoed by Chandler (1994) who believes the model reduces communication to the simple transmission of information where information has no meaning. Haworth and Savage (1989) point out that the model focuses on the communication skills of the sender and does not take into account non-verbal communication thereby ignoring

the inferences the receiver may have assumed. Weaver defends this by stating that information technologies, such as the telephone lines of communication are no longer simply technical devices but are a metaphorical description of language in general (Day, 2000). Finally, Genosko (2012) states that this model misses the concept of environment which shapes the senders and receivers meanings of messages.

The Generalizability of the Theory

The Shannon Weaver Communication theory has greatly contributed to the advancement of computer science (Chandler, 1994). The model has been widely adopted by many disciplines including psychology, sociology, education, organizational analysis and nursing and is the most widely used communication model due in part to its simplicity and generalizability (Chandler, 1994). According to Walker and Avant (2010) the more far-reaching a theory can be applied the more generalizable it is.

Patient-centered care is defined as "Providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions" (Institute of Medicine, 2001). Patient centered care first developed from the work of Neuman and Young (1972) has as its core value collaboration with the patient (Hart, 2010).Collaboration with the patient allows the patient and family to participate in healthcare decision making and requires effective communication skills (Hart, 2010). Shared decision making by patients and families is encouraged by the Center for Medicare and Medicaid Services (CMS) and whose language is included in the Affordable Care Act of 2010 (Lee & Emanuel, 2013). To achieve shared decision making all healthcare practitioners need to have effective communication skills. With medical treatment options comes the decision to determine if benefits outweigh any risks. This is particularly important when patients are approached to enroll

into a research study that may pose additional risks they would not necessarily be exposed to. Excellent communication skills by all healthcare personnel are needed to adequately inform potential research participants of these risks and must include the ability for the research personnel to assess for participant understanding. The use of the Shannon Weaver Communication Theory will allow the investigator and other research personnel the ability to transform their intended messages into language for lay persons to understand, assess for understanding through the feedback process and increase the likelihood of the message being delivered as intended.

The Testability of the Theory

For a theory to be considered valid, it must be tested (Walker & Avant, 2010). Nursing knowledge development begins with theory testing; yet testing theories has been acknowledged as being underutilized in nursing (McQuiston, & Campbell, 1997). "Theoretical thinking in nursing uses concepts and their relationships to organize and critique existing knowledge and guide new discoveries to advance practice" (Higgins, & Moore, 2000, p. 179). Although the quest for nursing knowledge never ends, theoretical models offer an important viewpoint for building a better understanding of nursing phenomenon (Carper, 1978). Bylund, Peterson, & Cameron (2012) tell us that studies may be grounded with the use of a theory as a starting point and additionally may add further explanation to the study's findings. Many aspects of the provider/patient relationship both verbal and nonverbal arise within the healthcare environment. Communication theories need to be further tested in the healthcare arena to determine its value and applicability and to add to the current state of the science. Although the Shannon Weaver Communication Theory was not originally developed to describe interpersonal communication, with the addition of the feedback loop, it appropriately describes interpersonal dialogue. To

communicate effectively, we need to familiarize ourselves with the issues involved in the communication process. Once we are aware of them, these issues will help to plan, analyze situations, solve problems, and make process improvements (Lee, 1993). The use of the Shannon Weaver theory will allow for this identification and analysis. Where there are untested theoretical concepts it is prudent to test those relationships which will add to the body of knowledge (Walker & Avant, 2010).

Significance to Nursing

Disciplines often share knowledge and borrow theories which continue to be transformed as practice environments change (Reed & Shearer, 2011). An important function of nursing practice is to communicate to patients and families about their illness and treatment options (Kruijver, Kerkstra, Francke, Bensing, & van der Wiel, 2000). Another important communication goal is to establish interpersonal relationships with patients in order to exchange information, give explanations, and provide physical care (Caris-Verhallen, Kerkstra, & Bensing, 1997). Peplau described a theory of interpersonal relations between the nurse and the patient by describing phases of the developing relationship (Caris-Verhallen, Kerkstra, & Bensing, 1997). Although this theory explains the intimate and unique relationships nurses have with patients it does not describe the nature or process of communication occurring within the relationship. Other nurse theorists have described the nurse patient relationship as one that is dynamic such as Orlando's interaction theory (Orlando, 1961) and King's interacting systems conceptual framework (King, 1981). However, neither of these theories describes how communication is channeled, by whom, what process and what happens when communicated messages fail. The Shannon Weaver model, born out of technology and communication studies may provide a

framework for the intimate messages shared in a bi-directional manner between nurses and patients.

Conclusion

Critique of a theory highlights the theory's strengths and limitations, identifies gaps, questions existing knowledge and identifies areas for further testing (Silva & Sorrell, 1992). Theoretical analysis consists of breaking down all the parts or concepts within the theory to determine how they relate to each other. This allows for the examination of the validity of the theory for its use in real world situations including need for further refinement (Walker & Avant, 2010). After analysis is complete the investigators may determine the theory's potential contribution to the discipline of nursing and the advancement of scientific knowledge (Walker and Avant, 2010).

The Joint Commission revealed that miscommunication was the root cause 65-70% of the time when analyzing more than 3000 sentinel events from 1995-2005 (Adamski, 2007). Not only does effective communication decrease medical errors, it also improves patient satisfaction, and better adherence to treatment plans leading to better health outcomes (Fink, Prochazka, & Wu, 2006). Communication between healthcare professionals facilitates the success of interventions by promoting learning and new sense making (Jordan, Lanham, Crabtree, Nutting, Miller, Stange, & McDaniel, 2009). In addition to miscommunication leading to medical errors it has previously been described how miscommunication leads to lack of understanding of the risks, benefits and other critical aspects of a research study. Therefore, communication, how we speak to patients, potential research participants, the messages we send, the language we use all impact how the received message is interpreted. Employing the feedback loop in the communication process has been recommended as an effective method to improve patient understanding of

medical information (Sayah, Williams, Pederson, Majumdar, & Johnson, 2014). Assessing for patient understanding is a critical element of good communication. The Shannon Weaver interpersonal communication theory with its feedback process from the receiver to the sender may be a good theoretical framework for further research into empirical studies testing the teach back method as interventions with different patient cohorts in different unique settings.

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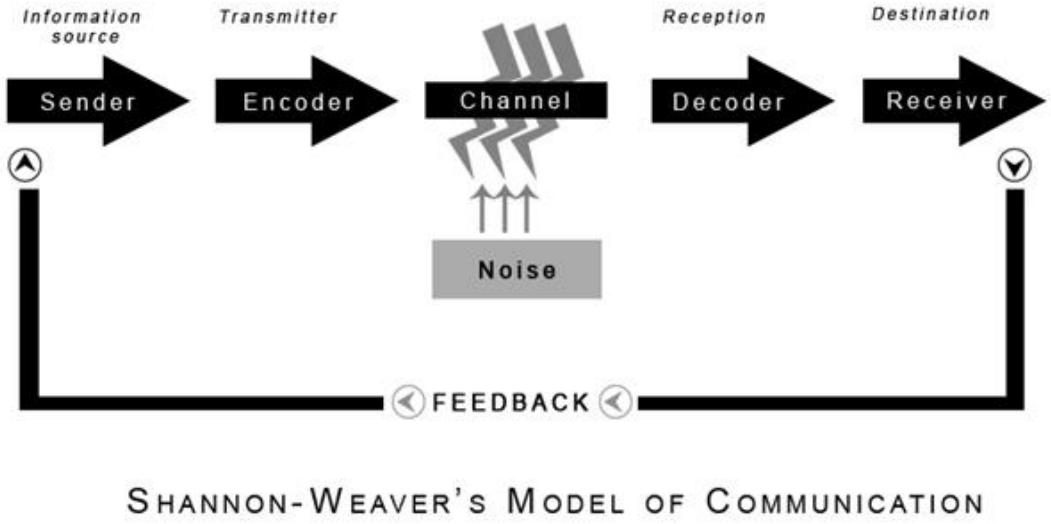

*Figure 3.*Shannon-Weaver Communication Model

Manuscript Two: Review of the Literature

For the second manuscript the *Journal of Advanced Nursing* was selected for submission of a systematic review of the literature on interventions to improve research participants' understanding of informed consent. As more and more hospitals are expecting nurses to become involved in research, there is a large learning curve on the regulatory requirements around informed consent for research. It is imperative that clinical nurses understand the significance of participants' lack of understanding when consenting to participate in research. Therefore, a journal that is primarily published for nurses was chosen. For the purposes of this chapter, APA format has been used to be consistent with all other chapters in this dissertation. Formatting, per the journals' requirements will be completed prior to submission.

TITLE PAGE

Interventions to Improve Research Participants' Understanding of Informed Consent: A Systematic Review

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Abstract

The United States Department of Health and Human Services (DHHS) mandates that informed consent information given to potential research participants be in a language and reading level understandable to them. Despite this, it is common for consent forms to contain structured and technical language to disclose participants' rights, and responsibilities often written at a college or graduate level. Significant misunderstandings about risks, benefits and other aspects of research are misunderstood by as many as 24-74% of participants. The purpose of this review is to systematically evaluate single, empirically tested interventions designed at improving research participants' understanding of informed consent.

Keywords: consent, informed consent, research, clinical trials, research participation, research subjects, research understanding, research comprehension and interventions

Introduction

In 1989 the United States Food and Drug Administration (FDA) joined Japan and the European Union (EU) in founding the International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. The purpose of the ICH is to standardize the pharmaceutical development procedures when conducting human subjects' research. As part of this effort, the ICH has developed "Good Clinical Practice" (ICH-GCP) guidelines including requirements for informed consent (Miller, 1997). These guidelines clearly state the language used in both oral and written information about the clinical trial, including the written informed consent form, should be as non-technical as practical and understandable to the subject. (International Conference on Harmonization-Good Clinical Practice, 2016). Despite this, it is common for consent forms to contain structured and technical language to disclose participants' rights, and responsibilities. Many studies have demonstrated that consent forms are typically written at a college or graduate level, the same level one would write for peers rather than lay persons (Buccini, Iverson, Caputi & Jones, 2011; Cheung, Pond, Heslegrave, Enright, Potanina & Siu, 2010 ; Green, Duncan, Barnes, & Oberklaid, 2003; Institute of Medicine, 2004*).* It is no wonder that as many as 24-74% of research participants have significant misunderstandings about their research (Joffe, Cook, Cleary, Clark, & Weeks, 2001).

Several authors have previously conducted systematic reviews on participants' understanding of research consent (Cohn & Larson, 2007; Dunn & Jeste, 2001; Falagas, Korbila, Giannopoulou, Kondilis, & Peppas, 2009; Flory & Emanuel, 2004; Montalvo & Larson, 2014; Nishimura, Carey, Erwin, Tilburt, Murady & McCormick, 2013; Palmer, Lanquette, & Jeste, 2012; Synnot, Ryan, Prictor, Featherstonhaugh, & Parker, 2014; Tamariz, Palacio, Robert, &

Marcus, 2012). All of these reviews were restricted to selected publication years, research designs, intervention type or a specific cohort. Therefore, the purpose of this review is to systematically evaluate single, empirically tested interventions designed at improving research participants' understanding of informed consent for research and report on studies that may have been previously excluded.

Methods

This review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) method (Moher, Liberati, Tetzlaff, & Altman, 2009). An extensive literature search was conducted using Medline, Ovid, PsycINFO, and Cumulative Index to Nursing and Allied Heath Literature (CINAHL) databases. The following key words were used in various combinations as Medical Subject Headings (MeSH) terms: consent, informed consent, research, clinical trials, research participation, research subjects, research understanding, research comprehension and interventions. Articles were retrieved if they contained any of the key words as a main subject heading. Inclusion criteria were English language, reports on empirical studies and publication in a peer-reviewed journal. Exclusion criteria were informed consent for surgery or other procedures not specific to research participation as this is not the aim of this review, research involving participants with a psychiatric disorder or cognitively impaired as this aggregate do not represent the general population, research conducted in emergent situations (such as the emergency room or during labor), studies examining consent from legal guardians not directly participating in the research as this is not the primary aim of this review and research involving children.

After conducting an extensive review, 45 articles were abstracted. When reviewing the references from all the articles, an additional 15 research studies were retrieved for a total of 60 articles.

Results

From the 60 articles retrieved, 27 were descriptive studies and 8 were systematic reviews and therefore did not meet the inclusion criteria. The systematic reviews were not included as the intent was to review single interventional studies described in more detail than traditionally presented in a review. Twenty five studies met the inclusion criteria (see Figure 4).

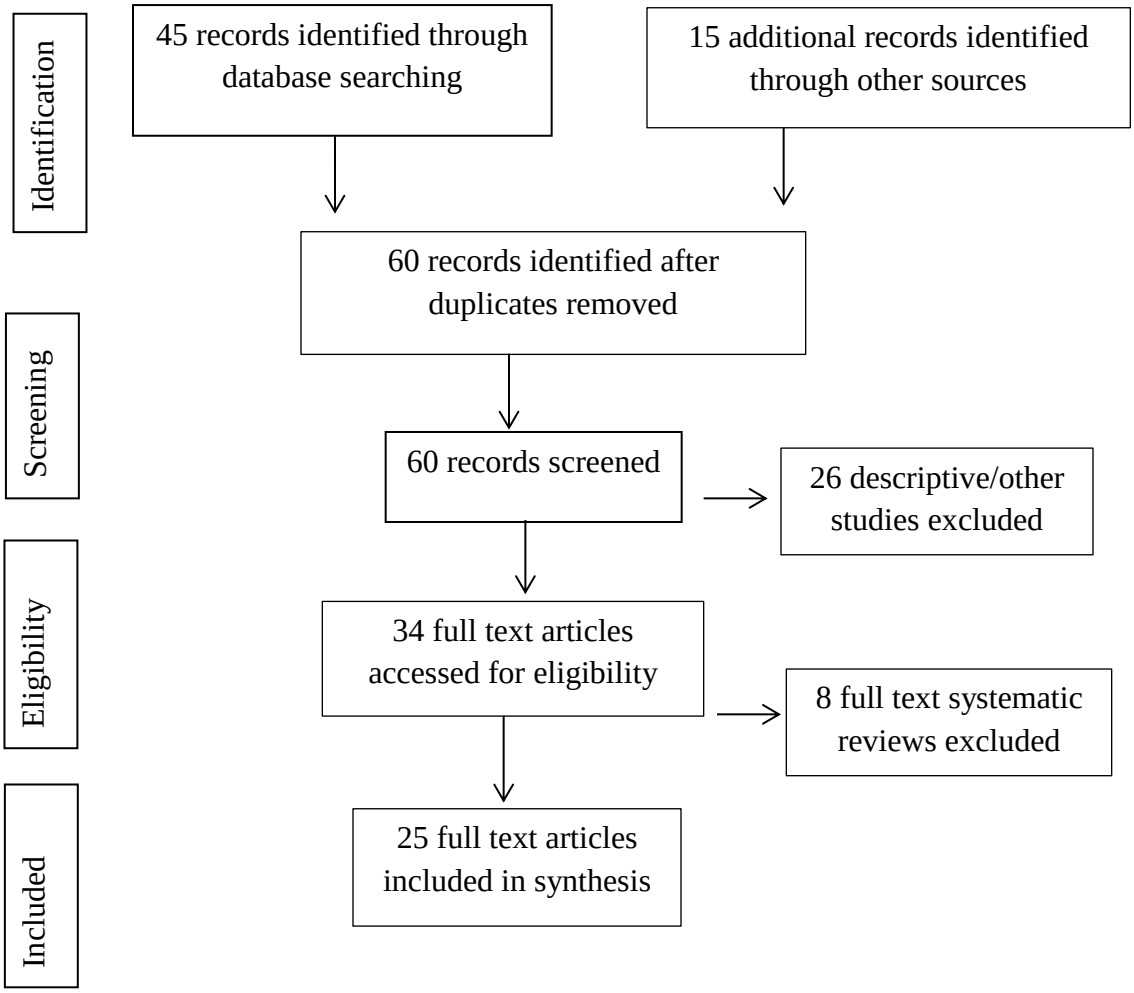

Figure 4. PRISMA Literature Search Process

Interventions

Articles describing interventions designed to improve participants' understanding are categorized as follows: 1. modifications to the informed consent form by simplifying the language and/or the use of informed consent supplements (n = 12), 2. educational offerings for research participants or investigators, (n = 2), 3. monetary rewards to participants as incentives (n = 1), 4. communication techniques, (n = 4), and 5. the use of multimedia tools for consenting (n = 6). The following is a report of these interventions in chronological order according to publication date, within category. Each study was also evaluated for its strength and hierarchy of evidence rating where levels range from I, Meta-analysis as the highest level to level VII, expert opinion as the lowest, as described by Melnyk and Fineout-Overholt (2011).

Studies were conducted in several countries including Australia (n = 2), Canada (n = 1), Denmark (n = 1), Finland (n = 1), France (n = 1), Malawi (n = 1), Netherlands (n = 1) and the United States (n = 17). See Table 1 for all studies' citations, intervention type and evidence rating included in the review listed in alphabetical order by first author's last name.

Modifications and/or Supplements to Standard Informed Consent Documents

Twelve studies focused on simplifying the language and other modifications to the informed consent document or provided supplemental material to improve participants' understanding (Bjorn, Rossel, & Holm, 1999; Campbell, Raisch, Sather, Segal, Warren, & Naik, 2008; Coletti, Heagerty, Sheon, Gross, Koblin, Metzger, & Seage, 2003; Coyne et al., 2003; Davis, Holcombe, Berkel, Pramanik, & Divers, 1998; Dresden & Levitt, 2001; Juraskova et al., 2008; Paris et al., 2007; Raich, Kennedy, Vanoni, Thorland, Owens, & Bennett, 2012; Stunkel, Benson, McClellan, Sinaii, Bedarida, Emanual, & Grady, 2010; Sudore, Landefeld, Williams, Barnes, Lindquist, & Schillinger, 2006 & Young, Hooker, & Freeberg, 1990).

Young et al., (1990) studied a sample of 666 consumers who had used a mouthwash product within the previous 3 months of enrollment into a hypothetical study. Part of the sample read an informed consent document written at the 6th grade reading level and the other part of the sample read a document written at the 10th grade reading level (as determined by the Flesch-Kincaid readability formula). All participants were then given a 21-item investigator developed questionnaire to ascertain their comprehension of the research study. Participants were told they could take as much as 15 minutes to decide whether or not to participate in the study. There were statistically significant higher comprehension scores between those participants who completed the survey immediately after reading the consent and those participants who choose to think about agreeing to participate or not for fifteen minutes. The participants were then divided into educational levels as higher school or less, college, or graduate college level or more. There were statistically significant improvements in comprehension the higher the educational level. The authors do not state how subjects were assigned to receive either document, nor do they describe the 21-item questionnaire used. This study used a quasi-experimental design and is an evidence rating of Level III.

Other investigators modified study leaflets distributed by a major pharmaceutical company, by reviewing the layout, style and language in order to improve participants' understanding of the graphics, symbols, and content (Bjorn et al., 1999). Medical language was replaced with lay language, long sentences were divided into additional, but shorter sentences and long text was broken into smaller sections with headings and subheadings. The revised leaflets, one describing a randomized clinical trial (RCT) for a hypertension study, and one describing a complex RCT for a new anesthetic used during sterilization, were piloted to ascertain participants' understanding of the language, the symbols, and the message itself. One

hundred thirty-five participants received the hypertension study leaflet and 100 received the sterilization leaflet. The authors had participants complete the Summative Cognitive Understanding Scale (developed by the authors) where there was a statistically significant improvement in understanding with both revised leaflets compared to the original leaflets (Bjorn, et al., 1999). This study used a randomized sampling technique which makes this level of evidence II.

Coletti et al. (2003) enrolled and randomized Human Immunodeficiency Virus (HIV) research participants into a hypothetical HIV study to evaluate the use of a prototype informed consent process. Randomization of sampling makes this study a Level II. Those in the intervention group received full disclosure of study information, an informed consent document written at 8th grade reading level with enhanced visual displays, intense educational session at the time of consenting and a booster educational session 6 months later, with a non-physician/non-investigator obtaining consent. This intervention had a statistically significant higher level of comprehension of key concepts in the informed consent document. Participants' understanding was evaluated using the knowledge questionnaire, developed by the investigators, where statements are written as true/false causing even those patients who do not know the correct response, a 50% chance of getting the correct answer. The authors do not report any psychometric properties of the instrument.

Sudore et al. (2006) conducted a study to assess research participants' understanding of a short, comprehensive written informed consent document by administering a simple 7-item true/false question after participants had the document read to them and had read it for themselves with all of their questions answered. Participants were recruited from a general medical clinic and were given 3 attempts at providing all correct answers on the test. In addition,

the authors administered the Short Form Test of Functional Health Literacy in Adults (S-TOFHLA) measurement of literacy. Sociodemographic variables including age, gender, ethnicity, income and educational attainment were also collected. Only 28% of the participants answered all 7 questions correctly at the first pass. The authors concluded that low literacy and being black were statistically significant indicators for requiring more attempts at passing the test (Sudore et al., 2006). This study used a descriptive design with no random sampling and is a Level IV.

Campell et al. (2008) (Level II study) studied the use of a clinical trial handbook as a supplement to the standard informed consent document in 146 patients recruited from an outpatient clinic in the Veterans' Affairs Health Care System. Participants were randomized to receive the standard informed consent document (n = 62) or the clinical trials handbook (n=84). The handbook, developed by experts in research conduct was a full color book explaining the basic elements of informed consent for research and was edited until a seventh grade reading level was achieved. Participants were asked to rate their understanding of their clinical trial on a Likert scale where very clear = +2, to very confused = -2. There was a statistically significant improvement in the intervention group including improved understanding of the option to stop at any time, side-effects of the experimental treatment, randomization and voluntariness. The use of a handbook as a supplement to informed consent seems promising, but these authors do not describe the data collection instrument used, but rather, state they modified an existing instrument.

Juraskova et al. (2008) supplemented the standard informed consent document with a decision aid (DA) and received feedback on the DA by conducting semi-structure telephone

interviews from thirty-one Australian women participating in a breast cancer clinical trial. The survey given to participants had been developed by the investigators following an extensive literature review, drafts, and editorial revisions, review by a team of investigators and pilot tested with healthy volunteers. The authors do not report the survey's psychometric properties. Participants reported the DA assisted them in understanding their research study, with 80% of the women answering the purpose and methods of the study correctly. The concepts of randomization and blinding were still poorly understood despite the use of the DA. This was a descriptive, Level IV study.

Other investigators have also simplified the informed consent document comparing them to standard consent forms. Coyne et al., (2003) compared standard consent forms to a revised consent form. Revisions included changes made to the text style, page layout, font size, and vocabulary. Readability was reduced to the seventh to eighth-grade level. Assessment of understanding was obtained by telephone interviews from trained interviewers to participants. Twenty-three true/false and multiple choice questions were asked of participants, but the authors do not describe the instrument. There was no significant improvement in understanding between either the standard or revised informed consent form. The participants in this study were randomized to the standard or simplified consent form making this study a Level II.

A similar study was conducted by Davis et al., (1998). The investigators compared a standard consent form with a 16th grade level to a revised form with a 7th grade reading level. Participants were then interviewed to complete a structured, oral 22-question survey to assess for comprehension. Although participants preferred the revised form, there was no significant improvement of understanding between the two groups. The authors do not describe

randomization of subjects for this study but did test an intervention giving this study a quasi-experimental, Level III rating.

Dresden & Levitt (2001) randomized participants to receive either a standard or a shortened informed consent form. Participants read the consent forms and then answered a 13-question multiple choice test. Reliability and validity of the test is not stated by the authors. The group with the shortened consent form had significant improvements in understanding of such concepts of purpose of the study, study duration, randomization, risks, benefits, alternative treatments and voluntary participation. Again, with randomization this is a Level II study.

Paris et al. (2007) randomized (Level II study) 200 healthy volunteers to one of 4 different versions of the informed consent form: a standard form, a consent form with systematic lexico-syntactic readability improvement, a consent form modified by a working group, and a consent form modified by the working group followed by systematic lexico-syntactic improvement. Participants were then asked to discuss what they had read as if they were explaining the study to a family member. No questions were asked by the investigator. Participants' responses were tape-recorded. Additionally, participants then completed the QCFic, the French adaptation of the Quality of Informed Consent survey. Significant improvements were evident in the group which read the consent form modified by working group compared to the other three. Exact details of the four consent forms were not described.

Another study compared standard consent forms to a modified consent forms (Raich et al., 2012). One hundred sixty-two male veterans were randomized to receive either the standard or the modified consent form. Telephone interviews were conducted 2 weeks later to assess participants' understanding using 22-item true/false and multiple choice questions. The standard consent form had a Flesch-Kincaid reading grade level of 7.9 where the modified consent form

had a Flesch-Kincaid reading grade level of 5.6. The group with the modified consent form demonstrated significant improvement in understanding. The authors conclude that modifications including reading level format and appearance improve understanding of key elements of consent. This study was a randomized controlled trial giving it a Level II rating.

Stunkel et al. (2010) randomized healthy volunteers to read either a standard or a concise modified consent form. Comprehension was assessed by a quantitative instrument developed by the authors. There was no difference in comprehension between the 14 page consent form or the 4 page consent form. The authors conclude that too much emphasis is spent on the details in the consent forms, possibly due to a fear of legal liability issues. The strength of evidence for this study is high due to the randomization of the sample. This is a Level II study.

Education

Two studies were found that used education as the intervention. Sengupta, Lo, Strauss, Eron, & Gifford (2011) evaluated informed consent understanding among 24 recently enrolled (within 1 month) HIV research participants. Participants who scored 85% or lower on the Quality of Informed Consent instrument (n = 21) were randomly assigned to receive either a targeted educational intervention or a delayed educational intervention in the Level II study. The intervention included providing participants with the consent form and a question and answer period lasting 20 minutes. Participants' understanding improved with the targeted intervention as compared to the delayed intervention. Understanding was assessed using the Quality of Informed Consent (QuIC) instrument, a valid and reliable tool. The authors, however, edited the tool, making many modifications to the instrument and deleting some questions.

Ndebele, Wassenaar, Munalulu, and Maslye (2012) conducted a Level II study to evaluate an educational offering among research participants' who had low scores in a previous

study that assessed their understanding of informed consent. For participants who scored less than 70% on the 3 concepts of randomization, double-blinding and placebo use, 18 were randomized to standard informed consent process and 18 were randomized to receive additional education. The educational intervention included a narrative on the study, translated into participants' Native language, ChiChewa, as well as a power point presentation with pictures explaining personal implications to the study. Thirteen of the 18 women scored greater than 75% on the post evaluation. There was a statistically significant increase in understanding of the 3 concepts within the intervention group when compared to the standard group. However, the authors neither describe the validity of the translated language nor the data collection instrument. Results should be replicated with these limitations addressed.

Monetary rewards

One study offered participants a monetary reward as an incentive to comprehension of the informed consent material. Apseloff, Kitzmiller, & Tishler (2013) conducted a study to determine if receiving a stipend as a reward would increase research participants' understanding of informed consent. Thirty healthy volunteers participating in a clinical trial were administered a questionnaire to evaluate their understanding of the informed consent form. Many subjects failed to comprehend a variety of basic concepts in the consent form directly impacting their clinical trial participation. The specific questions asked were related to the number of blood draws, whether the drugs in the study were experimental or not, the number of overnight hospital stays required by the study, the likelihood of them receiving a placebo, their right to withdraw from the study and other elements including if they felt the informed consent document difficult to understand. Demographic information including education, annual income, and employment status was also collected. Although only 13% felt the informed consent form difficult to

understand, a large percentage failed to comprehend many of the basic concepts of their clinical trial, including 33% not knowing if the study drug was experimental or not. However, 97% did know their chances of receiving a placebo. The sample size was small, however, and selected from a pool of healthy trial participants. In addition, the authors do not disclose the reading level of the informed consent document, therefore, we do not know the readability of the document. This was a descriptive, Level IV study.

Communication

Four studies empirically tested altered methods of communication that focused on either the investigator or the participants. Simes, Tattersall, Coates, Raghavan, Solomon, & Smartt (1986) randomized participants to either receive an individual discussion with the physician/investigator or the standard policy of total disclosure of all information in a Level II study. The participants in the individual approach group received information on the study's aims, expected results and potential risks to treatment. The total disclosure group was told the aim of the study, the chance of success, the experimental nature of the study, randomization, alternate treatments, possible side-effects, and the ability to withdraw without penalty. Both groups were given the opportunity to ask questions. Following this, each participant completed a questionnaire specifically designed for this study. Analysis was performed on 55 participants. Participants in the total disclosure group were much more knowledgeable about their illness and treatment as well as side effects of treatment, the research nature of the study, and randomization. This study would suggest that more information leads to better understanding. However, the illness severity of the participants as well as how new they may have received a devastating cancer diagnosis may play a factor in their abilities to comprehend new information.

In a study by Aaronson et al. (1996), 180 cancer patients were approached to participate in an oncology research study and randomized to receive either standardized informed consent procedure which included a discussion with the physician and a standard informed consent document (control group), or standard informed consent procedure plus a telephone conversation as a supplement from an oncology nurse (intervention group). The nurses making the telephone interviews were trained in telephone interviewing techniques, although this training is not described in detail and inter-rater reliability for this intervention was not measured. The intervention group had a statistically significant better understanding of risks and side-effects of the treatments, the context of the treatments, the purpose of the research study, the concept of randomization, the availability of alternative treatments, the voluntary nature of the study, and the right to withdraw from the study at any time (Aaronson et al., 1996). The authors conclude that this is a rather simple intervention to improve research study participants' understanding of key elements of their research study in this Level II, randomized study.

Hietanen, Aro, Holli, Schreck, Peura, & Joansuu, (2000) provided a short communication course to physicians and nurses enrolling participants into a breast cancer research study. Hospitals that were currently conducting a breast cancer study were randomized to be either the control group which did not receive the communication course, or the experimental group which received the short, one day communication course. The experimental group received training from a facilitator experienced in training physicians in communication and included psychological reactions to disease, interviewing techniques and the current research demonstrating research participants' lack of understanding. The lecture was followed by role-playing as both the healthcare provider and the potential research participant. Demographic data were collected from both groups. Three and half months after the communication course,

research participants were surveyed with the Quality of Informed Consent (QuIC) instrument to assess their understanding. Three hundred twenty surveys were mailed, with 288 (90%) responding. Participants in the intervention group were statistically more satisfied with the communication they received when enrolling into their study. Both groups felt they received enough information to make an informed decision. Participants in the intervention group felt they had been given sufficient time to make a decision, and had a statistically significant increase in the understanding of the purpose of the study and the comparison of two study arms. The authors also sought feedback from the staff who took the communication course. The physicians and nurses all felt the training was very valuable and 80% wished the training had been longer. The investigators concluded that the short communication course could be improved upon and be valuable for those obtaining informed consent for research. Randomization makes this study a Level II.

Kripalani, Bengtzen, Henderson, & Jacobson (2008) conducted a study of low income, inner city African Americans participants recruited from a Primary Care Clinic. The participants had previously consented to participate in a research study on medication adherence with Coronary Artery Disease and had been randomized to receive or not receive teach back methods when explaining their study to them making this a Level II study. Those participants in the teach back experimental group were asked to explain back to the investigator key elements of their research study. The ability for patients to teach back information ranged from 57.1% to 92.5% with lower rates among the elderly and those will lower literacy. The authors concluded that teach back allowed investigators to assess participants' understanding in real time. The author suggests that participants with low literacy should be considered a vulnerable population.

Multi-media

Six studies empirically tested the use of multi-media aids. The term multimedia is used when two or more forms or channels of communication are used conjointly such as the use of voice and other sound, visual still pictures with motion pictures or computer based communication (Palmer et al., 2012). Agre and Rapkin (2003) did not find an improvement in research understanding when comparing informed consent delivered by booklet, videotape or computer. The authors hypothesized that media tools would lead to better understanding of informed consent for participants in high risk research studies; however, this was not supported statistically. This study chose an interesting population from which to draw its sample. The sample included a total of 441 individuals, 204 whom were patients at a Day Surgery Center, 109 were family members and 128 participants, the authors called "surrogate subjects" who were individuals waiting for patients in the hospital's waiting room. Randomized participants' understanding was evaluated on a 12-15 multiple choice knowledge questionnaire developed by the authors for this Level II study. The authors concluded that no one in any of the three groups were able to correctly answer more than two thirds of the knowledge questions on the investigator's developed survey. As one third of the population was individuals in the waiting room, these results may refute the belief that a devastating cancer diagnosis or other health issues potential impact on the ability to comprehend the information in the informed consent document. Reliability and validity of the survey tool used for this study is unknown.

Informed consent consultation audiotapes were compared with standard informed consent audiotapes in a group of 69 women newly diagnoses with breast cancer in a study by Hack et al., (2007). All participants received standard research consent consultations and then randomized to receive one of the types of audiotapes, or both. Outcomes were assessed using the Informed

Consent Questionnaire adapted by the authors for this study which includes two subscales: The Patient Perception of Being Informed (PPBI) subscale and the Patient Knowledge of Information Relevant to Informed Consent to Clinical Trials (PKI). There were no statistically significant differences in participant knowledge of or perceptions of being informed with the consultation audiotape. The authors admit their study is limited by its small sample size and lack of a control group. This study was a Level II a Randomized Controlled Trial.

Bickmore, Pfeifer, and Paasche-Orlow (2009) randomized (Level II) the use of a computer agent, versus human communication, versus self-study information on potential research participants understanding of informed consent for a hypothetical study. Twenty-nine subjects were recruited from a university neighborhood mostly occupied by elder, minority adults. Participants' understanding was assessed using the Brief Informed Consent Evaluation Protocol (BICEP). While completing the BICEP, participants were allowed to refer to the paper copy of the informed consent document. The investigators also measured participants' health literacy using the Rapid Estimate of Adult Literacy in Medicine (REALM) which has previously demonstrated reliability and validity. Participants were then given either the computerized agent after a brief session on how to use the computer, human communication about informed consent for research or a written informed consent for them to read (with as much time as they needed to read it). The human conversation for informed consent was completed by a research assistant with experience in this area. Thirteen of the 29 participants (45%) had poor health literacy (defined as reading at 8th grade level or below). Analysis revealed that for those participants who had adequate health literacy, there was a statistically significant improvement in comprehension with both the computer agent and human conversation. For those participants with inadequate health literacy, there was no statistically significant difference with comprehension among the

three interventions. The authors recognize this study's generalizability is limited due to the small convenience sample used. These authors do not describe if participants were randomized into either intervention groups or the control group, we therefore do not know the sampling strategy.

Kass et al., (2009) also tested the use of a video for improving research participants' comprehension of informed consent. The investigators drew their sample from Oncology patients in a large metropolitan area, where participants were randomly assigned to either the intervention group where they watched a 20 minute video on clinical trials or the control group which received an information pamphlet developed by the National Cancer Institute. The video included 5 actors playing the role of patients deciding whether or not to enroll in a research study. Two hundred eighty-eight were randomized to receive the video with 130 completing the survey questionnaire. Of the 130 who completed the survey, 70 received the computer based video and 60 received the pamphlet. A trained investigator interviewed each of the participants to garner their knowledge about the purpose, risks and benefits of their study using a structured questionnaire developed by the investigators. Participants in the intervention group were significantly more likely to understand the purpose of the research study. Interestingly, there was no statistically significant difference between the two groups for participants' beliefs about how enrolling in the trial would impact their cancer.

In a study by Hoffner, Bauer-Wu, Hitchcock-Bryan, Powell, Wolanski, & Joffe, (2012) the authors tested the intervention of a video designed to prepare cancer patients with their decisions about potential research enrollment. Ninety cancer patients were randomly assigned to receive the video (intervention group) or the standard informed consent process (control group). The participants completed the Quality of informed Consent (QuIC) instrument, a valid and reliable tool, to assess their understanding of the key elements of their research study. All

participants also completed additional questions on their satisfaction with the video and patient/provider communication. There was no statistically significant difference between the groups with objective understanding of informed consent for research. The majority (85%) however, felt the video was an important source of information, and 81% felt they were better prepared to discuss the research study with their physician (Hoffner et al., 2012).

McGraw, Wood-Nutter, Solomon, Maschke, Benson, & Irwin (2012) pilot tested video vignettes 20 minutes in length with captions and narration after receiving input into its development by six African Americans and six non- Hispanic white individuals for clarity and content. Patients visiting several local Oncology clinics were recruited to participate. Recruitment was specifically designed to capture a widely diverse group of racial and ethnic backgrounds and educational levels. Forty-three participants were randomized to read an informed consent document or view the multi-media video with vignettes, then participate in a semi-structure interview. Twenty-two of the 32 participants (68%) who viewed the video felt it to be very useful and provided them with enough information to make an informed decision. Ten participants, however, felt the video alone was not enough and asked for additional resources. The most common complaint about the video was the length. Participants felt it too lengthy and tedious, especially the parts of the video that spoke about the role of the Institutional Review Board (IRB). Both groups had a good understanding that the benefits of research was primarily for future patients. Although more than half of the participants knew they might be contacted for future research, less than one fifth said they would refuse to participate, leaving the investigators to wonder if they did not fully appreciate the voluntary nature of research participation. This study's design and sampling make is a Level II.

Discussion

Studies assessing research participants' understanding of their specific study, have identified issues with lack of comprehension. This problem has been researched and described for more than twenty-five years. Several approaches have been taken to improve research participants' understanding, which included altering the language in the informed consent document, providing supplemental information or additional education, or the use of multi-media tools or altered communication techniques.

Several systematic reviews on interventions to improve research participants' understanding of informed consent have previously been published but were limited to publication years (Dunn & Jeste, 2001; Cohn & Larson, 2007; Montalvo & Larson, 2014), research design (Nishimura et al. (2013), intervention type (Palmer et al., 2012; Synnot et al., 2012), or specific cohort (Tamariz et al., 2012). This systematic review addressed these gaps but not applying those exclusionary criteria, but rather taking a more inclusive review of current research.

Each of the 25 studies reviewed were rated according to the hierarchy of evidence described by Melnyk and Fineout-Overholt (2011). The majority of the studies (n = 20) were Level II, a single randomized study. Two studies were Level III, due to non-randomization of the sample and 3 studies were Level IV, descriptive. Although all of the studies described research design and sample selection, none of the studies explained how the investigators arrived at their sample size. The authors acknowledged when they had a small sample which begs one to wonder why an *a priori* power analysis was not done. Therefore, it would appear as though many of these studies, though well designed might be underpowered. If this is the case, the results must be viewed with caution. Additionally, none of the communication studies was longitudinal and

therefore it is unknown whether a change in communication patterns and methods can be sustainable over time.

There are instruments currently available to measure research participants' understanding that have demonstrated reliable psychometric properties (Joffe et al., 2001; Sugarman, McCrory, Powell, Krasny, Adams, Ball, & Cassell, 2005). Despite this, only 6 studies used a valid and reliable instrument to gather quantitative comprehension scores. The majority of studies were conducted with instruments developed by the authors. A major limitation of these studies therefore, is the unknown reliability and validity of the instruments. This jeopardizes the internal consistency of the study and limits the generalizability of the results. Other research used hypothetical studies which begs one to wonder if participants would be less concerned with risks involved in enrollment, knowing the study is not actually occurring. The majority of the studies examining participants' understanding did so several weeks to months after the informed consent discussion which may introduce recall bias. Some studies have admittedly recruited a small sample size, and therefore may be underpowered. Results should be interpreted with caution

Lastly, the use of a theoretical framework supporting empirical research on informed consent has been absent from the literature. Meade (1999) suggests researchers look towards communication or adult education for theoretical frameworks to support future studies. Although none of the studies described in this review reported on the use of a theoretical framework it is believed that an intervention is more likely to be effective if based on a model or theory (Conn, Rantz, Wipke-Tevis, & Maas, 2001).

Limitations

This review set out to be more inclusive of the literature than previously published reviews; however it does have some limitations. First, it only included articles which have been

published in English. Although a comprehensive literature search was conducted, it is possible that some relevant articles may have been missed. Abstract presentations, dissertations and unpublished work are not reported here which may result in reporting bias.

Conclusions

More research is needed that addresses the limitations of the studies described in this review. Well-designed research studies with support of a theoretical framework, use of valid and reliable instruments, a randomized sampling strategy and enrollment of a large enough sample to have adequate power to determine statistical significance may yield interesting results and allow for strategies to improve participants' understanding to be implemented into practice. Without well-designed studies demonstrating reliable interventions for improving research participants' understanding this 25 year old problem will persist.

Table 1. *Citations in Systematic Review*

Citation	Purpose	Intervention	Evidence Hierarchy
Aaronson et al. (1996). Telephone-based nursing interventions improves the effectiveness of the informed consent process in cancer clinical trials. *Journal of Clinical Oncology*, *14*, 984-996.	To test a telephone intervention to increase participants' understanding of their clinical trial.	Communication	RCT Level II
Agre, P., & Rapkin B. (2003). Improving informed consent: A comparison of four consent tools. *IRB: Ethics & Human Research*, 25(6), 1-7.	To measure the effectiveness of videotape, computer, and booklet format-against the standard written consent form.	Multi-media	RCT Level II
Apeseloff, G., Kitzmiller, J.P., & Tischler, C. L. (2013). Credibility and comprehension of healthy volunteers in lengthy inpatient drug studies.	To assess motivation, comprehension and the effects of offering a stipend on knowledge of clinical trial.	Monetary Reward	Descriptive Level IV
Bickmore, T.W., Pfeifer, L.M., & Paasche-Orlow, M.K. (2009). Using computer agents to explain medical documents to patients with low health literacy. *Patient Education Counseling*, 75(3): 315-320.	To evaluate an animated computerized agent to explain research consent forms to potential research participants	Multi-media	RCT Level II
Bjorn et al. (1999). Can the written information to research subjects be improved? An empirical study. Journal of Medical Ethics, *25*, 263-267.	To determine if changes made to information leaflets from clinical trials improved perceived difficulty and understanding of the content.	Modifications to the Informed Consent Document	RCT Level II
Campbell et al. (2008). Impact of a clinical trials information handbook on patient knowledge, perceptions, and likelihood of participation. *IRB: Ethics & Human Research*, *30*(1), 6-14.	To assess an Informed Consent Handbook on participants' understanding of informed consent.	Modifications to the Informed Consent Document	RCT Level II

Coletti et al. (2003). Randomized, controlled evaluation of a prototype informed consent process for HIV vaccine efficacy trials. *Journal of Acquired Immune Deficiency Syndrome, 32,* 161-169.	To test a prototype informed consent process to improve participant understanding	Modifications to the Informed Consent Document	RCT Level II
Coyne et al. (2003). Randomized, controlled trial of an easy to read informed consent statement for clinical trial participation: A study of the Eastern Co-operative Oncology Group. *Journal of Clinical Oncology, 21*(5), 836-842.	To evaluate a modified easy to read informed consent document on patient anxiety, satisfaction and understanding of their clinical trial.	Modifications to the Informed Consent Document	RCT Level II
Davis et al. (1998). Informed consent for clinical trials: A comparative study of standard versus simplified forms. *Journal of the National Cancer Institute, 90*(9), 668-674.	To compare a standard consent written at 16th grade reading level to a simplified form written at 7th grade reading level.	Modifications to the Informed Consent Document	Quasi-experimental Level III
Dresden, G. M. & Levitt, A. (2001). Modifying a standard industry clinical trial consent form improves patient information retention as part of the informed consent process. *Academic Emergency Medicine, 8*(3), 246-252.	To ascertain patient retention of information from an industry sponsored consent form compared to a condensed, simplified form	Modifications to the Informed Consent Document	RCT Level II
Hack et al. (2007). Standardized audiotape versus recorded consultation to enhance informed consent to a clinical trial in breast oncology. *Psycho-Oncology, 16,* 371-376.	To compare two audiotape formats for the delivery of informed consent to	Multi-media	RCT Level II
Hietanen, et al. (2007). A short communication course for physicians improves the quality of patient information in a clinical trial. *Acta Oncologica, 46,* 42-48.	To determine if a communication course would improve participants' understanding of their clinical trial.	Communication	RCT Level II
Hoffner et al. (2012). Entering a clinical trial: Is it right for you? A randomized study of the clinical trials video and its impact on the informed consent process. *Cancer, 118*(7), 1877-1883.	To assess an educational video in preparing cancer patients for enrollment into a clinical trial	Multi-media	RCT Level II

Juraskova et al. (2008). Improving informed consent: Pilot of a decision aid for women invited to participate in a breast cancer prevention trial (IBIS-II DCIS). *Health Expectations, 11*, 252–262.	To pilot test a decision aid booklet to improve participant understanding of informed consent	Modifications to the Informed Consent Document	Descriptive Level IV
Kass et al. (2009). An intervention to improve cancer patients' understanding of early phase clinical trials. *IRB: Ethics & Human Research, 31* (3), 1-10.	To test a computer-based tool and pamphlet with cancer patients who were considering enrolling in an early-phase clinical trial.	Multi-media	RCT Level II
Kripalani S, Bengtzen R, Henderson L, & Jacobson T. (2008). Clinical research in low-literacy populations: Using teach back to assess comprehension of informed consent and privacy information. *IRB: Ethics & Human Research, 30* (2), 13-19.	To examine the association of patients' age, cognition, years of education, and literacy level with comprehension of informed consent	Communication	RCT Level II
McGraw et al. (2012). Clarity and appeal of a multi-media informed consent tool for biobanking. *IRB: Ethics & Human Research, 34*(1), 9-19.	What information regarding domains of informed consent in the multimedia tool and written consent document was salient to the participants	Multi-media	RCT Level II
Ndebele, P.M., Wassenaar, D., Munalula, E., & Masiye, F. (2012). Improving understanding of clinical trial procedures among low literacy populations: An intervention within a microbicide trial in Malawi. *BMC Medical Ethics, 13*, 29	To assess participants' understanding of randomization, double-blinding and placebo use.	Education	RCT Level II
Paris et al. (2007). Improvement of the comprehension of written information given to healthy volunteers in biomedical research: A single-blind randomized controlled study. *Fundamental & Clinical Pharmacology,21*, 207–214.	To identify if improvement in lexico-syntactic readability could increase comprehension of information given to volunteers enrolled in biomedical research	Modifications to the Informed Consent Document	RCT Level II

Raich, et al. (2012). Improved understanding and satisfaction with a modified informed consent document: A randomized study. *Patient Intelligence, 4,* 23-39.	To assessed the impact of an informed consent process	Modifications to the Informed Consent Document	RCT Level II
Sengupta, S., Lo, B., Strauss, R.P., Eron, J., & Gifford, A.L. (2011). Pilot study demonstrating effectiveness of targeted education to improve informed consent understanding in AIDS clinical trials. *AIDS Care, 23*(11), 1382-1391.	To pilot test an educational intervention to improve actual informed consent understanding	Education	RCT Level II
Simes, R.J., Tattersall, M.H., Coates, A.S., Raghavan, D., & Solomon, H.J. (1986). Randomized comparison of procedures for obtaining informed consent in clinical trials of treatment of cancer. *British Medical Journal, 293,* 1065-1068.	To compare 2 methods of consent to randomized treatment.	Communication	RCT Level II
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Chapter Summary

This chapter included two manuscripts for submission for publication. The first manuscript is a critique to the Shannon-Weaver Communication theory. The Shannon-Weaver Communication theory may serve as a framework for future nursing studies employing teach back, patient hand-offs or other aspects of nursing communication. A thorough critical review of the theory is warranted if it is to be applied to nursing and a critique of this theory has not previously been published.

The second manuscript describes a systematic review of the literature to examine interventions tested to improve research participants' understanding of informed consent. This systematic review describes interventions previously tested and allows the reader to understand the depth and breadth of the issue and various methods attempted at making improvements in research participant understanding. Armed with this information the following chapter describes the research design used to test the teach back method of communication for improvements in research participants' understanding of informed consent.

CHAPTER 3 METHODS

The research questions, hypotheses, methods, design, sampling strategies, intervention and data collection and analytical methods used for this study are presented in this chapter. Also included are limitations and processes for protection of human subjects. The teach back process of communication intervention is described.

Research Questions and Hypotheses

The research questions driving this study were 1. In research participants, will the use of the teach back method of communication compared to standard language, improve objective understanding of informed consent? 2. In research participants, is the relationship between objective and subjective understanding different in the control group (standard communication) compared to the experimental group (teach back communication)?

The following hypotheses were proposed for testing in this study: participants will have a greater understanding of the risks, benefits and other key elements of their research study after receiving the teach back process of communication. A secondary hypothesis is that there will be less of a difference between objective and subjective understanding within the experimental group.

Methods

Design

This study used a quasi-experimental sequential two group design with pre and post intervention groups. The pre-intervention group served as the control group and the post intervention group, the experimental group. This design was chosen as it was impractical in the clinical setting to randomize the participants.

Setting

This study was conducted at a large, tertiary care hospital in New England. The hospital serves as a major cardiology referral center for the state. The Cardiology department is actively participating in 7 national clinical trials.

Sample

This study used a convenience sample of 52 adult Cardiology patients (38 for the pre-intervention group and 14 for the post intervention group) identified by the Cardiology Research Coordinators when accessing their database for potential Cardiology clinical trial participants. The sample was drawn from participants in two cardiac clinical trials that were open at the time of recruitment. Inclusion criteria were English speaking and writing and enrolled in a cardiac clinical trial. Exclusion criteria were: 1) under the age of 18 years, 2) a current diagnosis of dementia, Alzheimer's or who are otherwise cognitively impaired or diagnosed with a mental illness, and 3) participation in a research study where assent was given by a legal guardian or someone other than the participant themselves.

A total of 74 participants was targeted as the sample size (A1 Therapy Statistics, 2016). To determine sample size, Cohen (1988) states there is a β of .2 or a 20% probability of failing to detect an effect when there is one (a Type II error). Therefore there is 1-β or a .8 or 80% probability of detecting an effect when there actually is one. The last number needed to determine a power analysis is the effect size. According to Cohen (1992), a small effect size is (r = .1), a medium effect (r =.3) and a large effect size (r = .5).

Only one prior research study has tested the use of the teach back process of communication as an intervention to improve research participants' understanding of informed consent (Kripalani et al., 2008). According to Hulley, Cummings, Browner, Grady, & Newman

(2007) when there is no *a priori* data on which to establish the effect size, the investigator may conduct a pilot study. Field (2011) suggests in the absence of prior research, the researcher needs to estimate the likely effect size based on similar studies. For this study the effect size was estimated to be large. Therefore, with an α of .1, power of .8 and effect size of .5, the estimated sample size for this study was 37 participants in each group.

Measurement

Participant Demographics. Demographic data were collected to describe the subjects. This included age, gender, socio-economic status and educational level.

Socioeconomic Status. It is believed that participants' socioeconomic status as measured by their educational level and income may impact their ability to read and understand their informed consent document. This may or may not have an impact on their ability to understand and comprehend the research study in which they are participating and therefore was collected and analyzed as a confounding variable. Socioeconomic status was measured by household income as defined by the United States Census Bureau. Years of completed education was collected as it may have an impact on participants' ability to read and understand the informed consent document. This can be found in Appendix C.

Instrument. The Quality of Informed Consent (QuIC) instrument was developed by Joffe et al. (2001). The overall purpose of the instrument was to evaluate participants' understanding of their clinical trial. The authors started with the basic elements of informed consent outlined in federal regulations (Code of Federal Regulations, 2012). These included elements such as the voluntary nature of the research, the risks and benefits, the use of Protected Health Information, the cost to the participant as well as other key points that must be in the consent form. However, some of these elements (such as "benefits to the subject or to others")

are actually a synthesis of two or more different concepts and therefore, Part A of the QuIC contains 20 questions that include 13 distinct domains of informed consent measuring objective understanding. Questions are answered on a Likert scale from 1 (*disagree*), 2 (*unsure*) and 3 (*agree*). Each correct answer in Part A is given a score of 100 points, an "Unsure" response is given a score of 50 points and incorrect answers are given 0 points. Unanswered questions are not scored.

Part B of the instrument measures subjective understanding which assesses what participants believe they understand (Joffe et al. 2001). Part B of the instrument contains 14 questions answered on a Likert scale from 1 (*I didn't understand this at all*), to 5 (*I understood this very well*). Part B of the QuIC is scored by taking the average responses to each of the fourteen questions and scaled from 0-100 (summary score = raw average -1 x 25). This allows for equal weighting among the domains in the instrument.

Part A of the instrument, participants' objective understanding was the primary outcome variable of interest in this intervention study. It was hypothesized that participants believe themselves to be informed when in reality are not. This hypothesis is supported by previous research where as many as 90% of participants were satisfied with the informed consent process and believed themselves to be fully informed, but when questioned in more detail, were unaware of the purpose of the study, the unproven nature of the intervention and other aspects of their trial (Joffe et al., 2001). Therefore, Part B of the QuIC instrument was used to assess participants' beliefs about being informed about their study. The QuIC is written at an 8th grade reading level. The interclass correlation coefficient (ICC) was .66 (Part A). It was noted that subjects with lower scores had greater test–retest variability than those with higher scores. Part A of the QuIC

instrument had a mean score of 76 and Part B summary scores averaged 87.2 and the interclass coefficient was .77 during pilot testing of the instrument (Joffe, et al., 2001).

Informed Consent Form. The Flesch-Kincaid readability of the informed consent form may impact participants' ability to read and understand their consent and was collected as a potential confounding variable.

Procedures

Human subjects protection. This research proposal was approved by the Institutional Review Board (IRB) at the University of Wisconsin-Milwaukee where the Principal Investigator was a student (Appendix A) and the IRB at the participating hospital (Appendix B).

Teach back intervention. The intervention for this study was the teach back process of communication. Teach back has been defined as "asking patients to repeat in their own words what they need to know or do, in a non-shaming way" (The Ethics Center, 2006, p. 2). Teach back is a communication method used to enhance comprehension and retention of information, and assess for understanding (Wilson, Mayeta-Peart, Parada-Webster, & Nordstrom, 2012). During teach back, the patient or participant is asked to repeat back to the educator, in their own words what they heard. This allows for assessment of understanding and the correction of any misinformation.

The Cardiology Research Coordinators at the participating hospital are Registered Nurses holding certifications from the Society of Clinical Research Association (SOCRA) or from the Association of Research Professionals (ACRP). Passing the certification exam from either of these national organizations allows the nurse to use the credential, Certified Clinical Research Coordinator (CCRC). The certification demonstrates competence and expertise in preparing or reviewing documents submitted to the Institutional Review Board (IRB), protocol

review and study procedures, planning, maintaining source documents, preparing for study site visits from a monitor, sponsor, or auditor, and obtaining informed consent. The Cardiology Research Coordinators are responsible for obtaining informed consent for all clinical trials within the department at the study site.

The curriculum for the teach back education was developed by the Student Principal Investigator who has previously been educated in teach back. The Teach Back curriculum included the purpose of the presentation, objectives, the Institute of Healthcare Improvement's (IHI) top patient safety measures, background on health literacy, a review of research describing communication challenges in healthcare and its impact on patients, a review of research on participant miss-understanding of their clinical trial, definition of teach back, examples of plain language, goals of teach back, a short teach back video demonstration, examples of questions to elicit teach back, and references.

The teach back education consisted of power point slides (Appendix G) provided to the Cardiology Research Coordinators as a live class, including a video of a demonstration of teach back. This educational presentation was approved for 1.0 contact hour of continuing nursing education by the Northeast Multi-state Division Continuing Nursing Education, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

Immediately after the educational session, the Cardiology Research Coordinators completed a 10-question quiz covering the educational content (Appendix H). The quiz was developed by the Student Principal Investigator and reviewed by a nursing faculty colleague for content and formatting of questions. The nursing faculty colleague has several years of experience as nursing faculty, holds a Master's Degree in Nursing Education and is certified in Nursing Education by the American Nurses Credentialing Center (ANCC). Interrater reliability

was achieved by the coordinators attaining a passing score of 90% or better on the quiz therefore establishing an inter-rater reliability of .90 or higher. If this score was not achieved, teach back content would have been reiterated with more demonstrations, role playing and a question and answer session until a minimal interrater reliability score of .90 was achieved. Inter-rater reliability values of 75- 90% (.75-.90) are considered acceptable levels of agreement (Barrett, 2001; Stemler, 2004).

Data Collection

Informed Consent Form

A blank copy of the informed consent form (ICF) that each participant had signed for their specific study was evaluated for reading level with the Flesch-Kincaid reading score.

Pre-intervention (Control Group)

Cardiac clinical trial participants, who signed informed consent and were currently participating in one of the departments open cardiology clinical trials, were mailed a study packet. The study packet contained a cover letter explaining the study (Appendix C), the demographic data collection tool (Appendix D), the QuIC instrument (Appendix E) and a stamped, addressed return envelope. As a strategy to potentially increase response rate, a reminder postcard was mailed 2 weeks after the study packet was mailed (Appendix F) (Dillman, 1991). All data collected by the Student Principal Investigator (SPI) (a total of 18 surveys) were kept in a locked file cabinet drawer in the SPI's locked office. Participants were assigned a study ID number consecutively beginning with 001. No Protected Health Information (PHI) was linked to the assigned study ID number.

Post Intervention (Experimental Group)

Fourteen cardiology clinical trial participants who signed consent after the teach back intervention were enrolled into the post-intervention group. Four participants were mailed the study packet. The study packet contained a cover letter explaining the study (Appendix C), the demographic data collection tool (Appendix D), the QuIC instrument (Appendix E) and a stamped, addressed return envelope. A reminder postcard was mailed two weeks later. Ten study packets were hand-delivered to potential participants per the research coordinator's request. A total of 5 surveys were returned for a 36% response rate.

Data Analysis

Data Management

Scores on the QuIC were calculated by the SPI, per the authors' instructions (Joffe et al., 2001). Data were then entered into the Statistical Package for Social Sciences (SPSS) v. 21. Returned surveys were reviewed by the student PI for completeness and missing data. Data were periodically checked by the SPI throughout the data collection process to examine for any odd findings or outliers.

Preliminary Analyses

Descriptive statistics (means and frequency distributions) were used for demographic variables to describe the study sample. Descriptive statistics were used to describe the pre and post-intervention groups' responses on the QuIC. The analyses included number and percentage of correct answers, and mean scores by domain.

Primary Analyses

To answer the study's primary research question, In research participants, will the use of the teach back method of communication compared to standard language, improve objective understanding of informed consent, an independent samples *t*-test was conducted. To answer the study's secondary research question, In research participants, is the relationship between objective and subjective understanding different in the control group (standard communication) compared to the experimental group (teach back communication) an independent samples *t*-test was conducted.

Additional Analyses

A Chi square test was used to explore the relationships of the categorical variables of education, income and history of research participation to the mean scores on the QuIC for the pre and post intervention groups.

Limitations

There were a few limitations to this research that merit discussion. First, is the sampling method. Ideally, randomization of participants would be preferred. Unfortunately, that is not possible within the current infrastructure of the setting for this research study. As Conn et al., (2001) state, research studies conducted in real world settings often

must compromise one aspect of an experiment in order to gain control over a more important source of variations within the study. Another limitation is that participants' were asked to recall the informed consent process. While the literature recognizes that recall, or memory and comprehension or understanding are two distinct concepts, (Dunn & Jeste, 2001; Falagas, Korbila, Giannopoulou, Kondilis, & Peppas, 2009) there is the potential for recall bias from the participants. The third limitation is the lack of blinding for the research coordinators. The

research coordinators were aware of the objectives of the study prior to the intervention and thus introduces the potential for bias.

Chapter Summary

This chapter described the methods used to examine research participants' understanding of informed consent. Specifically, to test whether or not using the teach back method of communication improved research participants' understanding of key elements of informed consent when agreeing to participate in a cardiology clinical trial. Procedures throughout the study have been described including the study's limitations. The following chapter will describe preliminary and primary analyses, and includes the third manuscript of the pre-intervention group study results.

CHAPTER 4 RESULTS

This chapter begins with a description of data cleaning procedures and preliminary analyses for both the pre and post intervention groups. The primary analyses follows. The third manuscript is included and focused on the results of the pre-intervention group only including descriptive analyses. Finally a summary concludes the chapter.

Preliminary Analyses: Pre-intervention Group

Data Cleaning

All data were entered into the Statistical Package for Social Sciences (SPSS v. 22). When conducting human subject research it is rare to have a complete dataset (Pallant, 2010). This is true of this study where two pre-intervention surveys were returned with missing data. Missing data were coded ˉ.9, a unique code not corresponding to any numeric data on the survey. Missing data were not used in computing summary statistics and the denominators were changed appropriately (Smith, Budzeika, Edwards, Johnson, & Bearse, 1986). Two participants in the pre-intervention group (11% of the sample) did not answer question A17 on the QuIC, a question on the concept of payment for research-related injury. One of these participants (6% of the sample) also did not answer question A 18. Question A18 seeks to identify if the participant knows who to contact should they have any questions about their clinical trial. These omissions of data are considered illegitimate missing data according to Osborne (2013). Illegitimate missing data can occur when participants intentionally or unintentionally skip a survey question. Given that two participants (11%) did not answer the same question, A17, may infer this data is missing not at random (MNAR) and could potentially result in bias (Osborne, 2013). Mean scores were calculated from only responses with valid values and denominators were changed appropriately to accurately reflect the number of completed responses on the QuIC (Smith et al.,

1986). When analyzing results for Part A of the QuIC, scores were calculated according to the author's instructions (Joffe et al., 2001).

Before beginning data analysis it is imperative to check for any inadvertent errors in the data. Undetected errors can greatly affect the data analysis (Pallant, 2010). Data cleaning procedures were completed in SPSS per recommendations found in Pallant (2010). This included running frequencies for each of the answers on the QuIC. Both categorical variables and continuous variables were checked for accuracy and no errors were found in the data.

Descriptive Analyses

The next step was descriptive analysis to check for assumptions. This was first done by looking at sample distributions by running descriptive statistics on the pre-intervention group (n = 18). Frequencies were assessed for all questions on the QuIC. For the categorical variables, descriptive statistics were run and frequencies were examined. For continuous variables, descriptive statistics were run including an examination of skewness and kurtosis. Skewness of a sample describes the symmetry of the distribution whereas the kurtosis describes the peak of the distribution. If both skewness and kurtosis were normally distributed a value of 0 for each would be seen. A negative skewness indicates a clustering of scores at the high end, or right side of a graph, with positive skewness indicating a clustering of scores at the left, or low end.

The general rule to follow is a skew of +2 to ¯2 range is considered normal distribution (Garson, 2012). A positive kurtosis indicates the sample distribution to be peaked (Pallant, 2010). For this sample a skewness of ¯1.4 and a kurtosis of 1.25 were noted. A Kurtosis of +2 to ¯ 2 is also considered normal distribution (Garson, 2012). These results indicated there was a normal distribution to the sample.

Assessing normality of the sample was completed by comparing the mean and trimmed mean scores. To obtain trimmed mean scores the top and bottom 5% of cases were removed and a new mean value was calculated. This allowed for a comparison of the original mean value to the new trimmed mean value to determine if there were any extreme scores influencing the mean. When comparing scores for both Part A mean and trimmed mean the scores were 75.44 and 75.38 respectively. Scores this similar indicate there were no extreme scores in the sample influencing the means (Pallant, 2010). The mean and trimmed mean scores for Part B were 88.72 and 89.61 respectively, again, indicating no extreme scores influencing the means. Additionally, the Schapiro-Wilk's W test was conducted to determine distribution. The Shapiro-Wilk's W test is recommended for small samples (Garson, 2012). The results were non-significant for the QuIC Part A indicating a normal distribution but were significant for Part B scores indicating an uneven distribution. Finally histograms and a Normal Q-Q Plot were evaluated in SPSS where no outliers were observed.

Descriptive analyses including frequencies and percentage distributions were conducted on questions on the QuIC instrument and are reported in Manuscript Three.

Preliminary Analyses: Post-intervention Group

Data Cleaning

All data were entered into the Statistical Package for Social Sciences (SPSS v. 22). When analyzing results for Part A of the QuIC, scores were calculated according to the author's instructions (Joffe et al., 2001).

Before beginning data analysis it is imperative to check for any inadvertent errors in the data. Undetected errors can greatly affect the data analysis (Pallant, 2010). Data cleaning procedures were completed in SPSS per recommendations found in Pallant (2010). This included

running frequencies for each of the answers on the QuIC. Both categorical variables and continuous variables were checked for accuracy and no errors were found in the data.

Descriptive Analyses

The next step was descriptive analysis to check for assumptions. The same procedures for preliminary analysis for the post intervention group (n = 5) were conducted as described above for the pre-intervention group. For the categorical variables, descriptive statistics were run and frequencies were examined. For continuous variables, descriptive statistics were run including an examination of skewness and kurtosis. For this sample a skewness of ˉ.901 and a kurtosis of 1.47 were noted. This sample was found to have a normal distribution.

To assess normality the mean and trimmed scores were examined. For Part A of the QuIC were 68.43 and 68.56 respectively. For Part B of the QuIC the mean and trimmed mean scores were 80.28 and 81.58 respectively. The Shapiro-Wilk's W test indicated a normally distributed sample. Finally histograms and a Normal Q-Q Plot were evaluated in SPSS where no outliers were seen.

Pre-intervention Sample Demographics

The sample included 12 males (67%) and 6 females (33%). Ages ranged from 36-84 years with a mean age of 66.6 years (*SD* = 17.35). See Table 4 for other sample demographics. The Flesch-Kincaid readability statistics for the cardiac clinical trial consent form signed by this cohort included the following: number of pages = 15, number of words = 5115, average number of words per sentence 19.1, and grade level 10.5.

Results of QuIC Part A

The total scores on the QuIC Part A (objective understanding) ranged from 55.76 to 96.15 out of a possible 100 with a mean score of 75.44 (*SD* = 12.86). See Table 4 for QuIC domains, concepts and percentage correct.

One area of misunderstanding was that of an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs, and if so, what they are and where to access further information. This concept is captured in Domain 11. Fifty percent of respondents answered this question correctly while the remaining 50% were either unsure or answered incorrectly. Here the mean score was 69.0 (*SD* = 35.93) with a range of scores from 0-100.

Other difficulties in understanding the concepts within the informed consent were found in Domain 4, (see Table 4), a description of the procedures to be followed. This domain includes two statements on the QuIC. Here, only 7 out of 18 participants (39%) answered correctly (scores ranged from 50-100 with a mean score of 78.0 (*SD* = 20.8). Further analyses and discussion for the pre-intervention group are found within the manuscript later in this chapter.

Teach Back Intervention

Teach back education was presented by the Student Principal Investigator (SPI) to two of the three Cardiac Clinical Research Coordinators (Appendix G). The education was held in the private office of one of the coordinators. Immediately after the educational session, the Cardiology Research Coordinators completed a 10-question quiz covering the educational content (Appendix H). Interrater reliability was achieved by the coordinators attaining a passing score of 90% or better on the quiz therefore establishing an inter-rater reliability of .90 or higher. Inter-rater reliability values of 75- 90% (.75-.90) are considered acceptable levels of agreement

(Barrett, 2001; Stemler, 2004). Although the two research coordinators were satisfied with the education and felt it would improve participants' understanding, one limitation was the inability to observe whether or not teach back was actually used during the subsequent informed consent process.

Intervention Implementation

Following the educational intervention 4 study packets were mailed followed by a reminder postcard 2 weeks later. Ten study packets were hand delivered to participants for a total of 14 study packets. Five surveys were returned (36% response rate).

Post Intervention Sample

The sample was 5 males (100%). Ages ranged from 67-88 years with a mean age of 75.8 (*SD* = 8.70) years. See Table 4 for other sample demographics. The informed consent documents signed by the post intervention group included the following: pages = 13, words = 4179, average number of words per sentence = 20.6 and grade level = 11.4.

Table 2. *Post Intervention Sample Demographics*

Variable	Sample % (n)
Annual Income	
Less than $25,000	20% (1)
$25,001-$50,000	40% (2)
$50,001-$75,000	20% (1)
$75,001-$100,000	20% (1)
More than $100,000	0% (0)
Highest Educational Level	
0-8 years	0% (0)
9-12 years	40% (2)
High School/GED	0% (0)
1-2 yrs. College	0% (0)
4 yrs. College	60% (3)

Sample Demographics

An independent-samples t-test was conducted to compare the mean ages between the pre and post-intervention groups. There was no significant difference in mean age for the pre intervention group (M = 66.67, SD = 17.35) and post intervention group (M = 75.80, SD = 8.70; t (13.76) = -1.61, p =.27). Cross-tabulations were performed to compare pre and post intervention groups with history of research participation. A Chi-square test for independence indicated no significant difference between pre and post intervention groups and history of research participation, X^2 (1, n = 23) = .24, p = .62. A Chi-square test for independence indicated no significant difference between pre and post intervention groups and income, X^2 (1, n = 23) = .96, p =.91). A Chi-square test for independence indicated no significant difference between pre and post intervention groups and level of education, X^2 (1, n = 23) = .86, = p =.35).

Quality of Informed Consent

The mean score on Part A was 68.45 (SD = 5.71). See Figure 4 for all mean scores by domain. One area of notable misunderstanding was found in Domain 11, the domain related to compensation for research-related injury, where 40% (n = 2) of participants answered correctly, while 60% (n = 3) were either unsure or answered incorrectly. The groups' mean score was 60 (SD = 41.83).

Another problematic area came in Domain 4, procedures to be followed. This domain is measured by two questions. For the first question 40% of participants answered correctly, 60% unsure. For the second question, no one answered correctly, 60% were unsure and 40% answered incorrectly. Here the mean score was 45.0 (SD = 11.18). For the post-intervention group, study procedures included a telephone or office visit at approximately 90 days, 180 days, 356 days, and 450 days at which time participants' medical status is evaluated. This concept was also

problematic for the pre-intervention group. See Table 4 for all domains, concepts and percentages of correct responses.

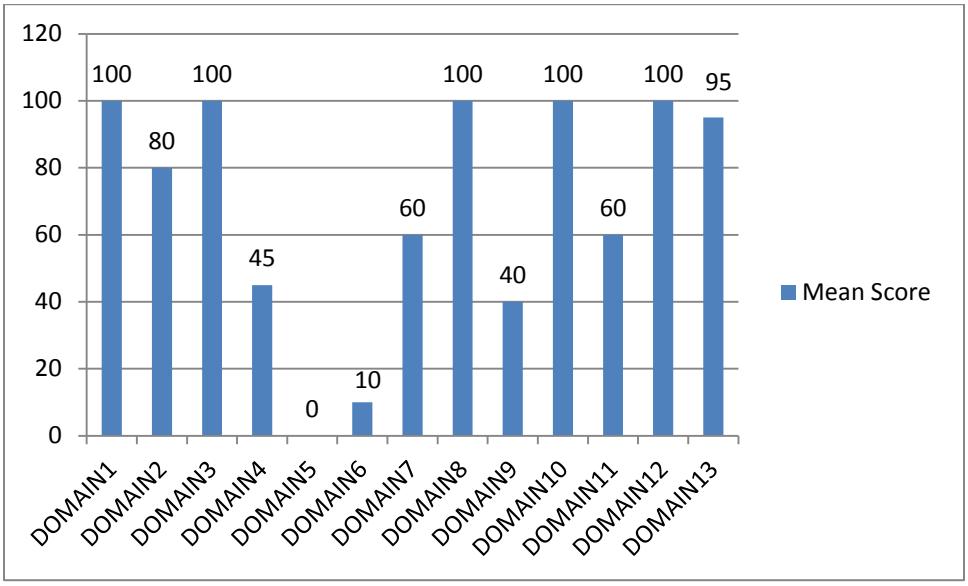

Figure 5. Post Intervention Group Mean Scores by Domain

Table 3. *QuIC Domains, Concepts and Percentage Correct (n = 5)*

DHHS Element	QuIC Domain	Domain and Corresponding Concept of the Quality of Informed Consent	Questions & % Correct
1	Domain 1	A statement that the study involves research	A1 = 100%
1	Domain 2	An explanation of the purposes of the research	A2 = 80% A5 = 80%
1	Domain 3	The expected duration of the subject's participation	A3 =100%
1	Domain 4	A description of the procedures to be followed	A10 =40% A11 = 0%
1	Domain 5	Identification of any procedures that are experimental	A4 =100%
2	Domain 6	A description of any reasonably foreseeable risks or discomforts to the subject	A12 = 0%
3	Domain 7	A description of any benefits to the subject that may be expected from the research	A9 = 0% A13 =80%
3	Domain 8	A description of any benefits to others that may be expected from the research	A14 = 100%
4	Domain 9	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	A16 =20%
5	Domain 10	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained	A15 = 100%
6	Domain 11	For research involving more than minimal risk, an explanation as to whether any compensation and/or any medical treatments are available if injury occurs, and if so, what they consist of and where further information may be obtained.	A17 = 0%
7	Domain 12	An explanation of whom to contact for answers to questions about the research, research subjects' rights and whom to contact in the event of a research-related injury to the subject	A18 = 100%
8	Domain 13	A statement that participation is voluntary, refusal to participate will involve loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled	A19 = 100% A20 =80%

Table 4. *Individual Mean Scores and Standard Deviations on the QuIC Part A Compared to Mean Scores on Part B*

Participant Number	Part A Mean and (Standard Deviation)	Part B Mean and Standard Deviation
1	69.23 (43.49)	40.00 (24.81)
2	71.15 (37.98)	87.14 (16.84)
3	75.00 (35.36)	80.00 (28.28)
4	59.61 (42.74)	97.14 (7.26)
5	67.30 (42.55)	97.14 (7.26)

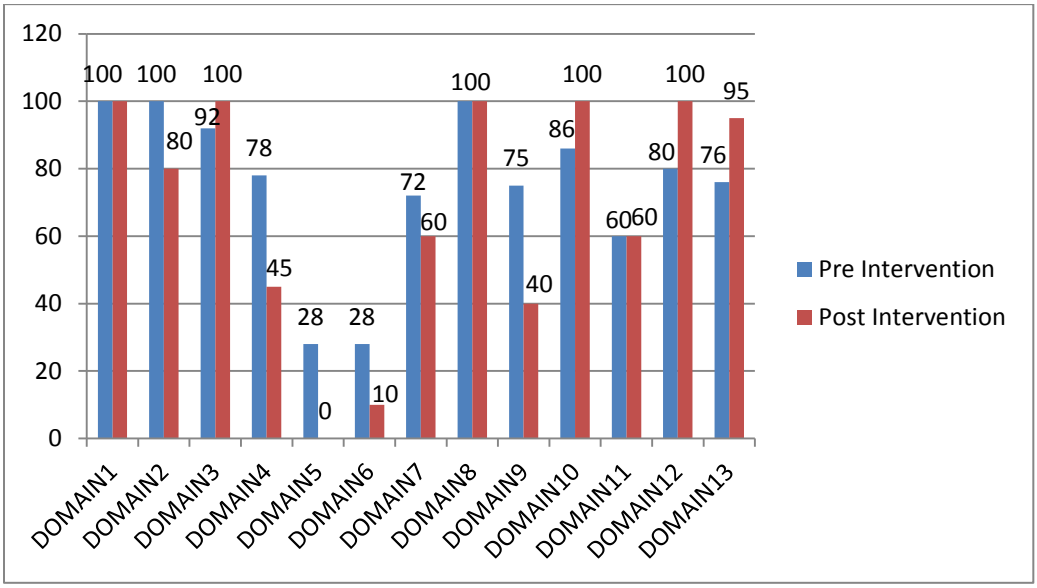

Figure 6. Pre and Post Intervention Mean Scores by Domain.

An independent-samples *t*-test was conducted to compare the mean scores on Part B of the QuIC between the pre and post-intervention groups. There was no significant difference in scores for the pre intervention group (M = 88.72, SD = 12.0) and the post intervention group (M = 80.28, SD = 23.65; t (21) = 1.11, p = .27). Based on previous research it is not surprising to see higher scores on Part B than Part A. The post-intervention group results demonstrated the same areas or concepts of misunderstanding as the pre-intervention group. See Figure 4 for mean scores for both the pre and post-intervention groups. The results of this sample also demonstrated

poor understanding of research-related injury compensation and procedures to follow, again, an unexpected finding not found in the literature.

Primary Analyses

The primary research question to be answered by this study was "In research participants, will the use of the teach back process of communication improve objective understanding of informed consent?" To answer this question an independent samples *t*-test was conducted to compare the mean scores on Part A (objective understanding) of the QuIC between the pre and post-intervention groups. There was no significant difference in mean objective understanding score between the pre intervention group (M = 75.44, SD = 12.85) and the post intervention group (M = 68.43, SD = 5.74; t (21 = 1.17, p = .057).

The second research question in this study was, "In research participants, is the relationship between objective and subjective understanding different in the control group (standard communication) compared to the experimental group (teach back communication?)" To answer this research question an independent samples *t*-test was conducted to compare the differences between objective and subjective understanding in the pre-intervention group to the post intervention groups. There was no significant difference on the mean difference between objective and subjective understanding between the pre-intervention group (M = 13.31, SD = 13.9) and the post intervention group (M = 11.82, SD = 25.1; t (21) = .174, p = .85.

Additional Analyses

Another step in the analyses was to examine what if any impact participants' educational level had on research comprehension. Cross-tabulations were conducted with highest educational level obtained and concepts that were problematic for both groups by examining

specific questions on the QuIC. Highest educational level obtained were categorized into less than high school (n = 6) and high school or higher (n = 17).

Question A4 measures understanding of procedures that are experimental. Both groups had a poor understanding of this concept. There was no significant association between educational level and understanding of experimental procedures, X^2 (2, n = 23) = 2.99, p = .22.

Cross-tabulations were conducted for the categorical variables of educational level with questions related to procedures to follow (Domain 4). A Chi-square test for independence indicated no significant association between highest educational level obtained and answers to question A10, one question in Domain 4, procedures to follow, X^2 (2, n = 23) = 3.03, p = .21. The same non-significant association was found with the second question, A11 in Domain 4, X^2 (2, n = 23) = 1.95, p = .37. Results for question A12, potential risks, also demonstrated no significant association with highest educational level obtained and understanding of potential risks, X^2, (2, n = 23) = 2.25, p = .32.

An understanding of benefits to self, as opposed to benefits for future patients are captured in Domain 7 by answering questions A9 and A13 on the QuIC. A Chi-square test of independence demonstrated no significant association between highest educational level obtained and benefits to self on question A9, X^2 (2, n = 23) = 1.95, p = .37, nor was there an association on question A13, X^2 (2, n = 23) = 3.55, p = .16.

The same procedures were performed to examine an association with highest educational level obtained and the answer on the QuIC that measures understanding of compensation for research-related injury, A17. A Chi-square test for independence indicated no significant association between highest educational level obtained and understanding of compensation for research-related injury, X^2 (2, n = 23) = 1.15, p = .56. While further statistical

analyses is limited due to the small sample size, these results demonstrate that having a higher education has no impact on understanding key concepts within the consent form and/or during the consenting process thus making comprehension difficult for all. This may be useful for investigators and research coordinators to understand as one should not assume that a more highly educated participant has a higher likelihood of understanding.

The final covariate in this study was the reading level of the informed consent document. This would have been a valuable covariate to analyze if there had been multiple consent documents read by these participants, however, only two consent forms were used for all participants. The Flesch-Kincaid reading level of the informed consent forms were 10.5 and 11.4 for pre and post intervention groups respectively both of which are greater than the recommended eighth grade level.

Descriptive statistics and frequencies were run on the pre-intervention group only and cultivated into a manuscript for the journal *IRB: Ethics & Human Research*. This journal was chosen because it is a peer-reviewed journal whose primary focus is ethical and policy related issues of human subjects' research, including results of empirical studies. The manuscript will focus on pre-intervention data analysis with a focus on findings from this study not seen in the literature and discuss any progress made to date on improvements for participants' understanding. In the manuscript the "sample" refers to this study's pre-intervention group. The manuscript will be formatted per the journal's requirements prior to submission.

TITLE PAGE

Research Participants' Understanding of Informed Consent

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Abstract

United States federal regulations requires investigators obtaining informed consent for research provide potential participants with information in a language and reading level easily understandable for them. Despite this, it is common for consent forms to be written at a graduate level. Previous studies have concluded that research participants' do not understand basic concepts of their clinical trial such as randomization, risks and benefits.

Thirty-eight cardiac clinical trial participants were mailed the Quality of Informed Consent survey and a demographic form following their agreement to participate in their trial. Eighteen surveys were returned for a response rate of 47%. Results demonstrate a poor understanding of what procedures needed to be followed in their clinical trial and potential compensation should they sustain a research-related injury. This report describes unexpected findings not reported in the literature to date, discusses any progress made on improvements for participants' understanding and suggestions for future research.

Key words: Clinical trials, compensation, participants' understanding, research-related injury, risks

Introduction

United States federal regulations requires investigators obtaining informed consent for research provide potential participants with information in a language and reading level easily understandable for them (Code of Federal Regulations, 2012). Despite this, it is common for consent forms to be written at a graduate level. There is a body of knowledge demonstrating that research participants have significant misunderstandings about the potential benefits, risks and experimental nature of their research study (Barrett, 2005; Flory & Emanuel, 2004; Hietanen, Aro, Holli, Schreck, Peura, & Joensuu, 2007; Jefford et al., 2010; Joffe, Cook, Cleary, Clark, & Weeks, 2001; Schwartz & Appelbaum, 2008). Seventy-five percent of the public reports they have little or no knowledge of clinical research or the participation process (Getz, 2007). This issue compounds the problem faced by investigators obtaining consent for research participation where many of the concepts required by federal regulations may be foreign to most of the public.

Background

In 2003, the National Center for Education Statistics (NCES) surveyed the American adult population to ascertain English language literacy skills. Results demonstrated that 75 million Americans (36%) have basic or below-basic health literacy (National Center for Education Statistics, 2003). Currently, approximately forty seven percent of Americans, roughly, 90 million, have difficulties understanding health information given to them by their providers (Wilson, 2009). It has been documented that patients absorb and recall only about half of what physicians have communicated to them (Schillinger et al., 2003). In addition, approximately forty to eighty percent of medical information is forgotten almost immediately with the greater the information being given proportional to the amount of information forgotten (Kessels, 2003).

The purpose of this study was to assess cardiology research participants' objective and subjective understanding of informed consent.

Methods

Research Design This study used a descriptive design.

Setting

This study drew its sample from a population of Cardiology clinical trial participants in a large, tertiary, acute care hospital in New England. This 600 + bed hospital is the major referral center for cardiology patients in the state where procedures include pacemaker implants, coronary artery bypass surgery, balloon angioplasty, robotic mitral valve replacement, trans-catheter aortic valve replacement and open heart surgery. At the organization where this study was conducted, there are 3 Clinical Research Coordinators in the department of cardiology that are responsible for the oversight and conduct of clinical research including obtaining informed consent.

Sample

The study used a convenience sample of cardiology clinical trial participants. Inclusion criteria included English speaking and writing and enrolled in a cardiac clinical trial. Exclusion criteria included anyone under the age of 18 years, patients with a current diagnosis of dementia, Alzheimer's or who are otherwise cognitively impaired or diagnosed with a mental illness, or participation in a research study where assent was given by a legal guardian or someone other than the participant themselves.

Measurement

Quality of Informed Consent. The Quality of Informed Consent (QuIC) instrument developed by Joffe et al. (2001) started with the basic elements of informed consent outlined in

federal regulations (Code of Federal Regulations, 2012). These include elements such as the voluntary nature of the research, the risks and benefits, the use of Protected Health Information, the cost to the participant as well as other key points that are required to be in the consent form. The overall purpose of the instrument was to evaluate participants' understanding of their clinical trial. Part A of the QuIC measures objective understanding, what participants' actually understand. Part B of the instrument measures subjective understanding which assesses what participants believe they understand (Joffe et al. 2001). Some of the elements such as "potential benefits" may actually be two different concepts i.e. benefits to self and benefits to future patients. Therefore the questions on the survey are composed of 13 independent domains (Joffe et al., 2001). (Table 4). The QuIC contains 20 questions in 13 domains in Part A answered on a Likert scale from 1 (*disagree*), 2 (*unsure*) and 3 (*agree*). Each correct answer in Part A is given a score of 100 points, an "Unsure" response is given a score of 50 points and incorrect answers are given 0 points. Unanswered questions are not scored.

Part B of the instrument contains fourteen questions answered on a Likert scale from 1 (*I didn't understand this at all*) to 5 (*I understood this very well*). Part B of the QuIC is scored by taking the average responses to each of the fourteen questions and scaled from 0-100 (summary score = raw average -1 x 25). This allows for equal weighting among the domains in the instrument. The QuIC is written at 8th grade reading level. The interclass correlation coefficient (ICC) was .66. It was noted that subjects with lower scores had greater test–retest variability than those with higher scores. Part A of the QuIC instrument had a mean score of 76 and Part B summary scores averaged 87.2 and the interclass coefficient was .77 during pilot testing of the instrument (Joffe et al., 2001). Permission to use the QuIC was obtained from the author.

Procedures

This study received approval from the Institutional Review Board (IRB) at the university where the primary author is a student and the participating hospital. A study packet containing a cover letter, demographic information sheet and the Quality of Informed Consent (QuIC) survey were mailed to a convenience sample of 38 cardiac clinical trial participants. Two weeks following the mailed surveys a reminder postcard was mailed to the same participants to increase the response rate (Dillman, 1991). A total of 18 surveys were returned (47% response rate). All data were entered into the Statistical Package for the Social Sciences (SPSS) v. 22.

Results

Sample Demographics

The sample included 12 males (67%) and 6 females (33%). Ages ranged from 36-84 years with a mean age of 66.6 years (*SD* = 17.35). See Table 4 for other sample demographics. The Flesch-Kincaid readability statistics for the cardiac clinical trial consent form signed by this cohort included the following: number of pages = 15, number of words = 5115, average number of words per sentence 19.1, and grade level 10.5.

Table 5. *Sample Demographics*

Variable	Sample % (n)
Annual Income	
Less than $25,000	12% (2)
$25,001-$50,000	35% (6)
$50,001-$75,000	35% (6)
$75,001-$100,000	12% (2)
More than $100,001	6% (1)
Highest Educational Level	
0-8 years	11% (2)
9-12yrs	17% (3)
High School/GED	22% (4)
1-2 yrs. College	17% (3)
4 yrs. College	33% (6)

Results of QuIC Part A

The total scores on the QuIC Part A (objective understanding) ranged from 55.76 to 96.15 out of a possible 100 with a mean score of 75.44 (*SD* = 12.86). See Table 4 for QuIC domains, concepts and percentage correct.

One area of misunderstanding was that of an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs, and if so, what they are and where to access further information. This concept is captured in Domain 11. Fifty percent of respondents answered this question correctly while the remaining 50% were either unsure or answered incorrectly. Here the mean score was 69.0 (*SD* = 35.93) with a range of scores from 0-100.

Table 6. *QuIC Domains, Concepts and Percentage Correct (n = 18)*

DHHS Element	QuIC Domain	Domain and Corresponding Concept of the Quality of Informed Consent	Questions & % Correct
1	Domain 1	A statement that the study involves research	A1 =100%
1	Domain 2	An explanation of the purposes of the research	A2 =100% A5 = 100%
1	Domain 3	The expected duration of the subject's participation	A3 = 83%
1	Domain 4	A description of the procedures to be followed	A10 =56% A11 = 78%
1	Domain 5	Identification of any procedures that are experimental	A4 = 6%
2	Domain 6	A description of any foreseeable risks or to the subject	A12 = 22%
3	Domain 7	A description of any benefits to the subject that may reasonably be expected from the research	A9 = 22% A13 = 89%
3	Domain 8	A description of any benefits to others that may reasonably be expected from the research	A14 =100%
4	Domain 9	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	A16 = 72%
5	Domain 10	A statement describing the extent to which confidentiality of records identifying the subject will be maintained	A15 = 78%
6	Domain 11	An explanation as to whether any compensation and/or medical treatments are available if injury occurs, and if so, what they consist of and where further information may be obtained.	A17 = 50%
7	Domain 12	An explanation of whom to contact for answers to questions about the research, research subjects' rights and whom to contact in the event of a research-related injury to the subject	A18 = 76%
8	Domain 13	A statement that participation is voluntary, refusal to participate will involve no loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled	A19 = 100% A20 = 41%

Other difficulties in understanding the concepts within the informed consent were found in Domain 4, (see Table 4), a description of the procedures to be followed. This domain includes

two statements on the QuIC. Here, only 7 out of 18 participants (39%) answered correctly (scores ranged from 50-100 with a mean score of 78.0 (*SD* = 20.8). All participants in this sample were enrolled in the same randomized clinical trial. For their study this cohort of participants was randomized to receive or not receive a study envelope of antibiotic during surgery for placement of a Cardiovascular Implantable Electronic Device (CIED). Study procedures included physician visit on the day of surgery and day of hospital discharge. Additional visits were required at 6 and 12 months post-surgery for the physician to monitor and download data from the device and participants to complete a health questionnaire. No other clinical trial procedures were required from the participants.

All participants scored 100 on Domains 1, 2 and 8 answering all questions related to these domains correctly. These domains cover the concepts of research, purpose and potential benefit to others (future patients). See Figure 4 for Part A mean scores for all 13 domains.

Part B scores ranged from 61.42 to 100 with a mean score of 88.73 (*SD* = 12.0). Only two respondents (11%) scored lower on Part B than their mean score on Part A. Table 4 shows the mean scores of Part A and Part B for all 18 respondents. Research has demonstrated that participants believe themselves to be informed, have asserted the information provided to them as easy to understand, but have demonstrated poor understanding (Hietanen et al., 2007). Therefore, higher mean scores on Part B of the QuIC, when compared to Part A were not unexpected. See Table 4 for a comparison of Part A and Part B mean scores.

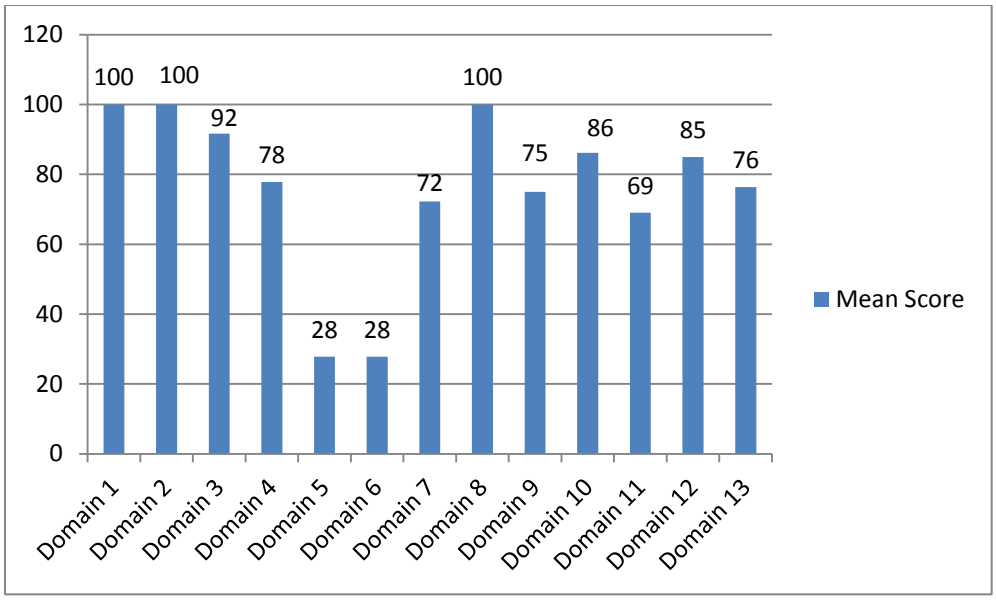

Figure 7. Mean Scores by Domain

Table 7. *Individual Mean Scores and Standard Deviations on the QuIC Part A and Part B*

Participant Number	Part A Mean and (Standard Deviation)	Part B Mean and Standard Deviation
1	96.15(13.87)	100.00(00.00)
2	57.69(49.35)	75.71(32.51)
3	79.16(38.19)	85.71(26.52)
4	92.30(18.78)	84.28(13.99)
5	69.23(39.73)	94.28(21.38)
6	80.76(34.09)	97.14(10.69)
7	55.76(37.02)	61.42(37.18)
8	63.46(36.25)	95.71(8.52)
9	65.38(36.14)	82.85(17.54)
10	76.92(31.39)	61.42(37.18)
11	84.61(29.82)	85.71(12.22)
12	65.38(41.51)	97.14(10.69)
13	75.00(38.19)	98.57(5.35)
14	75.00(20.50)	92.85(12.67)
15	65.38(42.74)	97.14(7.26)
16	92.30(18.78)	95.71(8.52)
17	96.15(13.87)	100.00(0.0)
18	67.30(37.34)	91.42(12.92)

Discussion

Interestingly, one concept poorly understood by participants was options for them should they sustain a research-related injury including who to call and whether or not they would be compensated. This domain is measured by the following question, "The consent form I signed describes who will pay for treatment if I am injured or become ill as a result of participation in this clinical trial." Fifty percent of participants were either unsure or did not know the correct answer to this question. This was an unexpected finding and not reported in the literature.

What may be clear language in an informed consent document to a healthcare professional is not always clear to a lay person. While consent forms may clearly state that research-related injury will not be paid for by the study's sponsor, it does not tell potential participants that it is against United States (U.S.) federal regulations to pay for treatment of research injuries. In fact, no agency within the U.S. federal health system has a formal compensation policy for research injuries (Hochauser, 2004). Although medical care for research-related injuries is mandatory, institutions are not required to provide compensation. Adding to the problem is the difficulties in determining if a medical illness or injury are related to the research, particularly if they occur several months later or if the patient has other illnesses and/or co-morbidities (Steinbrook, 2006).

There is much debate on whether compensation to participants for a research-related injury should be mandated or not. On one side there is the argument that sponsors and institutions are ethically obligated to provide compensation for a research-related injury. The other side of the argument is that compensation should not be provided because participants understand the potential risks of their study when enrolling and signing informed consent (Steinbrook, 2006). The results of this study would dispute this as participants' demonstrated a

lack of understanding of potential risks. This finding is also supported by previous studies. This debate continues today, but does beg the question of participants' understanding of risks and any compensation to which they may be entitled. This also raises the ethical issues for patients participating in clinical trials who do not have insurance and would therefore have no medical coverage should they sustain an illness or injury as a direct result of their research participation. If an un-insured research participant were to sustain an injury as a direct result of the clinical trial participation, the financial ramifications may be numerous and therefore pose an unduly fair burden to the participant.

The difficulty in understanding of procedures to be followed is cause for concern as only 39% of the sample understood this. The misunderstanding of this concept is also not described in the literature. One might wonder if participants' clearly understood what procedures they needed to follow in their clinical trial, might they still consent to participate. Additionally, if trial-specific procedures are not clearly understood and followed by participants accuracy of trial data may be jeopardized and/or protocol deviations may occur. For this cohort their clinical trial procedures included physician office visits and the completion of a health questionnaire. If participants missed any office appointment and/or the completion of the health questionnaire they received a phone call from the research coordinator in order to remain compliant with the protocol and collect the required data. For other clinical trials that may have more complex procedures to be followed such as certain dosing of medications or time-specific laboratory draws a lack of understanding of specific procedures to follow is very concerning.

Participants continue to fail to understand the critical differences between standard care and experimental procedures (Brody, Dalen, Annett, Scherer, & Turner, 2011). This was evident in the current study where 94% of participants were either unsure or did not understand this

concept. The domains covering procedures that are experimental and risks to subjects were also poorly understood and not surprising. Underestimating risks is a concept termed "therapeutic misestimation." In a study by Pentz et al. (2012) as many as 94% of the study sample of Oncology clinical trial enrollees misestimated risk and benefit when asked. Most of the misestimations were overestimations of potential benefit to themselves. When participants were asked their motivation for enrolling into the clinical trial, 76% of patients had direct medical benefit as at least one of several reasons for entering the trial (Pentz et al., 2012). Some investigators have argued that patients who participate in research and understand their clinical trial is not designed for their personal benefit, may still express high expectations of therapeutic benefit but may not be suffering from therapeutic misconception, rather therapeutic optimism (Horng & Grady, 2003; Sulmasey, Astrow, He, Seils, Meropol, Micco, & Weinfurt, 2010).

Based upon the results of this study it is especially important for clinicians and research coordinators obtaining consent for clinical trial participation to focus on areas that may be particularly problematic for participants to understand, especially the concepts of procedures to follow and compensation for injury. It is recommended that members of the research team, other than the physician treating the patient obtain consent to avoid further confusion between standard and experimental care. Informed consent is an ongoing process and assessment of participant understanding should not end once the informed consent document is signed. Additionally some standardized method for evaluating participants' understanding needs to be implemented in order to clarify any misconceptions. Currently, there is no standardized process in place. Perhaps this will occur only if regulations mandate it.

Limitations

There are a few limitations to this research that need to be acknowledged. The first limitation is the small sample size. The second limitation is that participants' were asked to recall the informed consent process in order to answer the questions on the QuIC. The concept of recall refers to a function of memory which is different from that of understanding (Dunn & Jeste, 2001; Falagas, Korbila, Giannopoulou, Kondilis, & Peppas, 2009). Therefore, there is the potential for recall bias from the participants. Lastly, two surveys had data missing not at random. Interestingly the missing question on both surveys was the question regarding compensation for injury. Data missing not at random may result in bias.

Conclusion

This study adds to the current body of knowledge by uncovering two unexpected findings of poor understanding of compensation for a research-related injury and clinical trial procedures to be followed. As early as 2003, the Institute of Medicine (IOM) recommended institutions conducting research compensate research participants who are injured as a direct result of participating in research, regardless of fault (Institute of Medicine, 2003). One argument regulatory bodies and bioethics committees have taken regarding compensation is the lack of quantifiable data on the number, severity, type and costs of research-related injuries (Federman, Hanna & Rodriguez, 2003; Henry, 2013; Steinbrook, 2006). The issue of whether or not to compensate participants should they become injured as a direct result of their clinical trial participation remains unresolved.

If participants continue to view themselves as informed, as prior research has suggested, a mixed-methods study employing both the QuIC questionnaire and targeted questions via

individual interviews to glean understanding, clarify misunderstandings and gather both inductive and deductive data may yield some interesting results.

Based upon the results of this study and other studies, research participants' misunderstanding of key concepts related to their clinical trial continues to be problematic. It is suggested that future research be conducted to test the teach back method with this cohort, enroll a larger sample and address the limitations in this and other studies. Additionally, more studies are needed to capture data on research-related injuries. The volume, extent and costs of those injuries need to be quantified in order to obtain data to guide policy development.

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Chapter Summary

The results of this study indicated there was no statistically significant difference in objective understanding between the pre and post intervention groups. Additionally, there was no significant differences between objective and subjective understanding in the two groups. Therefore the null hypotheses cannot be rejected. The reader is should interpret these findings with caution due to the small sample size.

Two important areas for informed consent mandated by United States regulations are what procedures to follow and compensation for a research-related injury. The results of this study demonstrated poor understanding of these two concepts not reported in the literature and therefore added to the current body of knowledge on this topic. Misunderstanding of other concepts such as potential risks, benefits and a distinction between experimental care and standard care are also evident in this study and support the literature. Additionally, having a higher education did not show an association with better understanding of other key concepts such as risks, benefits to self, experimental procedures, procedures to follow and research-related injury compensation.

The following chapter includes a description of major findings from the study, a discussion of study limitations and implications for nursing, policy and research.

CHAPTER 5 SYNTHESIS

This chapter includes a discussion of the major findings from the study, study limitations and implications for nursing, policy and research.

Major Findings from the Study

There was no statistically significant improvement in objective understanding of informed consent for the post intervention group. It was hypothesized that the teach back method of communication would decrease the noise as described in the theoretical framework supporting this study (Shannon & Weaver, 1948). This would be achieved by the research coordinator (sender) simplifying the language from medical and legal terminology into lay language during the consenting process where the participant (receiver) would teach back the content during the feedback loop, allowing for clarification of any misunderstandings.

Despite the challenges this study encountered the data analysis yielded interesting findings. Two specific findings from this study were unexpected as they are not reported in the literature. One unexpected finding was participants' lack of understanding on whether or not they are entitled to compensation for a research-related injury. This was evident in both the pre and post-intervention groups. Understanding of this concept is captured in Domain 11. Additionally, participants did not understand clinical trial procedures to follow per responses found in Domain 4. The lack of understanding of these two concepts was evident in both the pre and post-intervention groups.

Research-related injury and possible compensation are one of the elements required to be disclosed during the informed consent process and included in the informed consent document. Federal regulatory bodies and bioethics committees have debated the ethics of providing research-related injury compensation to participants of clinical trials. Some argue that

participants freely volunteer to enroll into clinical trials fully aware of any potential risks. Compounding the problem is the difficulty in determining if an injury or illness has occurred as a direct result of the clinical trial due to participants overall health, age, and other co-morbidities they may have. This makes an accurate assessment of causality challenging. Others disagree stating that providing financial compensation for a research-related injury would be the ethical thing to do. It is not safe to assume that all participants are covered through Medicare, Medicaid or private insurance and for those trial participants who do become injured as a result of their research participation and have no health care coverage would incur a significant financial burden. The lack of understanding of this concept is not reported in the literature and was an unexpected finding in this study.

For the pre-intervention group, clinical trial procedures included physician visits both in and out-patient and the periodic completion of a health questionnaire at specifically timed intervals. No other procedures were required from this group. For the post-intervention group, study procedures included a telephone or office visit at approximately 90 days, 180 days, 356 days, and 450 days at which time participants' medical status is evaluated.

While these procedures seem straightforward, the overall mental and physical health of participants and whether or not that had any bearing on results is unknown. A poor understanding of clinical trial procedures could potentially lead to poor quality data or protocol deviations if not strictly followed. These two finding add to the body of science on what is currently known about research participants' understanding of informed consent and merits further exploration.

Research participants' poor understanding of which procedures are standard care versus experimental, benefits to self and potential risks of the study were also apparent in this study for

both pre and post-intervention groups. A lack of understanding of these 3 concepts has been identified for more than 20 years.

Finally, these results demonstrate that having a higher education had no impact on understanding key concepts within the consent form and/or during the consenting process thus making comprehension difficult for all. This may be useful for investigators and research coordinators to understand as one should not assume that a more highly educated participant has a higher likelihood of understanding.

Research has also demonstrated the longer the consent form the increase in difficulties with comprehension (Mann, 1994). The Flesch-Kincaid statistics of the informed consent document for the pre-intervention group was a reading level of 10.5, 15 pages in length and contained 5115 words. For the post intervention group, the informed consent document had a reading grade level of 11.4, was 13 pages long and contained 4179 words. This may or may not have had any bearing on the participants' level of understanding but is clearly over the desired eighth grade reading level.

Many studies have attempted to test interventions to improve informed consent understanding but have mixed results as reported in Chapter 2. Despite the plethora of research describing clinical trial participants' poor understanding of key concepts of their study, and many various interventions attempting to make improvements in understanding the issue persists.

Study Challenges

This study was fraught with many site-specific challenges which ultimately lead to a change in the research design and data analysis. One of the challenges for this study was the student Principle Investigator not being an employee where the study took place. Not being embedded within the organization lead to a heightened sense of mistrust from one coordinator.

Despite best efforts to clarify confusion as to the purpose of the study, there was a general sense from the coordinators that evaluating participants' understanding may be a reflection on their capabilities to provide informed consent and therefore they were somewhat reluctant to offer their support. The research coordinators also declined to informed consent observations which, if completed would have added internal validity to the study. The director of cardiology was a key stakeholder and instrumental in the success of the study, however, communication with was challenging and his time very limited. Despite his being supportive of this study, his managerial style was very much hands-off allowing the coordinators to control and direct the flow of the study. Despite the many barriers the study was completed. Interesting the data yielded some unexpected results, not widely reported in the literature.

Limitations

The major limitation to this study was the sample size. Study challenges prevented data collection on the desired sample size determined *a priori* to the conduct of this study, despite many strategies at attempting to increase participation. Statistical analyses were conducted as planned to answer the primary research questions however results may reflect that of a Type II error. The small sample size increases the likelihood of concluding that the experimental intervention does not differ from the control, therefore power of the study may be inadequate (Guyatt, Jaeschke, Heddle, Cook, Shannon, & Walter, 1995). "The likelihood of missing an important difference (and making a Type II error) decreases as the sample gets larger" (Guyatt et al., 1995, p. 27).

Limitations to this study also include the quasi-experimental design. Ideally, randomization of the sample would have added scientific rigor to the study but was impractical given the clinical setting of the study. The ability to explain the effect of interventions or changes

that may have occurred simultaneous to the study intervention is limited with pre-post study designs. Bias can arise when nurses know that their performance and the impact of a practice change are being monitored for research purposes. It may be possible that the research coordinators' behavior changed when consenting participants as they were not blinded to the study's aim and intervention. Another limitation is the potential for recall bias from participants. The final limitation was the inability to observe the consenting process. Observations of the communication methods used by the coordinators, that of standard communication or teach back would have added internal validity to the study.

Implications for Nursing

Given the relocation of clinical trials from academic medical centers to community settings, nurses need to be cognizant of the functions related to clinical trials. Whatever the clinical setting, nurses are increasingly likely to confront patients who are participating in a clinical trial (Parreco, Ness, Galassi, & O'Mara, 2012). Therefore, nurses working in a variety of settings need to be knowledgeable about the regulatory requirements of informed consent and be able to answer patients' questions, even broadly about their clinical trial. To increase clinical nurses' awareness of this issue, in 2011, the journal, *American Nurse Today* published a four-part series discussing what clinical nurses need to know when taking care of patients enrolled in a clinical trial.

As much as 80% of medical errors are attributed to miscommunication among caregivers (American Nurses Association, 2012). This is echoed by The Joint Commission who states that poor communication was the root cause 65-70% of the time when analyzing more than 3000 sentinel events from 1995-2005 (Adamski, 2007). Nurses providing education and information to patients need to be aware of the patients' health literacy, functional ability and

capacity to understand. It is not uncommon to ask patients if they have any questions which does not provide for an accurate assessment of understanding. Teach back method of communication assesses patient understanding and allows for corrections of information as needed. Teach back communication takes training and practice, not universally available to many nurses today. The Institute of Medicine reports that "if health professionals were able to take the time to ask their patients to explain exactly what they understand about their diagnosis, instructions and bottle labels, the caregivers would find many gaps in knowledge, difficulties in understanding and misinterpretations" (Institute of Medicine, 2004, P. XI).

One provision of the Affordable Care Act is the implementation of shared decision-making. While this may be a strong recommendation few policies are available to guide practical application (Maughn et al., 2016). It has been suggested that the practical application of shared decision making may include the use of patient decision aids such as written materials, videos, or interactive electronic aids, all of which are intended to inform patients and their families about treatment options (Lee & Emanuel, 2013). Nurses, as frontline clinicians are well positioned to embrace shared-decision making as they will play a pivotal role in patient education and with training in communication techniques designed to improve understanding, could take an early lead on this initiative.

Implications for Policy

One of the major ethical principles guiding research conduct with human subjects as outlined in the *Belmont Report* is the principle of respect which honors individuals' right to choice (National Commission for Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Working within this principle, investigators are required to provide a consent process to potential research participants with sufficient knowledge and understanding of

research for informed decision making (Whitney, 2001). Despite this, it is common practice for physicians, investigators, research coordinators and others obtaining informed consent to not verify participants' understanding. The Office of Human Research Protection (OHRP) offers little guidance on how to obtain consent, but rather is instructive on regulatory requirements only.

The Code of Federal Regulations (2017) has recently been revised to improve participants' ease with decision-making and includes alterations to the requirements for informed consent relating to the content, organization, and presentation of information included in the consent form. These changes occurred as a result of studies claiming consent forms have significantly lengthened, become more complex and appear to be designed to protect institutions rather than to provide potential research participants with the most important information needed to make an informed decision (Beardsley et al., 2007; Code of Federal Regulations, 2017; Levine, 1991). Part of the organizational changes to the consent form mandate the eight required elements be disclosed first and all other information be added as appendices. It is the hope that this "core" of the consent form will provide clear concise information to potential participants in one location rather than having the required elements buried in other medical and legal verbiage throughout the document (Code of Federal Regulations, 2017). These new regulations will become effective in 2018 and therefore it remains to be seen whether these will lead to improvements in participants' understanding. Given the plethora of research demonstrating poor comprehension it would behoove researchers to apply the new recommendations now rather than wait until they become legally required.

The findings from this study warrant dissemination among Institutional Review Boards (IRBs) across the private and public sectors. IRBs are charged with the protection of human

subjects and are therefore key players in mandating informed consent documents be written and formatted in an easily understandable style and have the authority to request such changes prior to approval. IRBs and research compliance programs across healthcare and academic settings need to develop policies and protocols as guidance for investigators including templates using plain language. Research compliance programs need to be established that will develop quality improvement initiatives on informed consent such as follow-up inquiries with participants regarding their comprehension of the eight required elements.

Additionally, the Society of Clinical Research Association (SOCRA) and the Association of Research Professionals (ACRP), two national organizations certifying registered nurses as research professionals do not have a policy or regulatory requirement for competency in obtaining informed consent, nor verifying participants' understanding.

The impetus for this research study was born from a descriptive study previously conducted by the student Principal Investigator examining participants' understanding of research consent (Palmer & Trott, 2013). The descriptive study was conducted as a quality improvement initiative as part of the organization's application to achieve accreditation from the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). It was, at that time, a plan to develop a comprehensive program for the organization's research coordinators and other investigators to demonstrate competency in obtaining consent for research participation. This program would include a policy for developing competency in consenting and incorporate teach back communication as a method to assess for understanding. More policies from organizations' Institutional Review Boards and the national level could mandate some method for investigators to verify potential participants' understanding.

Medical care is designed to provide individual patients with the best treatments possible for their particular illness. Research, by contrast, has as its primary goal the creation of generalizable knowledge that may be of benefit to future patients. These different goals result in different relationships. Federal regulations require researchers to disclose potential harms of the research study, but researchers are not required to advise potential participants as to whether participation is in their best interests (Pike, 2012). "Some scholars argue that being a patient in a clinical care setting and a subject in a research study are so different that anything that would promote in subjects the view that they are in clinician-patient relationships is exploitative and deceptive" (Easter, Henderson, Davis, Churchill & King, 2006, p. 695). One solution to decrease confusion patients may have between standard care and experimental care would be to have a member of the research team other than the treating physician obtain research consent. Much of the literature suggests this practice but it is not mandated by federal regulations.

To address the issue of therapeutic misconception the National Institutes of Health (NIH) created a forum to examine the issue and make recommendations (Henderson et al., 2007). A panel of experts was formed and identified 5 major areas of understanding determined necessary for an adequate comprehension of research in order for potential participants to distinguish health research from health care. These domains included a clear understanding that the scientific purpose of a study is designed to produce generalizable knowledge, research participation may involve study procedures intended only to generate scientific knowledge not necessary for patient care, the interventions studied in clinical research are based on less certainty about risks and benefits to a population than when a doctor prescribes standard treatments, treatments are based on a strict adherence to a protocol with defined doses and scheduling and clinicians as investigators presents physicians in dual roles that may confound the distinction between

treatment and research. Despite these noble efforts, little has actually changed in the practice of enrolling participants into clinical trials.

Implications for Research

Informed Consent

Based on the unexpected results from this study, further research is needed to explore participants' understanding of compensation for research-related injury. More research into participants' understanding of this concept may determine whether this was problematic for this particular cohort or in fact, a more global issue. No studies to date have taken an inductive approach to glean participants' understanding and therefore this method may provide valuable insights into the issue.

Additionally, as some regulatory bodies have contended, studies are needed to quantify the volume of research-related injuries, the nature, extent and costs of those injuries to guide policy development. "Despite the requirement to report serious adverse events to sponsors, Institutional Review Boards and regulatory authorities, there are few systems in place to quantify the severity, frequency and types of injuries and the associated costs of managing medical care or rehabilitation in any country" (Kang, 2012, p.78). Future policies cannot be developed to protect clinical trial participants in the event of a research-related injury until there is the science to inform clinical practice.

Additionally, more studies are needed to glean rigorous data on clinical trial participants' understanding of procedures to follow. A misunderstanding of this concept was evident in this study yet is not widely reported in the literature. More studies are needed to support or refute this finding. If other research supports this finding and it becomes apparent this is a problematic area for clinical trial participants, strategies will need to be developed and tested to improve

participant understanding of this concept. Without a clear understanding of clinical trial procedures autonomous and informed voluntary participation is jeopardized as well as clinical trial data and protocol adherence.

Previous studies have agreed the concept of potential benefit associated with research participation is difficult for participants to understand (Joffe et al., 2001). Benefit for self, despite clear explanations from those conducting the consent is a concept originally described by Applebaum, Roth, Lidz, Benson, & Winslade (1987) as "therapeutic misconception" and is widely reported in the literature. "Unfortunately, therapeutic misconception has been used loosely to refer to any number of misunderstandings that subjects may have in the research context. This imprecise use of the term can itself cloud our assessment of when informed consent is compromised" (Horng & Grady, 2003, p.11). Jansen, Applebaum, Klein, Weinstein, Cook, Fogel, & Sulmasy (2011) suggests this may be a common occurrence, particularly in Oncology clinical trials. Exactly why participants may overestimate benefits and/or underestimate risks has been the topic of much discussion, yet remains unclear. The concept of unrealistic optimism needs further exploration.

To date, the vast majority of studies examining research participants' understanding have taken a deductive approach. Very few studies using inductive methods to glean participants' understanding are reported. Qualitative approaches to explore this concept may provide interesting results and add to the current body of science on this important topic.

This study could also build a comprehensive research program examining the issue of informed consent for surgery or other medical procedures. Informed consent for surgery, medical procedures not deemed research or in the construct of informed, autonomous shared decision-making are still lacking in the literature.

Teach Back

Teach back has demonstrated enhanced patient understanding leading to improved patient outcomes in a number of studies (Kornburger et al., 2013; Negarandeh et al., 2012, Peter, Robinson, Jordan, Lawrence, Casey, & Salas-Lopez, 2015). However, to date, only one study has empirically tested the teach back method in clinical trial participants (Kripalani et al., 2008). It is recommended that study be replicated with a larger sample of clinical trial participants. Further research is also recommended in other cohorts of clinical trial particiants, such as oncology where difficult and lengthy informed consent documents are common.

Communication

Patients have increased access to the internet and hospitals' public reporting of core quality measures thus are more educated, informed consumers. Poor communication is the primary reason for filing a medical malpractice suit in more than 80% of cases (Avery, 1985). Weiss, Reed, & Kligman (1995) demonstrated that patients have difficulties understanding instructions given to them by their physicians. Additionally, healthcare practitioners overestimate their own effectiveness in communication and underestimate patients' need for information (Schillinger, et al., 2003). Providers continue to use medical terminology, communicate too much to the patient causing information overload and do not routinely assess patient understanding (Kripalani & Weiss, 2006). Strategies to improve communication may diminish the number of litigious cases. However, to communicate effectively, nurses and other healthcare practitioners need to familiarize themselves with the issues involved in the communication process. Once there is an awareness of these issues plans can be made to analyze situations, solve problems, and make process improvements. The use of the Shannon Weaver theory will allow for this identification and analysis. According to Walker and Avant (2010) where there are

untested theoretical concepts it is prudent to test those relationships which will add to the body of knowledge. This communication theory would be an excellent framework for research regarding miscommunication during patient hand-offs as seen in the literature where shift report between nurses is often taking place in a busy, loud and distracting nurse's station.

Chapter and Dissertation Summary

Empirical studies assessing research participants' understanding of informed consent have been seen in the literature for a number of years. This study tested the teach back communication method as an intervention to improve research participants' understanding of informed consent and was supported by the Shannon Weaver communication theory. Many study site-specific challenges limited access to clinical trial participants resulting in a small sample size. Despite this the analyses demonstrated that participants in both the pre and post intervention groups had a poor understanding of compensation for research-related injury and clinical trial procedures to follow. These findings have not been previously reported in the literature. Targeted interventions need further assessment to develop appropriate methods to improve understandings and tackle the ethical issues of compensation for research-related injuries.

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APPENDIX A

UNIVERSITY of WISCONSIN
UWMILWAUKEE
Department of University Safety & Assurances

Melissa Spadanuda
IRB Manager
Institutional Review Board
Engelmann 270
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New Study - Notice of IRB Exempt Status

Date: May 14, 2015

To: Rachel Schiffman, PhD
Dept: College of Nursing

Cc: Debra Palmer

IRB#: 15.348
Title: Improving Research Participants' Understanding of Informed Consent

After review of your research protocol by the University of Wisconsin – Milwaukee Institutional Review Board, your protocol has been granted Exempt Status under Category 2 as governed by 45 CFR 46.101(b).

This protocol has been approved as exempt for three years and IRB approval will expire on May 13, 2018. If you plan to continue any research related activities (e.g., enrollment of subjects, study interventions, data analysis, etc.) past the date of IRB expiration, please respond to the IRB's status request that will be sent by email approximately two weeks before the expiration date. If the study is closed or completed before the IRB expiration date, you may notify the IRB by sending an email to irbinfo@uwm.edu with the study number and the status, so we can keep our study records accurate.

Any proposed changes to the protocol must be reviewed by the IRB before implementation, unless the change is specifically necessary to eliminate apparent immediate hazards to the subjects. The principal investigator is responsible for adhering to the policies and guidelines set forth by the UWM IRB, maintaining proper documentation of study records and promptly reporting to the IRB any adverse events which require reporting. The principal investigator is also responsible for ensuring that all study staff receive appropriate training in the ethical guidelines of conducting human subjects research.

As Principal Investigator, it is also your responsibility to adhere to UWM and UW System Policies, and any applicable state and federal laws governing activities which are independent of IRB review/approval (e.g., FERPA, Radiation Safety, UWM Data Security, UW System policy on Prizes, Awards and Gifts, state gambling laws, etc.). When conducting research at institutions outside of UWM, be sure to obtain permission and/or approval as required by their policies.

Contact the IRB office if you have any further questions. Thank you for your cooperation and best wishes for a successful project

Respectfully,
Melissa C. Spadanuda
IRB Manager

APPENDIX B

IRB # 4750

Maine Medical Center

MaineHealth

To: Debra Gillespie
Nursing Knowledge Solutions, LLC
PO Box 214
Canal Plaza
Portland, ME 04112

Attn: Doug Sawyer MD

Re: Notice of Exemption
IRB # 4750X Improving Research Participants" Understanding of Informed Consent

Date: **1/22/2016**

This is to inform you that the Maine Medical Center IRB has determined your project to be **Exempt** from review on **01/21/2016** according to federal regulation 45 CFR 46.101(b) *(2)*.

Additionally, this study received a waiver or alteration of informed consent according to 45 CFR 46.116(d), and a waiver of authorization according to the Common Rule and HIPAA Privacy Rule 164.512(i)(2).

The purpose of this study is to test the "Teach-back" method of communication for obtaining Informed Consent in research participants.
The IRB workgroup suggested that the following additions may strengthen this project:

- Identify the version of the Teach Back program used to train coordinators for consistency as part of the Methodology
- Ensure that you keep documentation of both the staff training and the subsequent request for survey (training log and survey log).
- Identify the type of clinical trial for which consent has been obtained, since there may be a significant difference in a subject's understanding between an intricate clinical trial with many overlapping standard-of-care procedures and a simple clinical trial that collects data from a subject's electronic medical record.

Please send a copy of any abstracts or publications to the IRB to be put in this study file.

If any changes are made to this research project, you must send them to the IRB prior to implementation to assure the study still meets the criteria for exempt status.

Please be aware that the IRB will be made aware of this action at the meeting on **02/23/2016**. Please call our office if you have any questions about the terms of this approval (Research Compliance, 207-396-8268).

APPENDIX C

Cover Letter

To Whom It May Concern:

I understand you are currently enrolled in a Cardiology clinical trial (a research study). I am conducting a research study to evaluate the informed consent process and your understanding of the information presented to you. By completing the information on the demographic form and the survey questions you are consenting to participate in this study.

There is no benefit to you to complete this survey, but I hope the information I receive from this study will benefit future research patients. There is no risk to you to complete the survey. Do not write your name on the survey. All completed surveys will be anonymous.

This is completely voluntary. If you do not wish to fill out the survey, you do not have to. The care you are currently receiving from your physician and the research study you are participating in will not be jeopardized by not completing this survey.

Some of the questions may not apply to your clinical trial. Please answer the questions to the best of your ability or simply write NA (not applicable) beside the answer. I hope that you and other research participants will fill out the survey, so that I may improve the process of informing future research participants before they agree to participate in a clinical trial.

Completion of the survey means that you are 18 years of age or older and have given your consent to participate in this study.

If you have any questions about this research project, or the survey, please email me at djpalmer@uwm.edu. Thank you for your time.

Sincerely:
Debra Gillespie, RN, MS
Principle Investigator

APPENDIX D

Demographic Information Sheet

Age: _____

Gender: Male ___ Female ___

Have you ever been a subject in clinical research before enrolling in your oncology study?
Yes ___ No ___

Approximate household income per year:

Less than $25,000 per year ___
$25,001- $50,000 ___
$50,001- $75,000 ___
$75,001- $100,000 ___
More than $100,000 ___

What is the highest level of education you have completed?
0-8 years ___
9-12 years (high school graduation) ___
High School Diploma/GED (no college) ___
1-2 years of college ___
4 years of college ___

APPENDIX E

Quality of Informed Consent

SECTION A: Below you will find several statements about clinical trials (otherwise known as 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 cardiology therapy, I knew that I was agreeing to participate in a clinical trial.	Disagree$_1$	Unsure$_2$	Agree$_3$
A2.	The main reason cardiology clinical trials are done is to improve the treatment of future cardiology 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 cardiac disease.	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 cardiac disease, 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$_3$
A8.	In my clinical trial, one of the researchers' major purposes is to find out what effects (good and bad) a new treatment has on me and my cardiac disease.	Disagree$_1$	Unsure$_2$	Agree$_3$
A9.	The treatment being researched in my clinical trial has been proven to be the best treatment for my type of cardiac disease.	Disagree$_1$	Unsure$_2$	Agree$_3$

A10.	In my clinical trial, each group of patients receives a higher dose of the treatment than the group before, until some patients have serious side effects.	Disagree$_1$	Unsure$_2$	Agree$_3$
A11.	After I agreed to participate in my clinical trial, my treatment was chosen randomly (by chance) from two or more possibilities.	Disagree$_1$	Unsure$_2$	Agree$_3$
A12.	Compared with standard treatments for my type of cardiac disease my clinical trial does not carry any additional risks or discomforts.	Disagree$_1$	Unsure$_2$	Agree$_3$
A13.	There may not be direct medical benefit to me from my participation in this clinical trial.	Disagree$_1$	Unsure$_2$	Agree$_3$
A14.	By participating in this clinical trial, I am helping the researchers learn information that may benefit future cardiac patients.	Disagree$_1$	Unsure$_2$	Agree$_3$
A15.	Because I am participating in a clinical trial, it is possible that the study sponsor, various government agencies, or others who are not directly involved in my care could review my medical records.	Disagree$_1$	Unsure$_2$	Agree$_3$
A16.	My doctors did not offer me any alternatives besides treatment in this clinical trial.	Disagree$_1$	Unsure$_2$	Agree$_3$
A17.	The consent form I signed describes who will pay for treatment if I am injured or become ill as a result of participation in this clinical trial.	Disagree$_1$	Unsure$_2$	Agree$_3$
A18.	The consent form I signed lists the name of the person (or persons) whom I should contact if I have any questions or concerns about the clinical trial.	Disagree$_1$	Unsure$_2$	Agree$_3$
A19.	If I had not wanted to participate in this clinical trial, I could have declined to sign the consent form.	Disagree$_1$	Unsure$_2$	Agree$_3$
A20.	I will have to remain in the clinical trial even if I decide someday that I want to withdraw.	Disagree$_1$	Unsure$_2$	Agree$_3$

SECTION 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

APPENDIX F

Reminder Postcard

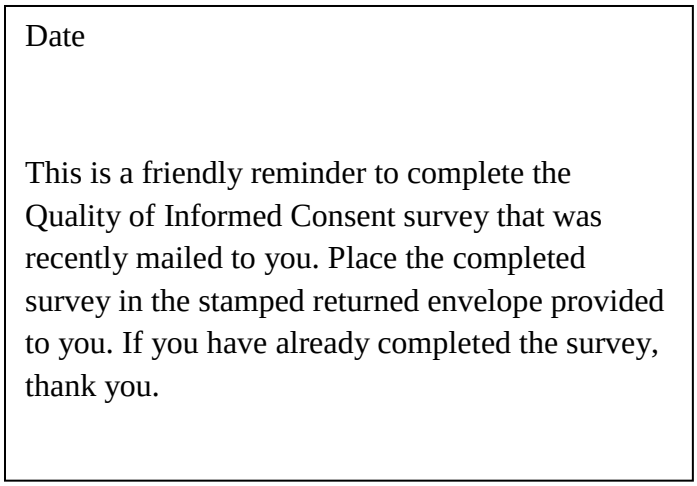


Figure 1. Front of Postcard

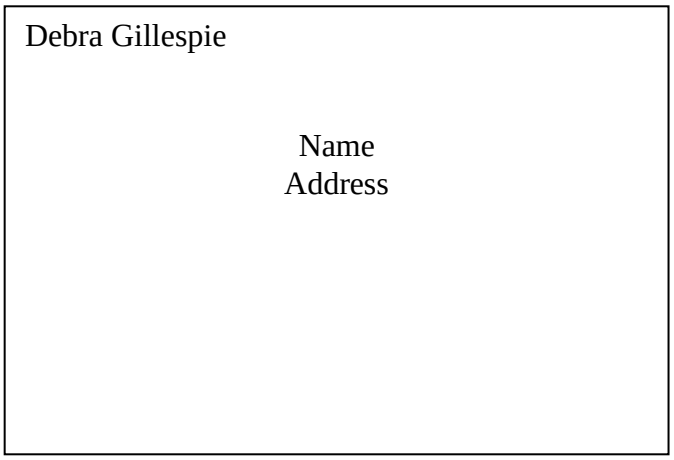
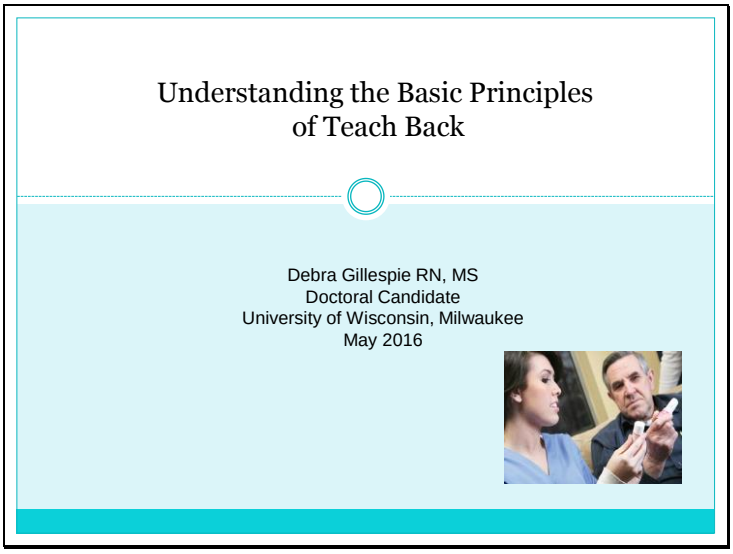


Figure 2. Back of Postcard

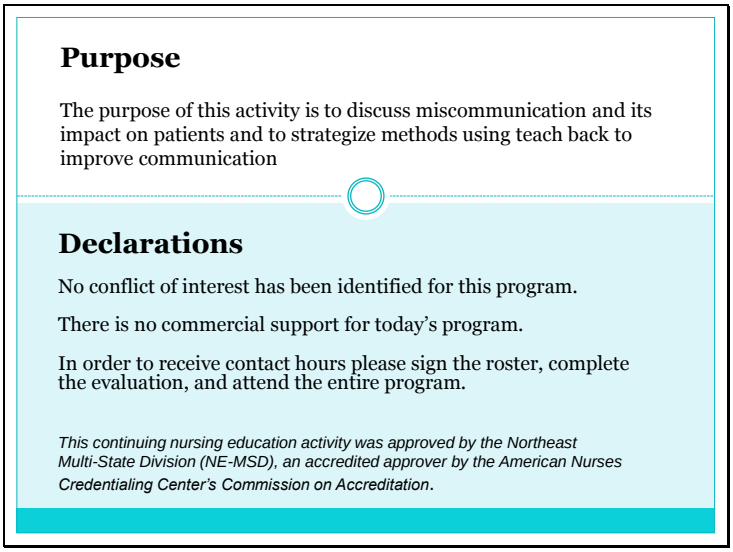
APPENDIX G

Teach Back Educational Presentation

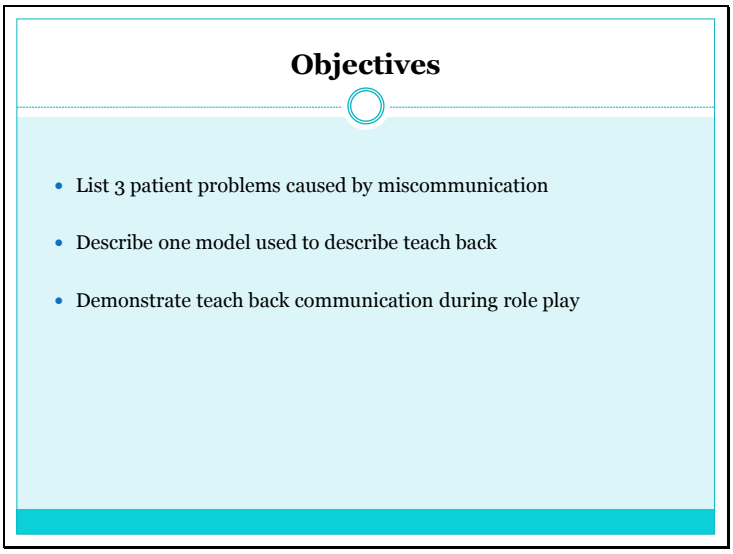
Slide 1



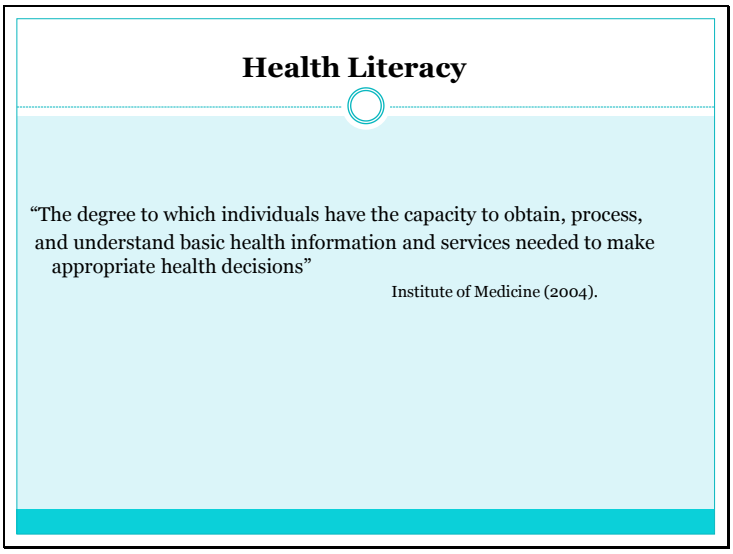
Slide 2



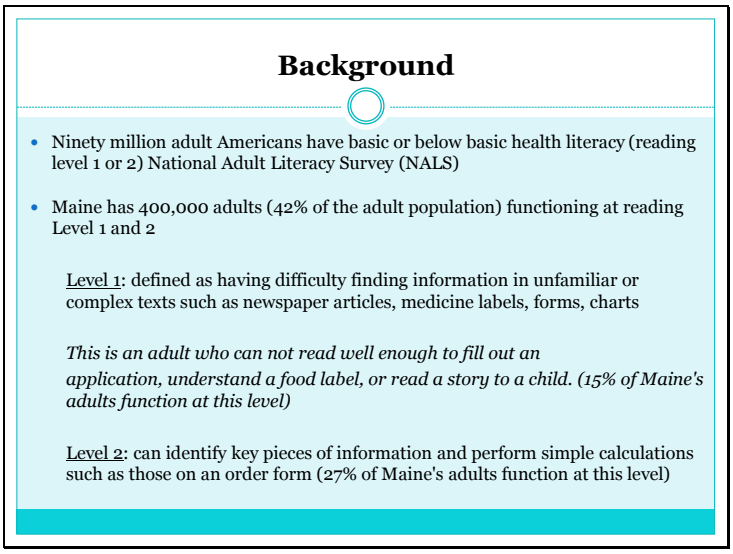
Slide 3



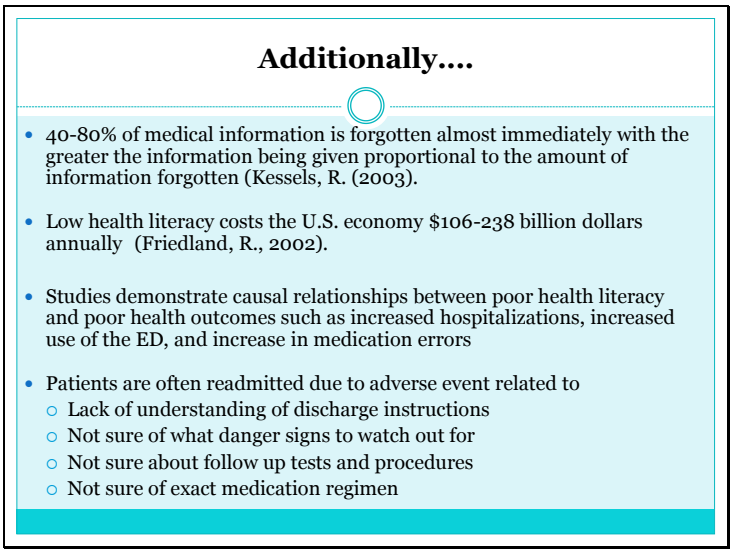
Slide 4



Slide 5



Slide 6



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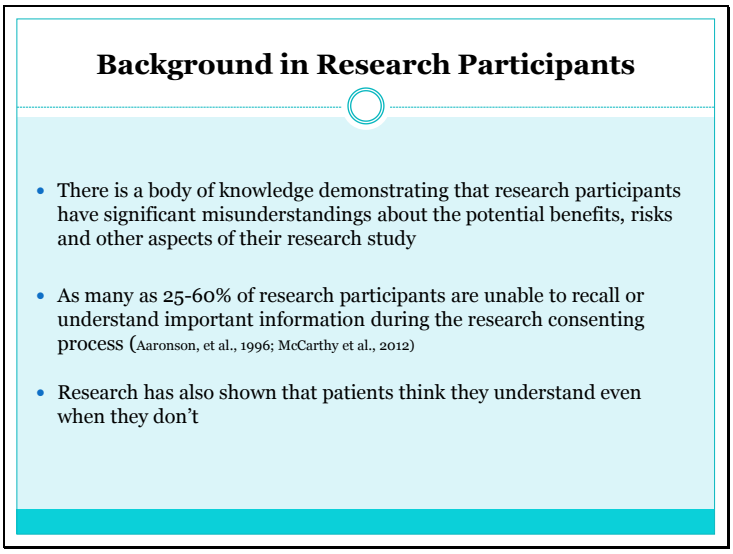

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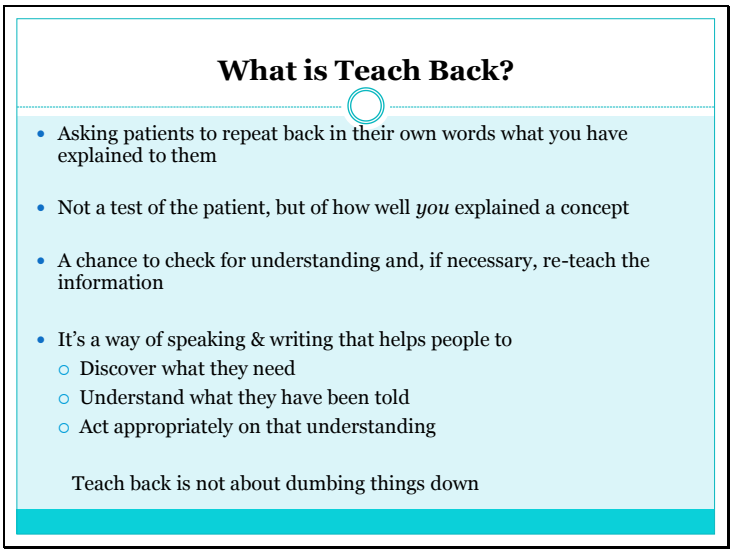


Slide 9

Examples of Plain, Non-Medical Language

Instead of this	Say this
Benign	Not cancer
Fracture	Broken bone
Inhaler	Puffer
Hypertension	High blood pressure
Oral	By mouth
Ambulate	Walk
Optimal	Best way

Slide 10

Use Language the Patient will Understand

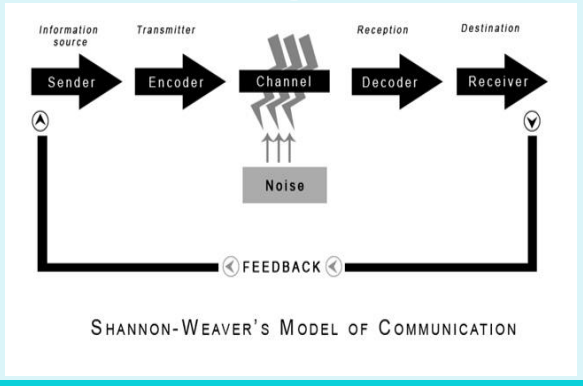
- Avoid Acronyms
  - instead of "HDL", explain "good cholesterol"
- Avoid Abbreviations and Technical Terms
  - instead of "anti-hypertensive", explain "drugs that help to lower blood pressure"
- Be Specific and Clear
  - instead of "don't go crazy with salt", explain "keep your salt intake to x mg per day"

Slide 11

Goals of Teach Back

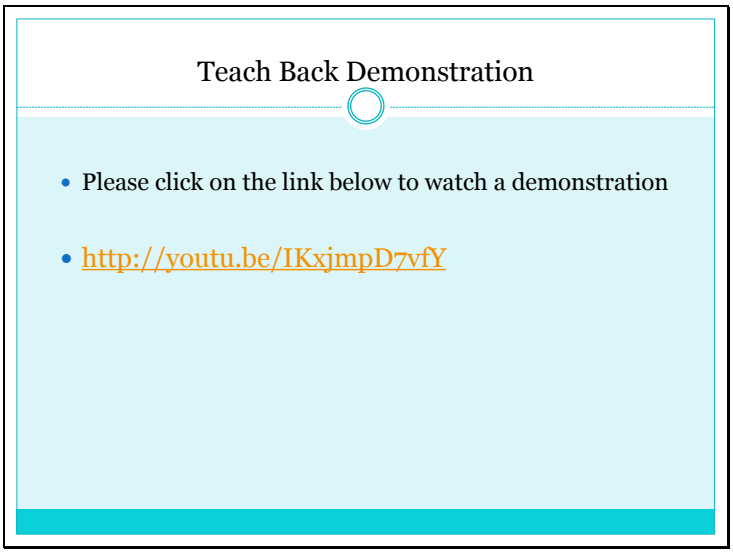
- Empower the patient to be able to make an informed decision
- Check for understanding and correct any misunderstandings
- Avoid rushing the patient
- Provide education when the patient is not hurried, anxious, bewildered, passive, or distracted
- Present factual information rather than a personal interpretation

Slide 12



SHANNON-WEAVER'S MODEL OF COMMUNICATION

Slide 13



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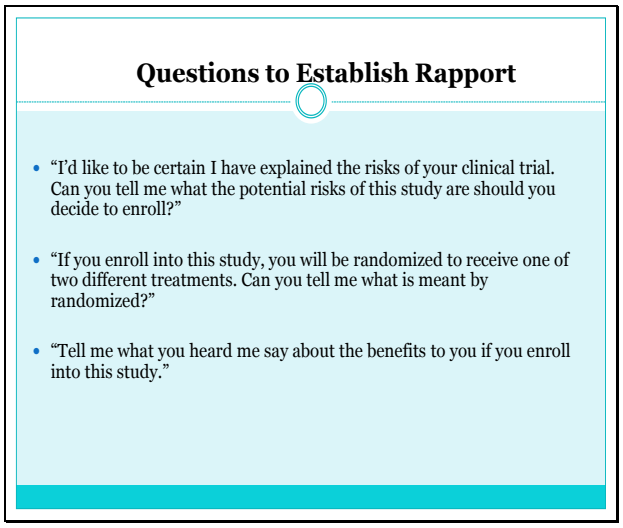

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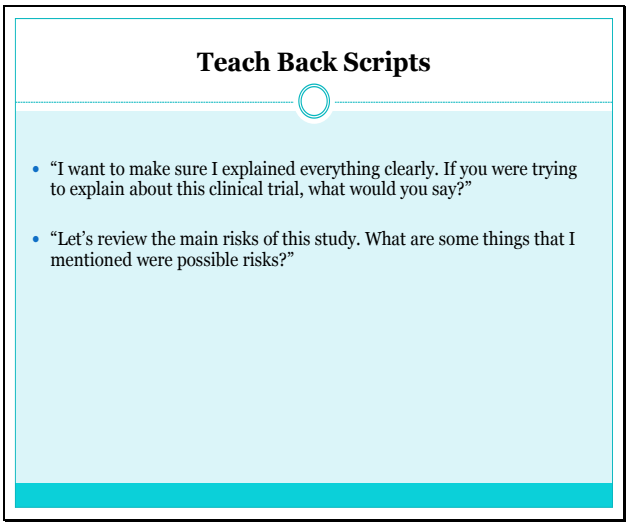

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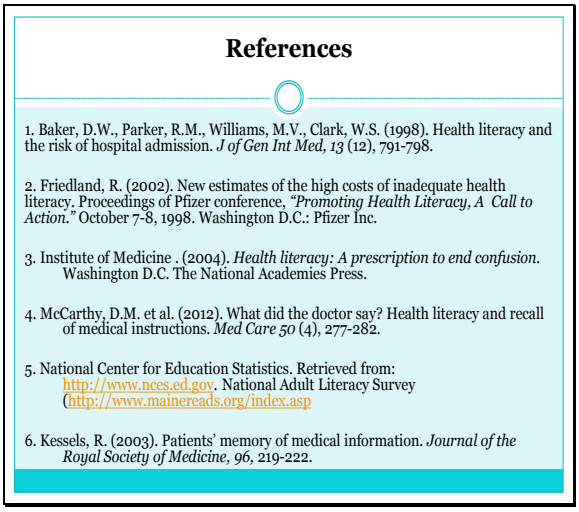

APPENDIX H

Understanding the Basic Principles of Teach Back-Quiz

Please answer the following questions by circling the correct response.

1. **Approximately how many Americans are said to struggle with health literacy?**

   A. 200,000
   B. 1 million
   C. 90 million
   D. 42 million

2. **Patients with limited health literacy are more likely to be re-admitted to the hospital due in part to which of the following?**

   A. Not understanding how and when to take their medications
   B. Not clear on when they may have follow up appointments and tests
   C. Not understanding their hospital discharge instructions
   D. All of the above

3. **According to research, approximately how many research participants do not understand their clinical trial?**

A. Up to 10 percent
B. Between 25-60 percent
C. Between 70-80 percent
D. Between 80-90 percent

4. **Some key concepts to discuss when consenting a patient for a clinical trial include (circle all that apply)**

A. The investigator's name and phone number
B. The potential risks to the subject
C. The voluntary nature of research participation
D. How research is no different than their standard care

5. Techniques to improve health literacy include (circle all that apply)

A. The patient repeats back to you in their own words what you have told them
B. If a patient nods "yes" in agreement, this indicates they understand you
C. Using plain language instead of medical jargon
D. Using simple yes/no questions to avoid confusing the patient

6. Communication theory may support clinicians to practice the use of teach back. What specific communication model guides this practice?

A. The Baxter Method of Communication
B. The Berlo Communication Theory
C. The Sherman Communication Theory
D. The Shannon-Weaver Communication Theory

7. Patients who are only able to read at reading level 1 would have difficulties reading the following:

A. A newspaper
B. A children's book
C. A job application
D. A and C only
E. All of the above

8. Studies have shown a causal relationship with poor health literacy and which of the following (circle all that apply)

A. An increase in hospitalizations
B. An increase in falls among the elderly
C. An increase in trips to the Primary Care Physicians
D. An increase in medication errors

9. Some examples of replacing medical jargon with plain language would include (circle all that apply)

A. Saying "hypertension" rather than "high blood pressure"
B. Saying "broken bone" rather than "fracture"
C. Saying "not cancer" rather than "benign"
D. Saying "ambulate" rather than "walk"

10. Teach back is (circle all that apply)

A. A way to capture the patient's attention
B. A way to check for patient understanding
C. A method used to dumb down information to patients
D. A measure of how well you have explained something to the patient

CURRICULUM VITAE

Debra Jean Gillespie RN, MS

ACADEMIC BACKGROUND

Doctorate Candidate for PhD in Nursing – University of Wisconsin – Milwaukee.....2014
Masters of Science (MS) - Northeastern University, Boston, MA. 1998
Bachelors of Science (BSN) -University of So. Maine, Portland, ME. 1995
Associates of Science (ASN) - Westbrook College, Portland, ME. 1982

PROFESSIONAL EXPERIENCE

Research Evaluator Faculty- Western Governors University, Salt Lake City, Utah 2017
Oncology Research Nurse - Exeter Hospital, Exeter NH. 2014-2015
Nursing Quality and Accreditation Coordinator- Exeter Hospital, NH. 2014
Adjunct Faculty - University of Southern Maine, Portland, ME. 2013-2017
Data Coordinator/Research Specialist Maine Medical Center, Portland, ME..... 1983-2014
Project Manager – Mid Coast Hospital, Brunswick, ME. 2010-2012
Research Education and Compliance Officer – MMC, Portland, ME. 2010
Research Nurse Coordinator – Maine Medical Center 2004-2009
Neonatal Nurse Practitioner, Eastern Maine Medical Center, Bangor, ME. 1998-2000
Clinical Nurse Liaison, Apria Healthcare, Yarmouth, ME. 2000-2004
Staff Nurse – NICU, MMC, Portland, ME. 1983-1998

PROFESSIONAL LICENSES

Maine RN License 1982
Massachusetts Nursing License 1997

PROFESSIONAL AFFILIATIONS/MEMBERSHIPS

Sigma Theta Tau International..... 1998-2017
Eastern Nurses Research Society.....2014

PUBLICATIONS (Surnames: Drew, Palmer, Gillespie)

Kunz, L., & Gillespie, D. (2016). Comparison of bowel preparations for colonoscopy in constipated adults. Accepted for publication, *Gastroenterology Nursing.*

Palmer, D., & Trott, J. (2013). An evaluation of participants' understanding of the informed consent process. *Monitor,* October, 1-5.

Jossee, L. L. & Palmer, D., & Lang. N. M. (2013). Caring for elderly patients with dementia: Nursing interventions. *Nursing: Research and Reviews, 3,* 107-117.

Fuller, V., Palmer, D. & Kramlich, D. (2013). Evidence-based practice: The scholarship behind the practice, *in DNP Education, Practice and Policy: Redesigning Advanced Practice Roles for the 21st Century.* New York: Springer Publishing.

Palmer, D. (2012). Leveling the research field through social media. Letter to the Editor. *AJN, 112*(3), 14.

Palmer, D., & Kramlich, D. (2011). An introduction to the Multi-system Model of Knowledge Integration and Translation (MKIT). *Advances in Nursing Science, 34*(1), 29–38.

Palmer, D. and Lancaster, K. (2010). Translating knowledge into best practice: A powerful nursing tool. *ANA Maine Journal,* May/June 2010, pg. 10.

Palmer, D. (2008). A qualitative approach to understanding patients' diagnosis of Lyme disease. Reprinted in: *Evidence-Based Nursing: The Research-Practice Connection.* Boston: Jones & Bartlett Publishers.

Drew, D. and Hyrkas, K. (2006). The "magnetic" research field: A stellar program for nurses' planetary alignment. *Advance for Nurses, 7*(1), 27-28.

Drew, D. & Hewitt, H. (2006) A qualitative approach to understanding patients' diagnosis of Lyme disease. *Journal of Public Health Nursing, 23*(1), 20-26.

Drew, D. (2005) Mark. *Neonatal Network, 24*(6), 55-56.

Drew, D. (2005) Umbilical cord blood banking: A rich source of stem cells for transplant. *Advance for Nurse Practitioners 13*(4), 1-7.

Schultz, A., Drew, D. & Hewitt, H. (2002) Comparison of normal saline and heparinized saline in IV locks in neonates. *Applied Nursing Research, 15*(1), 28-34.

POSTER/PODIUM PRESENTATIONS

Palmer, D. Jan. 2014 *Development and Application of the Multi-system Model of Knowledge Integration and Translation (MKIT) in Nursing Practice.* Transforming Healthcare: Pathway to Excellence, Honolulu, Hawaii.

Palmer, D. 2012 *Simplifying Change in a Complex Healthcare Environment.* Podium presentation at St Joseph's College Health Care Symposium Standish, Maine.

Palmer, D. 2011 *Putting Together the Pieces of Evidence-based Practice: Using the MKIT Model.* Podium presentation at Maine Magnet Networking Collaborative, Lewiston, ME.

Palmer, D. 2011 *How to Critically Appraise the Scientific Literature.* Maine Magnet Networking Collaborative, Lewiston, ME.

Palmer, D. 2010 *Utilizing an Evidence-based Practice Model at the Bedside.* Podium presneation at ANA-Maine Annual Convention and Business Meeting, Augusta, ME.

Palmer, D. 2010 *The Multi-system Model of Knowledge Integration and Translation (MKIT): A New Translation Model.* Podium presentation at Sigma Theta Tau International Research Congress, Orlando, FL.

Palmer, D. June 2008 *An Educational Program Focusing on Research and EBP: One Hospital's Innovative Initiative for Nurses at the Bedside* podium presentation at NETNEP Conference, Dublin, Ireland.

Palmer, D. April 2008. *Moving into EBP.* Podium presentation at 2nd Annual Evidence Based Conference, Eastern Maine Medical Center, Bangor, ME.

Palmer D. March 2008. *The Nuts and Bolts of Getting Started with Research*, 5th Annual Dr. Cox Jr. Memorial Conference, Maine Medical Center, Portland, ME.

Palmer, D. Sept. 2007 *State of the State Address of EBP*. Podium presentation at Organization of Maine Nurse Executives (OMNE), Augusta, ME.

Palmer, D. March 2007. *Steps to Implement EBP within A Successful Research Program*. Podium presentation at Central Baptist Hospital, Lexington, KY.

Palmer, D. April 2006. *Research Challenges in Homecare* Podium presentation at University of Iowa, Cedar Rapids, IA.

Palmer, D. Nov. 2005 *A Qualitative Approach to Understanding Patients' Diagnosis of Lyme Disease.* Podium presentation at Sigma Theta Tau International, Biennial Convention, Indianapolis, IN.

Palmer, D. June 1996 *Heparin vs. Saline for IV Locks in Neonates* Podium presentation at Toward Research-Based Clinical Practice: 1996 Update, Nashua, NH.

Palmer, D. April, 2015 *An Evaluation of Participants' Understanding of Informed Consent for Research.* Poster presentation at Eastern Nursing Research Society, Washington, D.C.

Palmer, D. Nov. 2011 *Application of the Communities of Practice Framework for Knowledge Translation and the Achievement of Evidence-based Practice.* Poster presentation at Sigma Theta Tau International, 41st Biennial Convention, Grapevine, TX.

Palmer, D. Oct. 2007 *Institutional Research Mentoring on the Magnet Journey* Poster presentation at ANCC Magnet Conference, Atlanta, GA.

Palmer, D. April 2007 *Research Beliefs and Barriers: A Statewide Survey of Nurses* Poster presentation at Maine Nursing Summit, Augusta, ME.

Palmer, D. July 2004 *A Qualitative Approach to Understanding Patients' Diagnosis of Lyme Disease* Poster presentation at Sigma Theta Tau International Research Congress, Dublin, Ireland

Palmer, D. July 2000 *Barriers to Pediatric Research* Poster presentation at Pediatric Nursing Society, Houston, TX.

AWARDS

Sigma Theta Tau International, Kappa Zeta Chapter-at-Large Research Award	2016
Sigma Theta Tau International, Kappa-Zeta Chapter-at-Large**,** Evidence Based Practice Writing Award	2008
Society of Vascular Nursing Research Award	2008
Sigma Theta Tau International, Kappa Zeta Chapter-at-Large Research Award	2003
Maine Medical Center Nursing Research Award	1999

PROFESSIONAL SERVICE

Abstract Reviewer - Sigma Theta Tau International	2010-2016
Manuscript Reviewer - *Nursing Research and Reviews*	2014-2016
Exeter Hospital – Member Institutional Review Board	2014
Research Grant Reviewer - Sigma Theta Tau International	2012-2016
Mercy Hospital – Member Institutional Review Board	2014
Research Committee Chair - Kappa zeta Chapter-at-Large	2014
American Nurses Credentialing Center (ANCC), Provider Unit Member	2006
Abstract Reviewer - ANCC Continuing Nursing Education Task Force	2006
Manuscript Reviewer – *Worldviews of Evidence-based Nursing*	2006
Manuscript Reviewer - *Journal of Advanced Nursing*	2004
