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Use Of Teach-Back During Informed Consent In Cancer Clinical Trials

Christa Varnadoe
christa.roe@yale.edu

Use of Teach-back During Informed Consent in Cancer Clinical Trials

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Christa Varnadoe

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Signed: _____
Dr. M. Tish Knobf, PhD, RN, FAAN

Date: _____

Signed: _____

Date: _____

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Abstract

Five percent of the 1.8 million patients diagnosed with cancer in the United States (US) enroll annually in a clinical trial (American Cancer Society, 2021; Institute of Medicine Committee on Cancer Clinical Trials; National Cancer Institute Cooperative Group Program, 2010). Flawed research consent practices are detrimental to patient safety and costly to the US Healthcare system (Eisenberg et al., 2012; Unger et al., 2019). Well trained nurses are imperative to conducting rigorous, reproducible, and quality research (Brandt et al., 2011). Programs designed to educate nurses on how to implement comprehensive communication strategies confidently during the Cancer Clinical Trials (CCT) consent process remain scarce (Nusbaum et al, 2019; Purdom et al., 2017). The purpose of this quality improvement project was to develop, implement, and evaluate the effects of an evidenced-based education program on nurse confidence with use of the teach-back method during the CCT consent process. An evidenced based education program was developed. It was implemented as a synchronous webinar to members of the International Association of Clinical Research Nurses. Pre and posttest program surveys measuring confidence levels were disseminated. There was on overall increase in post-survey responses suggesting an improvement in confidence levels with use of the teach-back method during the CCT IC process. Further study can explore if patient understanding of CCTs during the IC process is developed proportionally to levels of nurse confidence with use of the teach-back method.

List of Common Abbreviations

AHRQ- Agency for Healthcare and Research Quality

ANA- American Nurses Association

CCT - Cancer Clinical Trials

CCTN- Caner Clinical Trial Nurse

CFR- Code of Federal Regulations

CCC-Comprehensive Cancer Center

CRN- Clinical Research Nurse

CTN- Clinical Trial Nurse

FDA- Food and Drug Administration

GCP- Good Clinical Practice

IACRN- International Association of Clinical Research Nurses

IC- Informed Consent

ICH- International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use

NCI- National Cancer Institute

NCTN- National Clinical Trial Network

ONS- Oncology Nursing Society

RCT- Randomized Controlled Trial

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Chapter 1

Introduction

Informed Consent in Cancer Clinical Trials

1.8 million adults are newly diagnosed with cancer every year in the US and around five percent of those enroll in cancer clinical trials (CCT) (American Cancer Society [ACS], 2021; Institute of Medicine Committee on Cancer Clinical Trials; National Cancer Institute [NCI] Cooperative Group Program, 2010). International and national laws, regulations, and guidelines serve as a reference for the US Office of Human Research Protection (OHRP) to govern the scientific community and frame their policies for human subject protection in research (Belmont Report, 1979; Declaration of Helsinki, 1964; International Council for Harmonisation [ICH], 2016; Nuremberg Code, 1947; World Health Organization Good Clinical Practice [GCP] 1996). To modernize and improve the US research enterprise, efforts were made through funding from the National Research Act of 1974 to create The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research that formed the Federal Policy for the Protection of Human Subjects, or the "Common Rule" in 1991 and revised in 2017, and the Health Insurance Portability and Accountability Act of 1996. These laws, regulations, and guidelines are enforced by the US Department of Health and Human Services (HHS), the 14 other agencies which govern the conduct of research operations in the US, and by the US Food and Drug Administration (FDA) [Bierer et al., 2017].

To contrast the breakthroughs made over the past 30 years in cancer treatment efficacy, the level of patient understanding during the IC remains unchanged (NCI, 2021). An example of "responsible conduct of research involving human subjects," is obtaining Informed consent (IC) prior to clinical trial participation with "sufficient opportunity for patients to consider whether or

not to participate, to understand the potential risk, benefits or alternatives, and that minimize the possibility of coercion or undue influence" (FDA, CFR Title 21, Section 50, 2020; ICH, 2016). Having well trained nurses is imperative to conducting rigorous, reproducible, and quality research (Brandt et al., 2011). Evidence-based training programs designed to educate nurses on the ways to implement clear, comprehensive, and engaging communication methods to improve patient understanding during the CCT consent process remain limited (American Nurses Association [ANA] & International Association of Clinical Research Nurses [IACRN], 2015; Bevans et al., 2012; Castro et al., 2011; Oncology Nursing Society [ONS], 2016).

Problem Statement

Barriers to patient understanding during the CCT IC process have persisted for over 50 years (Krieger et al. 2015; Nishimura et al., 2013; Pentz et al., 2012; Schumacher et al., 2017). Evidenced-based training programs designed to educate nurses on the ways to implement clear, comprehensive, and engaging communication methods during the consent process remain limited (Glaser et al., 2015; Kass et al., 2015). Teach-back is an evidence-based, feasible, and affordable method of practice to use during the CCT IC process for real-time assessments of patient understanding and to test how well nurses explain complex concepts (Anderson et al., 2020; Dinh et al., 2016; Lentz et al., 2014; Talveski et al., 2020). A nurse's confidence with the use of the teach-back method during the consent process could conceivably develop patient understanding of CCTs and promote safety. The author of this project developed, implemented, and evaluated the effects of an evidenced-based education program on nurse confidence with use of the teach-back method during the CCT consent process.

Significance of Addressing the Problem

Flawed research consent practices are detrimental to patient safety and costly to the US Healthcare system (Unger et al., 2019). How to best support the necessary infrastruture and fund one of the world's most expensive and least efficent research systems has become a national concern (Eisenberg, et al., 2012). US Food and Drug Administration warning letters issued to healthcare organizations demonstrate investigator failures to ensure understanding, to inform on research terms, the procedures, and treatment goals during the consent process (IMARC, 2019). Moreover, levels of comprehension and retention, and differences in language contribute to unrealistic expectations of benefits for potential participants in CCTs (Godskesen et al., 2013; Hillyer et al., 2020; Kao et al., 2017; Pentz et al., 2012). Patients must be considered competent, should have the opportunity to be an informed voluntary participant with discussion of the confidential nature of the decision, and undergo a content comprehension assessment by the person who is responsible for obtaining consent (NCI, 2020). Patients should be advised to read the entire form before consenting to participate and there should be a review of the reasonable alternatives to the proposed intervention and the relevant risks, benefits, and uncertainties related to each alternative including compensation, medical treatment in the event of injury, and whom to contact about the research (NCI, 2020). When fully informed, the goal of research will never sacrifice the rights, interests, and autonomy for humans participating as subjects in research.

During the consent process, teach-back is a communication method which incorporates summary and review of topics to ensure patient understanding of CCTs, and to promote their safety (Agency for Healthcare and Research Quality [AHRQ], 2015; Fidyk et al., 2014). When use of the teach-back method was implemented into nursing practice, disease-specific knowledge, treatment adherence, and self-efficacy improved by 82% for patients diagnosed with cancer (Anderson et al., 2020; Krieger et al., 2015; Lentz et al., 2014; Nishimura, et al., 2013;

Talveski et al., 2020). Competency for the use of the teach-back method is acknowledged in the Scope and Standards of Practice for Research Nurses and in the Oncology Clinical Trials Nurse Competencies and Framework, but evidence-based training programs used to reinforce the practice remain limited (ANA and IACRN, 2016; Bevans et al., 2012; Castro et al., 2011; ONS, 2016; Purdom et al., 2017).

Chapter 2

Review of the Literature

Literature was reviewed and evaluated to appraise the evidence to support the question "Does an evidence based education program increase nurse confidence with the use of the teach-back method during the CCT consent process?" A summary of main findings and synthesis of evidence offers implications for practice. Three electronic databases Ovid MEDLINE, Cumulative Index of Nursing and Allied Health Literature, Pub Med MEDLINE, and ancestry searches from the reference lists of the Scope and Standards of Practice for Clinical Research Nurses (ANA & IACRN, 2016) and Manual for Clinical Trials Nursing *(*Klimaszewski et.al, 2016) were used to identify articles published in English from 1990-2021. The process for identifying articles is shown using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flowchart (Appendix A). In total, 45 articles were used for this review of literature. Based on "Johns Hopkins Nursing Evidence-Based Practice: Model and Guidelines" the "Evidence Level and Quality Guide" tool, this author rated the body of evidence as level "III" which is equal distribution between "good quality" and "bad quality." Keyword search terms included: *clinical research nursing, cancer clinical trial nurse, informed consent, teach-back, patient understanding, and cancer clinical trials.* A matrix was developed to organize extracted information on topics related to IC, CCTs, CCTNs, and teach-back (Appendix B). Results focus on the barriers and facilitators to patient understanding of IC in CCTs, the nurse's role in and confidence level with consent practices, and implementation of the teach-back method into practice.

Cancer Clinical Trials

Treatment decisions in cancer care are influenced by structural, clinical, physician, and patient associated barriers (Unger et al., 2019). The National Cancer Act of 1971 authorized the NCI, the federal government's principal agency for cancer research and training, to coordinate and maintain a national infrastructure of hospitals that "meet rigorous standards for transdisciplinary, state of the art research focused on developing new and better approaches to preventing, diagnosing, and treating cancer" (NCI, 2021). NCI centers disseminate evidence-based findings into their local communities with personalized programs, services, and trials that match the needs of the populations served (Eisenberg et al., 2012; NCI, 2021). CCTs start with a hypothesis based on clinical expertise, collaboration, review of literature, and involve phases (Curigliano et al., 2016). The design and phase of the trial is determined by the hypothesis of the investigator and goals are aimed at an improvement in the prevention, diagnosis, and treatment of cancer (Nathe & Krakow, 2019; Pentz et al., 2012). Considered the gold standard of design, randomized controlled trials provide scientific characterization of therapeutic interventions by limiting bias, and overall survival is the primary endpoint studied (Fiteni et al., 2014). CCTs determine drug, vaccine, and medical intervention safety and efficacy, modify existing treatment standards, and evaluate patients diagnosed with cancer in real-world settings (Miller et al., 2013; Unger et al., 2021). The bio-marker driven therapies, the field of immunology, and how to expedite treatment delivery to patients influenced the FDA to establish the Oncology Center of Excellence (Kurtin & Taher, 2020). To streamline the development of cancer therapies, these efforts utilize an accelerated pathway to measure efficacy through biomarkers, objective/overall response, and clinical benefit (Mayawala et al., 2017).

Nurse Role in Informed Consent

Patients develop a greater understanding when nurses are incorporated into the consent visit (Barrett, 2005; Joffe et al., 2001a). Having well trained nurses is imperative to conducting rigorous, reproducible, and quality research (Brandt et al., 2011). In a study by Cantini, & Ells (2007) over half of the nurses (38, 58.5%) reported having no job description when hired and developed the competence to perform consent by "on the job training." Nurses view their role during IC as fundamental to GCP and patient safety but evidence-based training programs on how to implement such skills in clinical research settings are scarce (Forbes and Phillips, 2020; Kunhunny & Salmon, 2017;). In 2004, Ehrenberger and Lillington developed the first validated role delineation tool named the Clinical Trial Nurse Questionnaire (CTNQ). This role delineation tool provides guidance and competency assessment measures for a nurse's scope of practice in clinical research settings (Bevans et al., 2012; Castro et al., 2011). In 2016, the ANA and IACRN published the Scope and Standards of Practice defining five Domains of Practice for Clinical Research Nursing (CRN) and 52 associated activities including IC. Further, the ONS (2016) Competency Model and Framework defines skills nurses must demonstrate to perform initial and ongoing IC. Evidence-based education and skill training programs help nurses translate what they learn into practice (Nusbaum et al., 2019: Purdom et al., 2017). Quality improvement projects implemented in the US have increased consent training opportunities for nurses and results revealed increased mean confidence levels with use of the teach-back method because they (Herena, et al., 2018; Regan, 2018; Showalter et al., 2018).

Patient Understanding During Informed Consent in Cancer Clinical Trials

Patient understanding of IC has not changed over the past three decades, and importantly, it mediates the relationship between a patient's self-efficacy and decisional conflict to participate in CCTs ($p=0.003$) [Tam et al., 2015]. Factors that contribute to a patient's level of CCT

understanding during IC include innovations in clinical trial desisgn, changes in the setting of clinical reseach delivery, first in human studies, an increasing number of procedures per protocol, readability, and length of consent forms (Godskesen et al., 2013). Further, many patients with low levels of health literacy are unaware that alternative treatments exist and perceive clinical trial participation as personal medical care instead of research (Pentz et al., 2012; Schumacher et., al, 2017). The Institute of Medicine (2010) defines Health Literacy as: "The degree to which individuals have the capacity to obtain, process, and understand basic health information and services.'' Health literacy is fundamental to informed decision-making and is influenced by individual, cultural, social, and political factors (Fidyk et al., 2014; Speros, 2011). The patient may develop a lower level of comprehension which compromises their safety when there is a breakdown in communication between them and the clinical research team (Miller et al., 2013; Hillyer et al., 2020).

Methods that improve the quality of communication during IC include extended contact with healthcare professionals and discussion with a question and answer session (AHRQ, 2020). They significantly increase comprehension of a patient's treatment options, the risks and discomforts associated with participation, the research design, and the unproven nature of the trial (Bergenmar et al., 2014; Kass et al., 2015; Nishimura et al., 2013). The Quality of Informed Consent Questionnaire (QuIC) is a tool used by researchers to measure a patient's objective and subjective understanding, and to assess for adequacy of the CCT IC process (Joffe et al., 2001a; Joffe et al., 2001b). The QuIC tool was used in four studies for researchers to measure patient understanding and when compared to standard practice, their comprehension improved by 100% when teach-back or test/feedback components were implemented into the consent process (Gillies, et. al., 2018). For patients diagnosed with cancer, teach-back decreases uncertainty

related to randomization, significantly improves comprehension of disease knowledge ($p < 0.001$), medication adherence ($p < 0.001$), and self-efficacy ($p = 0.0026$) [Dinh, et al., 2016; Juraskova, et al., 2014; Krieger, et al., 2015].

Use of Teach-back as an Intervention to Improve Patient Understanding

Teach-back is an effective method available for nurses to communicate complex trial-specific information to patients during the consent process (Lentz et al., 2014). Teach-back, a communication method used for real-time assessment to confirm patient understanding of complex health concepts, is recognized as one of the 50 essential practices to support patient outcome improvement by the National Quality Forum (Anderson et al., 2020; AHRQ, 2020; Regan, 2018; Speros, 2011). The use of the teach-back method is effective across a wide range of settings, populations, and outcome measures and is an affordable, and feasible technique which promotes health literacy and ensures patient understanding during the CCT IC process (Glaser et al., 2020; Kass et al., 2015; Krieger et al., 2015; Schumacher, et al., 2017; Talveski et al., 2020). Use of the teach-back method helps nurses facilitate the process and helps them consider the patients' psychosocial situation, family support, and appropriate timing of consent (Nishimura, et al., 2013). An observation tool called "the 5Ts for Teach-Back," proved useful for training, and implementation of the teach-back method (Anderson et al., 2020). A nurse must choose the pertinent information for the patient to comprehend, use tools when teaching, verbalize that material presented to the patient is obscure, explain that the clinician is the one being tested for how well the concepts are explained, encourage the patient to give an explanation of concepts, and repeat parts of the discussion if needed when implementing teach-back into practice (Anderson et al., 2020).

Implications for Practice

Nurses should be sensitive to factors which influence health literacy and must make greater efforts to use clear, comprehensive, and engaging communication methods to help patients make informed healthcare decisions that are consistent with their goals and values during the consent process (Anderson et al., 2020; Bergenmar et al., 2014; Fidyk, et al., 2014; Kass et al., 2015; Pentz et al., 2012; Talveski et al., 2020). Nurses must personalize the consent discussion to meet the individual needs of a patient, provide adequate time for questions, and use methods that confirm understanding (AHRQ, 2020; Glaser et al., 2020; Speros, 2011). As shifts in funding occur, and as the volume, complexity, and regulations of clinical trials increase, use of the teach-back method has potential to affect a great number of patients (Getz & Campo, 2018; Krieger et al., 2015). While few strategies exist to support the translation of the teach-back method into clinical practice, an evidence-based education program may improve nurse confidence with its use during the CCT consent process (Dinh et al., 2016).

Project Management Framework

Kurt Lewin's Change Management Model (1947) was chosen to understand how change occurs and it is segmented in to three stages: *Unfreeze, Move, and Refreeze* (Lewin, 1947; Appendix C). Lewin (1947) postulated that individuals need to feel the necessity for change and that successful implementation is created by sensitizing the change process, strengthening all changing forces, and reinforcing the newly achieved change (Lewin 1947). According to Lewin (1947), driving forces originate in ambitions, goals, needs and fears whereas restraining forces oppose driving forces. The first stage in Lewin's Change Management Model (1947) is *Unfreezing,* which began when the project author recognized the need for nurses to have a standardized process of consent in CCT. When questioned, members of IACRN reported no

standardization of consenting practices, little formalized trainings on the topic, and varying levels of confidence with use of the teach-back method during the process. A stakeholder analysis was conducted. It revealed the need for a project which increases educational opportunities for clinical research nurses. The second stage in Lewin's Change Management Model (1947) is *Move* and is when the construction and implementation of the DNP project commenced. In this stage, nurses resolve their uncertainty about the need for change of IC processes and begin to accept new ways of practice. The third stage in Lewin's Change Management Model (1947) is *Refreeze.* If the project was successful, the nurses will have more confidence with use of the teach-back method during the IC process.

Organizational Description and Assessment

Organizational Description

The International Association of Clinical Research Nurses (IACRN) is a professional nursing organization. Established in 2009, IACRN's purpose and mission is to define, validate, and advance clinical research nursing as a specialty across all settings through research, education, collaboration, and dissemination of best practices (IACRN, 2012). It supports the professional development of nurses who directly or indirectly influence the care of clinical research patients and defines clinical research nursing as, "the specialized practice of professional nursing focused on maintaining equilibrium between care of the research participant and fidelity to the research protocol and incorporates study management throughout a variety of roles, and practice settings'' (IACRN, 2012). The vision of IACRN is: "Enhancing clinical research quality and safety through specialized nursing practice" (IACRN, n.d.).

Organizational Assessment

IACRNs has a board of directors and officer positions. They include a president, president-elect, secretary and treasurer who are elected for two year terms (IACRN, 2021). General membership meetings are held at a minimum of one time per year (IACRN, n.d.). IACRN has outlined its strategic initiatives for the years 2020-2024. Initiatives are to grow the professional nursing organization, advance organizational infrastructure, define clinical research nursing as a specialty practice, and to support the professional development of clinical research nurses consistent with its mission and vision (IACRN, n.d.). Particularly, IACRN intends to increase brand awareness, offer live streaming of webinars and presentations, and support organization driven evidence based practice with research nurses globally (IACRN, n.d.). IACRN has a research committee and its purpose is to uphold the mission and vision of the organization through promotion of evidence based practice that drives excellence in clinical research nursing by supporting the research needs of its members and advancing clinical research nursing science (IACRN, n.d.).

SWOT Analysis

A SWOT analysis was conducted to identify the strengths, weaknesses, opportunities, and threats to this DNP project. The strengths and opportunities identified for this project outweighed the potential weaknesses and threats (Appendix D).

Strengths: Strengths of this project included access to abundant teach-back resources. The project was congruent with the vision and mission of IACRN. It operationalized ICH-GCP for nurses and reinforced how to skillfully communicate alternative treatments, the relevant risks, benefits, and uncertainties of CCT participation to patients. This project empowers nurses to provide opportunities for patients to clarify misconceptions in real-time during IC process.

Weaknesses: Weaknesses of this project included exclusivity of the education program to IACRN members only which resulted in a reduced amount of nurses who participated in the program. The event was virtual and it made it more difficult for the project author to develop meaningful connections with the attendees. This program was only advertised to IACRN members for three weeks before implementation.

Opportunities: This project increased nurse confidence with use of the teach-back method during the CCT IC process. This education program may become part of a training session offered by IACRN on a yearly basis. This education program may be replicated at the project author's workplace an in similar CCT settings.

Threats: The program was only presented once. Despite evidenced-based training, nurses may refuse to use the teach-back method in their consent practices. Some nurses may have missed the opportunity to attend the live webinar due to prior commitments, or time constraints related to their current workload. Some nurses may have been unaware of the opportunity.

Project Goal and Aims

Goal

The purpose of this project was to develop, implement, and evaluate the effects of an evidence-based education program on nurse confidence with use of the teach-back method during the CCT consent process.

Aims

The aims for this project were:

1. To develop an evidence-based education program on use of the teach-back method during the CCT consent process.

2. To implement, and evaluate the effects of an education program on nurse confidence with use of the teach-back method during the CCT consent process.
3. To make recommendations for sustainability, scalability, and dissemination of the evidence-based education program within the current environment and to provide recommendations for piloting the practice in other settings.

Chapter 3

Methods

Overview of Methods

The purpose of this DNP project was to develop, implement, and evaluate the effects of an education program on nurse confidence with use of the teach-back during the CCT consent process. Pre and posttest evaluation survey results were analyzed to evaluate if nurse confidence with use of the teach-back method improved after implementation of the education program. Finally, after careful evaluation of results, the author made recommendations for sustainability, scalability, and dissemination of the project.

The project aims were as follows:

Aim 1: Develop an evidence-based education program on the use of the teach-back method during the CCT consent process.

Methods

This evidence-based education program was developed to inform nurses on the use of the teach-back method during the CCT consent process**.** Through the synthesis of literature organized in the evidence matrix, the teach-back method was identified as an evidence-based, feasible, and cost-effective method of practice that provides real-time assessments of patient understanding, tests how well nurses explain complex concepts, and promotes safety. Additional guidance was obtained from the AHRQ toolkit, and from internal and external project advisors (Abrams, et al., 2012; Shoemaker & Brach, 2017).

Specifically, the objectives for this evidence-based education program were:

1. The participant will be able to identify factors that influence patient understanding and promote learning.

2. The participant will be able to define health literacy.
3. The participant will be able to understand and describe steps of the teach-back method.
4. The participant will be able to describe the role and value of the teach-back method.
5. The participant will be able to identify strategies to facilitate the use of teach-back into their oncology clinical trial consenting processes

Teaching Plan. Multimodality teaching and learning strategies were chosen to reinforce comprehension of teach-back principles (Abrams, et al., 2012; Anderson et al., 2020; Lentz et al., 2014; Shoemaker & Brach, 2017; Talevski et al, 2020). A formalized training program is an existing strategy to support the translation of teach-back into clinical practice (Dinh et al., 2016; Talevski et al, 2020). A teaching plan was developed to help the project author organize and formalize the important elements of the evidence-based education program (Appendix E). The teaching plan includes methods, objectives, and program content, and the slide deck lecture that includes interactive knowledge checks, and a case study presentation (Appendix F). For quality improvement purposes, the project author gave mock presentations with external project advisors until the program was implemented.

Tools. The Teach-back method toolkit was created by key opinion leaders of patient teaching and learning from Picker Institute, Des Moines University, the IOWA Health system, and Health Literacy Iowa (Abrams et al., 2012**).** Some topics and tools chosen for inclusion into the education program were found in the AHRQ teach-back toolkit. Permission from the original authors to use the AHRQ Teach-back toolkit for this project was obtained (Abrams, et al., 2012) [Appendix G]. The education program slide deck was developed by the project author using

Microsoft PowerPoint software. The project author presented the education program as a live webinar which lasted 90 minutes.

Evaluation

The project author identified guiding principles through the synthesis of literature found in the evidence matrix, the AHRQ toolkit, and consensus among the internal and external project advisors. Each step of development added to rigor of the work and content validity. Until it was implemented, external advisors reinforced content of the evidence-based education program and allowed the project author to review principles of the webinar at regularly scheduled intervals.

Aim 2: Implement and evaluate the effects of an education program on nurse confidence with the use of the teach-back method during the CCT consent process.

Methods

The purpose of this evidence-based interactive webinar was to implement and evaluate if nurse confidence with the use of the teach-back method during the CCT consent process improved. After the project proposal was approved by internal project advisors, an email request was sent to the IACRN research committee (Appendix H) explaining the purpose of the education program, length of time for completion, timeline for implementation, a list of the pre and posttest survey questions, and a PDF of the presentation slide deck. Then, verbal approval from the research committee chair was obtained. A date for implementation was identified, and recruitment efforts commenced. IACRN promoted the program in their monthly newsletter that was sent to their general members. Attendees were required to email the project author in advance for program registration. Then, they received emails immediately before and after the program which included pre and posttest evaluation survey links (Appendix I). The post program email reinforced the content of the program because it included the teach-back toolkit, teach-

back observational tool, and the project author's slide deck presentation. Email reminders to complete the posttest evaluation survey were sent at one and two week intervals.

Instruments. During the program, the nurses were introduced and encouraged to use the Teach-back Observational Tool as a guide to help them implement the method into the CCT IC process (Abrams, et al., 2012) [Appendix J]. When nurses previously implemented use of this tool into cancer settings, patient outcomes improved (Anderson et al., 2020; Fidnyk et al., 2014; Nusbaum et al., 2017; Talveski et al., 2020). Permission to use the Teach-Back Observational Tool was obtained from the original authors (Abrams, et al., 2012).

Measures. Pre and posttest evaluation survey questions were based on best available literature. Completion of the surveys implied consent. Participation was voluntary, answers were anonymous, and no incentives for the responses were offered. Criteria for participation included being a registered nurse who is an active member of IACRN. Four of the pre and posttest evaluation survey questions were used to identify essential elements of teach-back used in practice and were adopted from the Conviction and Confidence Scale (CCS) found in the AHRQ teach-back toolkit (Abrams, et al., 2012) [Appendix K]. The CCS questions included two Likert type, a multiple choice, and a check all that apply which asks nurses to identify essential elements of teach-back used in their practice (Abrams, et al., 2012). Four demographic questions were adopted from the CTNQ and permission to use was not required as they are accessible in the public domain (Bevans et al., 2012; Castro et al., 2011; Ehrenberger & Lillington, 2004; Purdom et al., 2017).

Tools. This DNP project utilized the Yale Qualtrics tool interface. It is an online tool that creates, distributes, and analyze survey answered. Both surveys were accessed and tabulated

using Qualtrics survey software. It enabled organized management of the data collection and analysis of the survey responses.

Evaluation

Data were collected, analyzed, and used to identify if nurse confidence and conviction with the use of the teach-back method during the CCT consent process improved after implementation of an evidence-based education program. Demographics were used to describe the population of nurses who participated.

Aim 3: To make recommendations for sustainability and scalability of the education program within the current environment and to provide recommendations for piloting the practice in CCT settings.

Recommendations to ensure sustainability:

1. Present the data collected from project to the IACRN research committee
2. Consider revision of the education program after data analysis.
3. Develop a sustainability plan and implement based on IACRN's needs and the professional organization's strategic initiatives.

Recommendations to ensure scalability:

1. Implement a method validation assessment for the nurses who participate in the training.
2. Live stream the webinar multiple times a year to IACRN members. Invite original participants to attend as "teach-back champions" to share their experiences during the open dialogue portion of the program.

Recommendations to ensure dissemination:

1. Submit an abstract for consideration to present findings at the annual IACRN Congress.
2. Present the education program to nurses at the project author's workplace.

Project Timeline

Aims developed, implemented, and evaluated were used as milestones in the project timeline. Development of the education program ended in December 2021. Implementation of the education program was done in January 2022. Evaluation of implementation began in January 2022 and ended in the final semester of the DNP program. The Gantt chart (Appendix L) was monitored by the DNP student and internal/external project advisors (Stakeholder analysis Appendix M). This ensured appropriate progress, and adjustments were made in a timely manner.

Statement about Human Subjects

While this project is quality improvement in nature, non-research determination by the Yale University IRB was determined. It was reviewed and met criteria as outlined in 100 CH.9 Clinical Quality Improvement Form (Appendix N). Collection of empirical data through pre and posttest evaluation surveys maintained nurse confidentiality.

Chapter 4

Results

After completing the development and implementation portions of the project, the following section details evaluation of the results. The first aim involved synthesizing the best evidence to develop a training program delivered by webinar on the use of the teach-back method during the CCT IC process. The second aim involved implementation and evaluation of an evidence-based education program. The third aim involved developing a sustainability, scalability, and dissemination plan for the project.

Aim 1: Develop an evidenced-based education program on the use of the teach-back method during the CCT consent process.

A review of literature was conducted with results synthesized to guide development of the education program curriculum on the use of the teach-back method during the CCT process. A matrix was developed to organize extracted information on topics related to IC, CCTs, CCTNs, and use of the teach-back method. Results focused on the barriers and facilitators to patient understanding of IC in CCTs, the nurse's role in and confidence level with teach-back, and implementation of the teach-back method into practice. The project author focused on cost avoidance for patients and staff. A staffing, start up, capital, and operational projected and total costs analysis was completed for project development, preparation and implementation. The projected total cost of this DNP project was $3,414 US Dollars.

Implications for Practice

For patients to make informed choices that are consistent with their goals and values, discussion must be personalized to meet individual needs (Lentz et al., 2014; Juraskova, 2014). Use of the teach-back method has the potential to affect a large number of patients as

shifts in funding occur in the US, and as the volume of clinical trials, complexity of research procedures and regulations increase (Krieger et al., 2015). Nurses must be sensitive to factors which influence a patient's health literacy and should make efforts to use clear, comprehensive, and engaging communication methods during the consent process (Anderson et al., 2020; Bergenmar et al., 2014; Dinh et al., 2016; Fidyk, et al., 2014; Kass et al., 2015). Education and training programs for nurses centered on teach-back may help them to develop confidence when performing the IC process (Talveski et al., 2020). Use of the teach-back method helps nurses facilitate the consent process and helps them consider the appropriate timing of consent, the patients' psychosocial situation, and family support (Nusbaum et al., 2019).

Evaluation

The evidence-based education program content was successfully developed for nurses to learn about the factors that influence patient understanding and promote learning, health literacy, steps of the teach-back method, the role and value of the teach-back method, and strategies to facilitate the use of teach-back into their oncology clinical trial consenting processes. Content was based on results synthesized in the literature review, evidence-based guidelines, and best practice recommendations from internal and external advisors. The actual total cost of this DNP project was $235.00 US Dollars. Over 40% of the projected cost was related to the online platform which was used to administer and collect pre and posttest evaluation survey responses from the participants. Use by the DNP author was free of charge through the university. Further, over 50% of the actual total cost was the professional organization membership fee. The objectives, methods and content of the program followed the format outlined in the teaching plan.

Aim 2: To implement and evaluate the effects of an education program on nurse confidence with the use of the teach-back method during the CCT consent process.

The project author presented a livestreamed Webinar on January 6, 2022 that lasted 90 minutes. Attendance was free of charge for IACRN members. During the session, nurses were encouraged to participate in three interactive multiple choice knowledge checks. A 30 minutes dialogue on the use of the teach-back method during the CCT consent process concluded the presentation. At the end of the program, those who participated in the live webinar were eligible to participate in a gift card raffle. First names were written on to small strips of paper, placed into a hat, and one participant was chosen at random by the project author to receive a $100 US Dollar gift card. However, no incentives were given for survey responses. Survey completion was based on convenience, was voluntary, and anonymous. A total of 12 participants completed both the pre and posttest evaluation surveys for the evidence based education program.

Evaluation

Four demographic questions were asked and sample characteristics of participants were described in table 1. Four pretest and posttest questions were asked to identify essential elements of teach-back used in practice and were adopted from the Conviction and Confidence Scale (CCS) found in the AHRQ teach-back toolkit (Abrams, et al., 2012). Participant scores were reviewed and analyzed. Mean scores were calculated for each item in tables 2 and 3. Frequency distributions were calculated for each item as shown in tables 4 and 5.

Nurse Demographics

Table 1 presents the demographics of the IACRN members who attended the education program and participated in the pre and posttest evaluation surveys.

Table 1

Sample Characteristics of Participants (N= 12)

Characteristic/Question	**N**	**%**
Age (years)		
18-25		
26-35	4	33.3%
36-45	2	16.7%
46-55	3	25%
56+	3	25%
Highest Nursing Degree		
Associate		
Bachelors	3	25%
Masters	8	66.67%
Doctorate	1	8.33%
Years in clinical trial setting		
Less than 1	5	41.67%
1-2	1	8.33%
3-4	1	8.33%
5-6		
7+	5	41.67%
Have you ever had formalized training on how to perform IC in CCTs?		
Yes	4	33.33%
No	8	66.67%

This project demonstrates the need for formalized training programs for research nurses on how to conduct the process of IC in CCTs. Of the 12 active IACRN members that participated, the highest category of participants was between the ages of 26-35 years (n =4, 33.3%), the majority had a master's degree in nursing (n =8, 66.67%), most had less than one year of experience in the clinical trial setting (n =5, 41.67%) or more than 7 years of experience (n =5, 41.67%) and significant amount (had never had formalized training on how to perform IC in CCTs n =8, 66.67%).

Nurse Confidence with Use of Teach-back

Table 2 presents mean scores of pre and posttest program survey evaluation responses for confidence with use of the teach-back method. The question is measured on a 10-point ordinal scale ranging from 1 (not confident), to 10 (very confident).

Table 2

Mean scores of "On a scale from 1 to 10, how confident are you in your ability to use teach-back? 1- Not at all confident, 10- Very confident"

Question	**Pretest** ***(N =12)*** **Mean**	**Posttest** ***(N =12)*** **Mean**	**Percent Increase**
How confident are you in your ability to use teach-back?	6.91	9.91	30%

Pre-test evaluation survey responses revealed that nurses had a lower mean confidence score before program implementation (M =6.91, SD = 2.28). One nurse was not at all confident 1 (n =1, 8.33%). One nurse had a low level of confidence 4 (n =1, 8.33%), Four nurses had moderate levels of confidence 6 (n =1, 8.33%), 7 (n = 3, 25%). Six nurses had very high levels of confidence 8 (n = 4, 33.34%), 9 (n =1, 8.33%), 10 (n =1, 8.33%). Post-test evaluation survey responses revelated nurses had a higher mean confidence score after program implementation (M =9.91, SD =0.27). One nurse chose the second highest level of confidence 9 (n =1, 8.33%). The majority of the nurses were very confident with use of the teach-back method 10 (n =11, 91.67 %)

Importance of Teach-back Use

Table 3 presents mean scores of the pre and posttest program survey evaluation responses on conviction for the importance of teach-back use. This question is measured on a 10-point ordinal scale ranging from 1 (not very important) to 10 (very important).

Table 3

Means scores of pre and posttest survey evaluation survey responses to "On a scale from 1 to 10, how convinced are you that it is important to use teach-back? 1- Not at all important, 10- Very important"

Question	**Pretest *(N =12)* Mean**	**Posttest *(N =12)* Mean**	**Percent Increase**
How convinced are you that is important to use teach-back?	8.25	9.91	16.6%

Pre-test evaluation survey responses revealed that nurses had a lower mean conviction score before program implementation (M = 8.25, SD= 3.03). Three nurses chose level (3) of importance and had low conviction (n =3, 24.99%). Nine nurses chose very important (10), and had the highest levels of conviction (n = 9, 75.01%). Post-test evaluation survey responses revealed that the nurses had a 16.6% higher mean conviction score after program implementation (M =9.9, SD =0.27). One nurse chose the second to highest level of importance (9) and had high

conviction (n =1, 8.33%). The majority of the nurses chose the highest level of conviction (10), very important (n =11, 91.7%).

Teach-back Use in Current Practice

Table 4 presents frequency distribution of pre and posttest program evaluation survey responses and the question asked how long have the participants used teach-back.

Table 4

Frequency distributions of responses for "How often do you ask patients to explain back, in their own words, what they need to know or do to take care of themselves?"

Question	**Pretest** ***(N =12)***	**Posttest** ***(N =12)***
I have been doing this for 6 months or more.	7 (58.33%)	7 (58.33%)
I have been doing this for less than 6 months.	1 (8.33%)	0 (0%)
I do not do it now, but plan to do this in the next month	4 (33.34%)	5 (41.67%)
I do not do it now, but plan to do this in the next 2 to 6 months	0 (0%)	0 (0%)
I do not do it now and do not plan to do this.	0 (0%)	0 (0%)

Pre-test evaluation survey responses revealed that most nurses had been using teach-back for six months or more (n =7, 58.33%), one nurse had been using teach-back for less than six months (n =1, 8.33%), and four nurses did not use teach-back but planned to do it in the next month (n =4, 33.34 %). Posttest evaluation survey responses revealed that the majority of nurses had been using teach-back for six months or more (n =7, 58.33%), and that five nurses did not

use teach-back but planned to do it in the next month (n =5, 41.67%). The number of posttest survey evaluation responses for the question, “I do not do it now, but plan to do this in the next month,” increased from 33.34 % at baseline by 8.33% up to 41.67 %. None of the posttest evaluation responses included “ I have been doing this for less than 6 months.”

Effective Elements of Teach-back

Table 5 presents frequency distribution of pre and posttest program evaluation survey responses for the question on effective elements of teach-back asked to the nurse participants. This question was a choose all elements that apply with up to 11 possible choices.

Table 5

Frequency distribution of responses to, “Check all the elements of effective teach-back you have used more than half the time in the past work week.”

Element	Pretest *(N =12)*	Posttest *(N =12)*
Number of total responses	82	87
Use a caring tone of voice and attitude.	8 (9.2%)	8 (9.41%)
Display comfortable body language, make eye contact, and sit down.	10 (11.49 %)	10 (11.49%)
Use plain language.	10 (11.49 %)	8 (9.41%)
Ask patients to explain, in their own words, what they were told.	8 (9.2%)	8 (9.41%)
Use non-shaming, open-ended questions.	9 (10.32%)	8 (9.41%)
Take responsibility for making sure you were clear.	9 (10.32%)	8 (9.41%)
Avoid asking questions that can be answered with a yes or no.	7 (8.05%)	8 (9.41%)
Explain and check again if the patient is unable to teach back.	6 (6.90%)	9 (10.59%)

Use reader-friendly print materials to support learning.	6 (6.90%)	7 (8.24%)
Document use of and patient's response to teach-back.	7 (8.05%)	7 (8.24%)
Include family members or caregivers if they are present.	7 (8.05%)	8 (9.41%)

Nurse participants reported using effective elements of teach-back more than half the time in the past work week before the program implementation. However, participants reported using effective elements of teach-back with a higher frequency after program implementation. The participants (n =12) chose a total of 82 effective teach-back elements in the pretest evaluation survey. Elements used least frequently included explain and check again if the patient is unable to teach back (n = 6, 6.90%) and use reader-friendly print materials to support learning (n = 6, 6.90%). Elements used most frequently included display comfortable body language make eye contact, and sit down (n =10, 11.49 %), and use plain language (n =10, 11.49 %). The participants (n =12) chose a total of 87 effective teach-back elements in the posttest evaluation survey. Elements used least frequently included explain and check again if the patient is unable to teach back (n = 7, 8.24%) and use reader-friendly print materials to support learning (n = 7, 8.24 %). Elements used most frequently included display comfortable body language, make eye contact, and sit down (n =10, 11.49 %), and explain and check again if the patient is unable to teach back. (n =9, 10.59 %).

Aim 3: Make recommendations for sustainability, scalability, and dissemination of the education program within the current environment and provided recommendations for piloting the practice in CCT settings.

Implications for Practice

In 2022, the project author will invite original program participants to share their experiences. Anecdotal evidence will be collected. They will be asked to describe if use of the teach-back method during the CCT IC process is feasible in their practice. Program participants will be encouraged to share if they continue to have confidence with the use of the teach-back method during the CCT IC process. Further, they will be asked if they have implemented use of the Teach-back Observational Tool in their teach-back practice.

Evaluation

To ensure sustainability the project author will present an overview including introduction, objectives/aims, methods, implementation, data analysis, and evaluation of results in to the IACRN research committee in June 2022. Then, consideration for revision of the will commence in July 2022. This will be based on IACRN's strategic initiatives along with revision recommendations. To ensure scalability recommendations include implementation of a method validation assessment for future attendees. Based on the sustainability plan, webinars will commence in the fall of 2022. Webinars will be offered on a quarterly basis. Frequency will depend on the demand from active IACRN members. Original participants will be invited to attend as "teach-back champions" and will be encouraged to share their experiences with use of the method during the CCT IC process. To ensure dissemination, the author will submit project findings for publication to the Clinical Journal of Oncology Nursing in 2022. Further, the author will submit the project findings to the 2023 Annual IACRN Congress.

Chapter 5

Discussion and Conclusion

Discussion

The aim of this quality improvement project was achieved: to develop, implement, and evaluate the effectiveness of an evidence based education program on nurse confidence with use of the teach-back method during the CCT IC process. This DNP scholarly project was affordable, feasible, and nurse confidence improved after implementation of the evidence-based education program. Primary outcome objectives were analyzed and evaluated: Mean confidence score with use of the teach-back method *before* implementation of the program (M = 6.91, SD = 2.28) and mean confidence score with use of the teach-back method *after* implementation of the program (M = 9.91, SD = 0.27). Results revealed a 30.00% increase in nurse confidence with use of the teach-back method after implementation of the evidence-based education program. Secondary outcome objectives were analyzed and evaluated: Mean conviction score for importance of teach-back use *before* program implementation (M = 6.91, SD = 2.28) and conviction score for importance of teach-back use *after* program implementation (M = 9.91, SD = 0.27). Results revealed a 16.6% increase in for importance of teach-back use during the CCT IC process after implementation of the evidence-based education program. While posttest survey responses from the 12 participants revealed that a majority of nurses had been using teach-back for six months or more (n =7, 58.33%), the five nurses who had not been using it before program implementation planned to do so in the next month (n =5, 41.67%). All 12 participants reported using 82 elements of teach-back more than half the time in the past work

week before the program implementation in the pretest evaluation surveys. However, all 12 participants reported using 87 elements of teach-back, a higher frequency, after program implementation in the posttest evaluation surveys.

Strengths and Limitations

This project meets the training demands of research nurses and translates the use of the teach-back method into the consenting process. This project empowered nurses to proficiently identify components of the IC process for which patients need assistance in understanding. It reinforced how to skillfully communicate to patients the alternative treatments, the relevant risks, benefits, and uncertainties of participation in CCTs. Use of the teach-back method allows patients to clarify misconceptions in real-time and operationalizes GCP. This project supports attempts to standardize skills of research nurses. There are abundant online teach-back resources available free of charge for nurses to use. This project was congruent with the vision and mission of IACRN, which is the only existing international professional organization for clinical research nurses. While the event was held virtually, the project author developed meaningful connections with the attendees.

The author initially planned to implement the project in person at a large academic NCI-CCC. Staffing shortages, turnover, the SARS-CoV-2 pandemic, limited time, and resources forced the author to find an alternate location for implementation. The design of the project was changed. This resulted in changes to project implementation, data collection, analysis, and evaluation of results. The audience size of program was limited to IACRN members only. The program was only advertised for three weeks before implementation. This may not have been long enough for nurses to learn about the opportunity. Due to prior commitments or time constraints related to their current workload, some nurses may have missed the opportunity to

attend the live webinar. The limited amount of nurses who participated in the program resulted in a small number of pretest and posttest evaluation survey responses. Lastly, despite evidence presented in the program, the nurses may refuse to use the teach-back method in their consent practices.

Implications

Nurses are at the center of patient care, safety, and research (Purdom et al., 2017). Having well trained nurses is imperative to conducting rigorous, reproducible, and quality research (Brandt et al., 2011; Fidyk et al., 2014). However, nurse turnover leaves few trained or skilled research professionals to cover many responsibilities including how to competently obtain IC (Herena et al., 2018). The more specialized a nurse's skill set, the more time it takes to develop, and to replace a role vacancy (Showalter et al., 2017). Turnover is costly, creates a state of underdevelopment, creates a risk for low levels of participant recruitment, and creates gaps in enrollments due to protocol suspension (Stroo et al., 2020). Employers save approximately $40,050 US Dollars for every one research nurse not lost to turnover (Duffield, et al., 2014). Retention rates may improve and healthcare costs may decrease if nurses are offered training opportunities, become more confident and knowledgeable of the skills required to perform their roles in research (Kunhunny & Salmon, 2017). To the authors knowledge this is the fourth quality improvement project in the US that has increased consent training opportunities and nurse confidence with use of the teach-back method during the CCT consent process (Herena, et al., 2018; Regan, 2018; Showalter et al., 2018). These quality improvement projects increased job satisfaction, and increase retention rates for research nurses. Further, there is no evidence which suggests that a clinical trial's enrollment rates are negatively altered by attempts to improve the consent process (Nishimura et al., 2013). Further, online platforms may be used free

of charge to replicate similar programs and to increase global sustainability for this method of training.

Future Work

For patients to make informed decisions, the consent process must be clearly defined and consistent with their goals and values. Professional development opportunities for research nurses that support adherence to the principles of ICH-GCP and to the HHS federal regulations during the consent process foster patient safety (Bierer et al., 2012; Stroo et al., 2020). Further, these educational opportunities may decrease the financial burden associated with participant dropout rates. Also, there may be a decrease of bias in treatment efficacy estimates for clinical trials if patients develop an understanding during the IC process for the level of commitment needed to attend clinic appointments and to complete medical interventions (Unger et., al, 2021). Around $20,000 US Dollars can be saved for every one research participant that does not dropout before collection of primary outcome data (Borno, et al., 2016). To strengthen this project, further study can explore if patients may begin to understand CCTs proportional to the level of nurse confidence with use of the teach-back method during the IC process.

Conclusion

Programs designed to educate and train research nurses on the skills needed to implement clear, comprehensive, and engaging communication methods during the CCT consent process remain limited (Glaser et al., 2015; Kass et al., 2015). A significant gap exists in professional development and training opportunities for research nurses. The purpose of this quality improvement project was to develop, implement, and evaluate the effects of an evidenced-based education program on nurse confidence with use of the teach-back method during the CCT consent process. An evidence based education program was developed by the

utilization of literature pertaining to: Cancer clinical trials, research nurse role in informed consent, patient understanding during informed consent in cancer clinical trials, and the use of teach-back as an intervention to improve patient understanding. After program implementation, the mean score of nurse confidence with use of the teach-back method during the CCT consent process improved by 30%. To date, the technical and specialized skill set required for clinical research nursing is not encompassed in undergraduate nursing school curriculum. Employers must implement consistent evidence-based education programs for new research nurses during orientation, and increase training opportunities for existing staff. Thus, results present an argument for expansion of this DNP project to a boarder audience of nurses outside of the IACRN setting.

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Appendices

Appendix A: PRISMA FLOW DIAGRAM

Figure I - Adapted PRISMA Flow Diagram

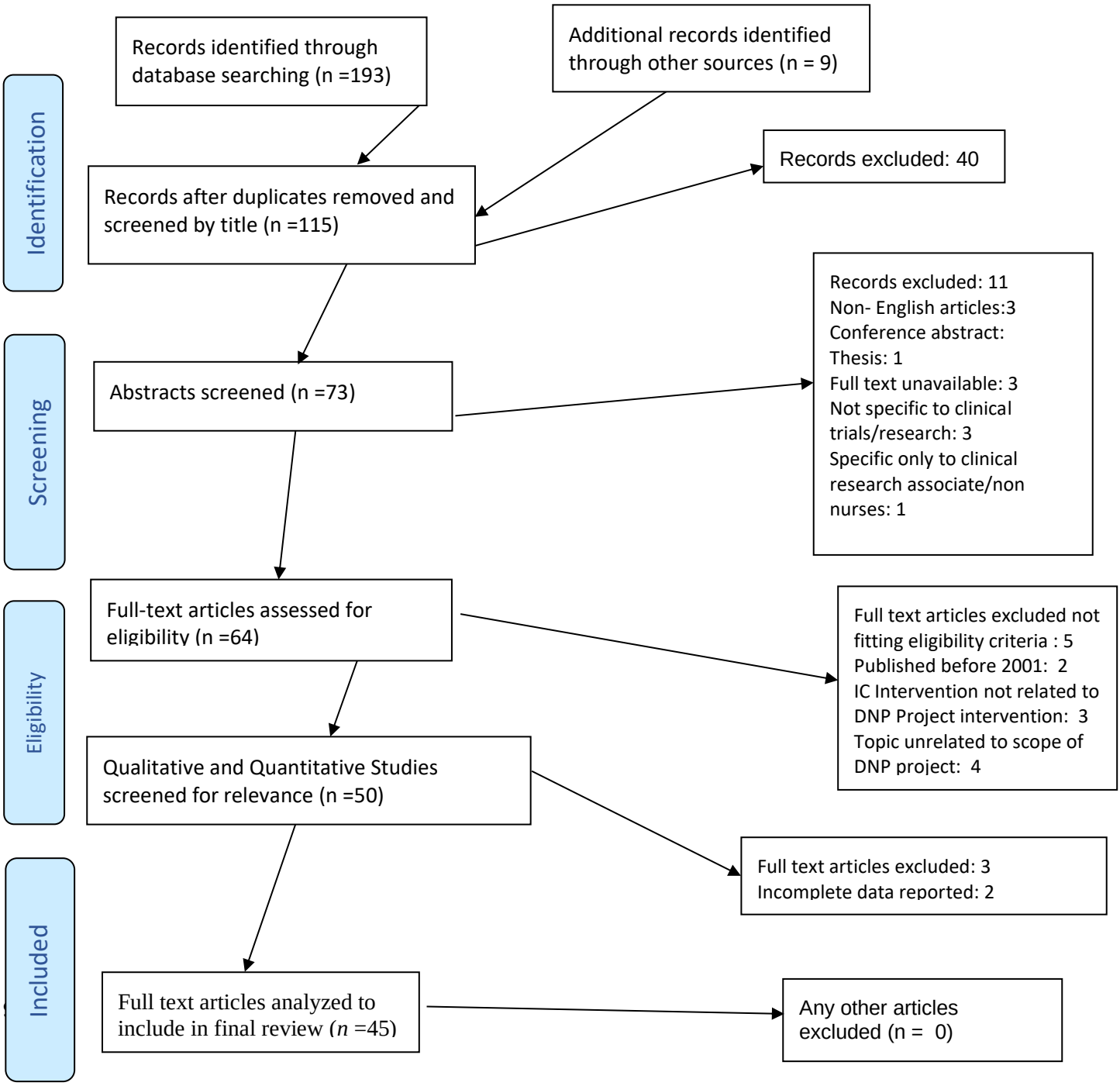


Figure 1 Flow diagram to show number of studies remaining at each stage of literature review. Source: From Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G., & the PRISMA Group. (2009). Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. PLOS Medicine, 6(7), e1000097. https://www.doi.org/10.1371/journal.pmed.1000097.

Appendix B: Evidence Matrix

Title, Authors, Date	Purpose	Sample	Evidence Level/ Design/Method	Strengths	Weaknesses	Results	Contribution: Science and or Practice
Nishimura., A., Carey, J., Erwin, P., Tilburt, J., Murad, M., & McCormick, J. (2013, p. 28-40) Improving understanding in the research informed consent process	RCTs testing interventions to research IC process	Start of Database until September 2010 (N =39) RCTs & 54 interventions	Level I A, Systematic Review & Meta-analysis	Novel & no negative impact on participant satisfaction or study accrual	RCTs only	Multimedia approaches non-significant increase in understanding scores (SMD 0.30, 95% CI, -0.23 to 0.84), Extended discussion, with significant increase (SMD 0.53, 95% CI, 0.21 to 0.84), 31% of multimedia interventions showed significant improvement in understanding, 41% for enhanced consent form, 50% for extended discussion, 33% for test/feedback	Prioritize interventions to improve communication skills
Tam, N., et. al. (2015, p. 186-198) Participants' understanding of informed consent in clinical trials over three decades	Participants in clinical trials who understand different components of IC	(N =103) studies 135 cohorts of participants world-wide up to Oct. 2013	Level I A, Systematic review and meta-analysis	Data needed on when a nurse is involved in IC and the proportional level of pt. understanding	Not able to analyze the effect on pt. understanding of IC or the effect of understanding in the presence of a nurse	Subgroup/meta-regression analyses covariates that significantly affected understanding: age, educational level, critical illness, the study phase and location of alternative treatment	New practices are needed for pts. to have a comprehensive understanding of IC
Unger, J. M., Vaidya, R., Hershman, D., Minasianr, L., & Fleury, M. (2019, P. 381-402).	Identify barriers to CCT participation	13 studies with 8883 pts.	Level I A, Systematic review and meta-analysis	8 of 13 studies used were in the academic setting. Need more evidence	Large patient sample	Rate of trial participation has not changed over the past 50 years. Barriers are trial availability,	CCTs that enroll at higher rates, have faster advances and improvements for cancer patients

Magnitude of structural, clinical, and physician and patient barriers to cancer clinical trial participation				for pts. In community.		eligibility and attitudinal. 3 out of 4 cancer pts. are not able to participate in trials.	
Juraskova, I.,Butow, P., Bonner, C., Bell, M. L., Smith, A. B., Seccombe, M., Boyle, F., Reaby, L., Cuzick, J., & Forbes, J. F. (2014, p. 1-7). Improving decision making about clinical trial participation	Does a decision tool help breast cancer pts. make more informed decisions to participate in CCTs	146 pts. diagnosed with breast cancer	Level I A, RCT,	Needs to be piloted in other cancer patient populations	Was the first RTC to evaluated decision aids in the CCT setting.	The use of decisional aids improves a patient's knowledge of CCT understanding. The control group had a 63.8% rate of objective understanding while the aid group had 77.7% rate of objective understanding (P=0.008).	Patients need multiple modalities of learning to have a holistic understanding of CCTs.
Bergenmar, M, Johansson, Wilking, N, Hatschek, T., & Brandberg, Y. (2014, p.1197-1204) Audio-recorded information to patients considering participation in cancer clinical trials	Audio-recorded information on knowledge and understanding in patients considering participation in a clinical trial	Pts. considering phases 2 or 3 trial participation by 1 of 13 oncologists in the dept from 2008–2013 (N =130) were randomized	Level I B, RCT	CCT IC process research is needed	No subgroup analyses & study was underpowered	Levels of obj. knowledge (< 50%) regarding risks and discomforts involved in participation, the unproven nature of the trial, & confidentiality	Improvements to presentation of risks to patients during IC are needed
Joffe, S., Cook, E., Cleary, P., Clark, J., & Weeks, J. (2001, p. 1772-77) Quality of informed consent in cancer clinical trials	Pts. actual and perceived understanding of CCTs	Dana Farber Cancer Institute (n =3) bioethicists (n =3) experts in CCTs design (n =207)	Level II A, Cross sectional survey	Provides future research directions	Limited to cancer setting	The QuIC, 20 questions for objective understanding and 14 for subjective understanding & time & ease of administration & an average of 7.2 minutes to finish	Pts. do not comprehend elements of IC

Glaser, J., Nouri, S., Fernandez, A., Sudore, R., Schilinger, D., Klein-Fedyshin, M., & Schenker, Y. (2020, p. 119-143) Interventions to improve patient comprehension in informed consent for medical and surgical procedures	Update to prior systematic review & studies publish of IC interventions	(N =49)-RCTs, 3-NRCTs from 2008-2018 & 60 interventions	Level II B, Systematic Review	Built on previous systematic review	Variation in interventions/outcome measures	100% (8/8) of interactive interventions with test/feedback or teach-back resulted in improved patient comprehension compared to standard IC practice	Test/feedback or teach-back are better when compared other interventions
Kass, N., Taylor, Holly., Ali, J., Hallerz, K., & Chaisson, L. (2015, p.54-66) A pilot study of simple interventions to improve informed consent in clinical research	Feasibility testing of 2 IC interventions in studies and measured effectiveness	From 2009 to 2011, (N =144) participants enrolling in 8 ongoing clinical trials at JHSM and JHSPH	Level II B, Pilot study to determine feasibility and effectiveness	Relevance and transferability of findings	Failure to randomize which may lead to bias or contamination in consent delivery and data collection	Statistically significant higher open- ended scores were:: White participants ($z = 23.02$, $p = .00$), being employed full time ($p = .03$), having a higher income ($p = .00$), having a high reading level (REALM level 4) ($p = .00$, $z = 23.99$), and receiving the consent form in advance ($z = 22.83$, $p = .00$)	Way to improved pt. Understanding when compared to standard practice
Gillies, K., Duthie, A., Cotton, S., & Campbell, M. (2018, p. 1-20) Patient reported measures of informed consent for clinical trials	Conceptualization and item content of validated patient reported measures of IC for clinical trials, and to identify core domains of potential importance for IC	(N 14) articles, 179 items across 14 instruments	Level II C, Systematic review	Systematic search & rigorous method	No formal assessment of interrater reliability, No formal assessment of the methodological quality of instruments	5 Core domains: Autonomy, Consequences, Expectations, Purpose, Individualism	Variability in domains across measures

Joffe, S, Cook, E, Cleary, P & Weeks, J. (2001, p. 381-402) Quality of informed consent	Design the Quality of Informed Consent (QuIC)	Dana Farber Cancer Institute (N =32) respondents was selected, of whom 17 (53%) completed the questionnaire a second time from the original cohort of survey participants	Level III A, Assess test–retest reliability of a cross-sectional survey	Ensured validity of QuIC	Limited to cancer setting	The QuIC, consists of 20 questions for objective understanding and 14 for subjective understanding, tested for time and ease of administration and required 7.2 minutes to finish test–retest reliability with correlation co- efficient of .66	Most frequently cited tool used in studies of patient understanding
Ehrenberger, H., & Lillington, L. (2004, p.E64-E68) Development of a measure to delineate the clinical trials nursing role	Dimensions of the CTN role & construct a reliable and valid survey instrument to reflect these dimensions	Judge panel 6 national nurse executives, focus 24 CRNs from US, 5 CRNs from Canada, sample Instrument testing 40 CCTNs from US	Level III A, Methodologic Survey to develop the Clinical Trials Nursing Questionnaire (CTNQ)	Has content validity, internal consistency, stability reliability	High item number in survey could inflate Cronbach's alpha	Developed using a mixed-method approach and had high content validity index of 0.95, Cronbach's Alpha was 0.92 for the frequency scale and 0.95 for the importance scale	First questionnaire developed & used to evaluate dimensions of the CTN
Pentz, R., White, M., Harvey, D., Farmer, Z., Liu, Y., Lewis, C., Dashevskaya, O., Owonikoko., T., & Khuri, F. (2012, p.4571-4578) Therapeutic Misconception, Misestimation, and Optimism in Participants Enrolled in Phase 1 Trials	Misunderstanding, measured with careful attention to recent conceptual advances, is as widespread as feared, to identify the characteristics of participants who suffer from TM or TMis , & to search for associations between TM and TMis and TO	(N =95) participants in phase 1 trials at a single academic institution	III A, Cross-sectional survey study	Conceptual analyses for TM and TMis	Results not generalizable	Sixty-five of 95 patients (68.4%) had TM, associated in a multivariate analysis with lower education and family income (P 1⁄4 .008 and P 1⁄4 .001, respectively	TM is prevalent in clinical trials
Bevans et. al., (2012, p. 421-427) Defining clinical research nursing practice	Frequency and importance of activities within each dimension of CRN practice & provide	NIH Intramural Campus in Bethesda, Maryland, RN and NP Participants (N =	Level III A, Non experimental, cross-sectional design using a	Large sample size & results are generalizable, internal	Small size serving as RNC and even fewer as an NPs	Results include: CRN, has a significantly ($p <$ 0.05) higher level of activity frequency within the CP	Important to improve the IC process for nurses and for patient outcomes

	additional validation of the proposed conceptual framework of the NIH Clinical Center CRN domain of practice	412) were predominantly female (90%) with 11 or more years of research experience (70%)	web-based survey	validity is strong		dimension (CRN M = 4.20 ± 0.84; RNC M = 3.43 ± 1.14) and significantly lower level of frequency in SM (CRN M = 1.59 ± 0.75: RNC M = 2.65 ± 0.77), CCC (CRN M = 2.22 ± 0.91; RNC M = 3.46 ± 0.93), HSP (CRN M = 1.89 ± 0.89; RNC M = 2.53 ± 0.81), and CS (CRN M = 1.30 ± 0.86; RNC M = 1.98 ± 0.83)	
Barrett, R. (2005, p.751-756). Quality of Informed Consent	Describe pts knowledge and understanding of the CCTs	March 2002-February 2003 (N =8) adult patients in ambulatory setting	III, C Descriptive, Correlational study	validated the QuIC questionnaire	small sample size difficult to generalize and threatens external validity	Pt. perceptions relationship between knowledge of basic elements of IC federal regulations vs. using physicians other than their oncologists as sources of information (r =0.762, p =0.028)	Nurses can aid in the IC practice and improve patient understanding
Krieger, J., Wackerly, A., Krok-Schoen, J., Schoenberg, & Pasket, E. (2015 p. 743-745). Comprehension of randomization and uncertainty in cancer clinical trials decision making among rural, Appalachian patients	Pt. comprehension of the randomization process and sources of uncertainty	(N =49) patients who were offered a cancer treatment with RCT within the last 2 years and lived in or were treated for cancer in 1 of 32 Appalachian Ohio counties	Level III B, Semi-structured interviews	Brings awareness to concerns of rural cancer patient population	all types of cancers and treatments and could not be generalized to focused studies	High comprehension: RCI score of 4 or 5 (n = 18; 39 %), Low comprehension: RCI score of 3 or lower (n=28; 61 %)	Concerns and emotions about safety of randomization must be addressed during IC
Schumacher, A., Sikov, W., Quesenberry, M., Safran, H., Khurshid, Mitchell, K., &	Understanding of critical components of IC of patients enrolling in trials of conventional or novel	Between June 2012 and Oct. 2014 , (N =54) pts. at Brown University	Level III B, Prospective observational cross-sectional study	Common problem	Not sufficiently powered & did not evaluate the contents of the ICFs	Understanding with education < than high school diploma (mean, 64.3 ±10.4, compared with 77.8±8.5 for high	IC is shaped by regulatory and legal polices, & pts. have

Olszewski, A. (2017, p.29-57). Informed consent in oncology clinical trials	biologic/targeted therapies & evaluated how patient age, sex, race, education level or trial sponsorship influence level of understanding					school diploma, 80.6±5.0 for associate degree, 77.2 ±6.4 for bachelor's degree, and 79.2 ±10.0 for master's degree; ANOVA F = 3.7, *P* = .011)	little understanding of research treatment
Hillyer, G., Beauchemin, M., Hershman, D., Kelsen, M., Brogan, F., Sandoval, R., Schmitt, K, Reyes, A., Terry, M., Lassman, A., & Schwartz, G. (2020, p.184-194). Discordant attitudes and beliefs about cancer clinical trial participation between physicians, research staff, and cancer patients	Framework to assess barriers to cancer clinical trial enrollment (CTE)	In 2017 -2018 at Columbia University Irving Medical Center (N =120) physician/clinic-al research staff (39.2% MD/DO) (60.8% staff), (N =150) cancer patients	Level III B, Single site, observational study	First published comprehensive assessment across physicians, staff, and patients to understand differences in CCT perceptions	Did not include pts. in development of survey & limited generalizability	Pts. reported negative beliefs about CTE (e.g. being in a trial does not help patients personally, 32.9% vs. 1.8%, p<0.001), pts. less often felt they had no other options when agreeing to join (38.1% vs. 85.6%, p<0.001), pts. less often refused CTE due to lack of under-standing (9.1% vs. 63.3%, p=0.001) than reported by MDs/staff	MDs/research staff do not understand the patient related barriers to CCT participation
Cantini, F. & Ells, C. (2007, p.126-144). The role of the clinical trial nurse (CTN) in the informed consent process	Current practice of CTNs in the IC process including the role of CTN in IC PI is a MD & conflicts of interest and ethical dilemmas by CTNs during IC	(N =65) CTNS from hospitals affiliated with McGill University in Montreal, Quebec, Canada.	III B, Descriptive study design & Correlational analysis	2 levels of data were made	Poor external validity & results were not well dispersed	Ethical dilemmas : Ethical training: Age (p =-0.08), Years of experience (p =-0.21), Hours of training in research ethics (p =0.177)	Need standardized and mandatory training for CTNs
Nathe, J., & Krakow, E. (2019) The challenges of informed consent in high-stakes, randomized oncology trials	Barriers to IC in high-stakes CCTs and best consent practices for multi- stage RCTs	From 1/1/1990 to April 5, 2018 (N =27) articles were retained	Level III, B Systematic Review	Includes A-level of research	Results in narrative form, no meta-analysis, & limited search	Variables that influence understanding of the IC form: Readability, simplicity, length quality, & stakes involved	Pts. recruited to CCTs may have multivariable problems related to IC

Nusbaum, L., Neenah., Estrella-Luna Orlow, M., & Damus, K. (2019, p.937-950) Survey of risks and benefits communication strategies by research nurses	Attitudes and practices of CRN and ways to improve the IC process	(N =107) CRNs in US	Level III C, Systematic review for survey questions	Database to expand knowledge on attitudes, training, and practices related to IC process	Small sample size & selection Bias,	(87%) of CRNS used a teach-back method to assess participant comprehension, (33%) not prepared to communicate related statistics, (20%) not prepared to tailor information, (50%) not competent using supplemental materials to enhance risks and benefits comprehension	Education and CRN training should help to improve and standardize the ethical IC process
Miller et al., (2013, p.481-489) The relationships among knowledge, self-efficacy, preparedness, decisional conflict, and decisions to participate in a cancer clinical trial	Preparation for consideration of an CCT as a treatment option mediates the relationship between knowledge, self-efficacy, and decisional conflict & if lower levels of decisional conflict are associated with greater likelihood of CCT enrollment	(N=105) were at least 18 years old and had a cancer diagnosis, and were scheduled for their initial consultation with an oncologist at the study site	Level III C, Pre-post-test intervention study	First to report on the association of self-efficacy with decisional conflict in an CCT	Unable to assess interrelations of emotion, self-efficacy, and CCT decisional conf	Decisional conflict was reported as 26.29 (SD=19.28) -This result reinforces previous findings that knowledge alone is not sufficiently potent to reduce conflict, even when pts. feel prepared	Educational intervention to impact knowledge, self-efficacy, preparation and decisional conflict is needed
Dinh, H., Bonner, A., Clark, R., Ramsbotham, J., & Hines, S. (2016, p.210-247). The effectiveness of the teach-back method on adherence and self-management in health education for people with chronic disease	Evidence on using teach-back method in health education programs for improving adherence and self-management of people with chronic diseases	(N=10) studies on the use of teach-back, 8-RCT/NRCTs, 1-cohort, 1-before/after	Level III C, Systematic review	First systematic review of teach-back described in English literature	No meta-analysis & results are in narrative from	Positive effects in outcomes ($p < 0.001$), statistically significant improvements in self-efficacy ($p = 0.0026$ and $p < 0.001$) in the intervention groups	Does not require literacy, allows pts. with low literacy levels to actively participate and for reinforcement of information during appointments Prioritizes disadvantaged people

Godskesen, T., & Nygren, P., & Nordin, K., & Hansson, M., & Kihlbom, U. (2013, p. 3137-3142) Phase 1 clinical trials in end-stage cancer: patient understanding of trial premises and motives for participation	Difficult ethical problems related to patient information and motives for participation in trials	14 cancer patients from three different phase 1 trials in end-stage cancer	III C, Descriptive/ explorative qualitative study	Socio-psychological aspects powerful	Small Sample Size, may lead to bias, & not generalizable	unrealistic expectations of therapeutic benefit and inadequate understanding of the trials' purpose, so-called therapeutic misconception	Pts. unaware of small potential for treatment benefit and risks for har Offers hope, social, & emotional support
Kao, C., Aranda, S., Krishanasamy, M., & Hamilton, B. (2017, p.1-13) Interventions to improve patient understanding of cancer clinical trial participation	Interventions to improve patient understanding of OCT participation	(N =9), pre-post-test (1), case–control (1), or RCTs (7), Adults with cancer, participating in drug-related clinical trials (N =1368) (phase I, II or III) between 2000 and 2013	Level III C, Systematic Review	Guides future research	Lacked reliable and valid outcome measures	Teach-back Interventions may improve patient satisfaction of the IC process	Level of comfort with the decision made or decisional regret indicate success of IC interventions
Forbes, S. G., & Phillips, C. A. (2020, p.428-436) Ethical challenges encountered by clinical trials nurses	Ethical challenges experienced by CCTNs during the management of clinical trials and examine how they resolve those conflicts	(N =12) licensed RNs who have been CCTNs two years or more at US academic medical centers in the US	Level III C, Qualitative survey study, CGT data extrapolation and analysis	Provides framework for CCTNs	Study sample size, selection bias, data collection method limited generalizability	CGT data analysis revealed the CCTNs' main concern was implementing an undefined job	Novice CCTNs need basic knowledge and skills to fulfill responsibilities of new role
Cresswell, P., & Gilmour, J., (2014, p.17-28). The informed consent process in randomized controlled trials	The CRN in the IC process in-depth	(N =3) CRNs with post-graduate degrees in an academic cancer institute in New Zealand in April of 2012	Level III C, Qualitative descriptive study	Contributes to CRN role understanding	small sample size & not generalizable	3 themes were identified in gaining informed consent, preparatory, partnership with participants, & partnership with the project	IC can be led by CRNs who use teach-back
Talevski, J., Shee, A., Bodil Rasmussen, G., Kemp, A.,	Synthesize evidence about the translation of teach-back into	(N =20) studies of moderate quality , (n =4) rated high, (n	Level III C, Systematic review	First systematic review	No assessment of implementation	(n = 15), teach-back was delivered as a structured educational	Teach-back is effective , no studies adapted teach-back

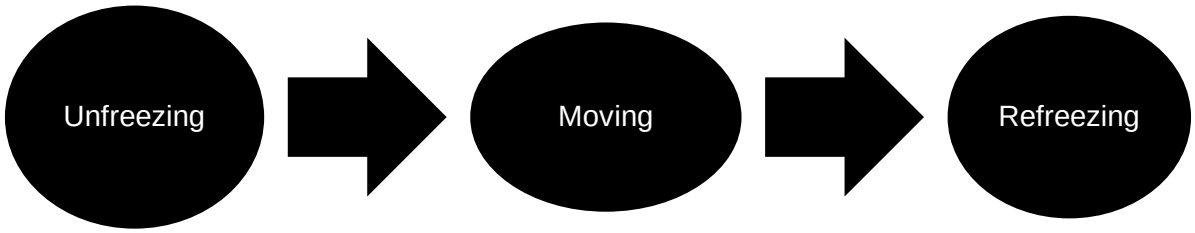
Beauchamp, D. (2020, p.) Teach-back: A systematic review of implementation and impacts	practice including mode of delivery, use of implementation strategies, and effectiveness	=9) rated moderate , (n =7) rated weak		appraising the translation of teach-back into practice	fidelity & no meta-analysis	approach, Implementation strategies were infrequently reported (n = 10), implementation strategies: training and education of stakeholders (n = 8), support for clinicians (n = 6) and use of audits and provider feedback (n = 4), Use of teach-back was 19 of the 20 studies, learning-related outcomes to objective health-related outcomes	intervention to the specific patient population
Lentz, J., Kennett, M., Perlmutter, J., Forrest, A. (2016, p.65-69). Paving the way to a more effective informed consent process	Problems in the current IC process and to formulate recommendations for improvement	In 2014, Clinical Trials Transformation Initiative (CTTI) project, expert interviews, & expert meeting from a diverse (FDA) and, academic	Level IV A, Literature review, telephone expert interviews, multi-stakeholder meeting	Implementation of new processes in clinical research is challenging	Pt. at forefront of considerations related to IC	4 topics were foundation of recommendations	Can be used as a tool for my DNP project
Kurtin, S. E., & Taher, R. (2020, P. 736–751). Clinical trial design and drug Approval in oncology: A primer for the advanced practitioner in oncology.	EBP requires appropriate and well-timed incorporation of scientific discoveries	Literature review of key elements of clinical trials in drug approval	Level IV A, Literature review	All currently FDA cancer treatments originated from clinical trials	Must understand clinical trial process to adequately perform IC	Elements include: Phases of and primary objectives of trials, hierarchy of clinical data, endpoints, adverse event attribution, and common graphs and diagrams	Familiarity with clinical trial definitions is imperative to effective conduct and report of trials

Oncology Nursing Society (2016, P. 1-20). 2016 Oncology Clinical Trials Nurse Competencies	Ensure that 2016 competencies reflect the current clinical trials and CCTN competencies	Revision, competency development, expert review panel, field review	Level IV, A Model and framework	Generalizable	Field review was conducted through ONS members only	CCTN model and framework includes behaviors and competencies required to coordinate clinical trials and manage research patients	Experts from ANA & IACRN Organizations should develop indicators to measure competencies
Fidyk, L., Ventura, K., & Green, K. (2014) Teaching nurses how to teach	Development of a training course for nurses that focused on teach-back as a strategy to improve patient education and understanding	(N =15) clinical nurses from inpatient and outpatient settings completed a pilot-education course	Level V, A, QIP & Expert opinion	Catalyst for a formalized and standardized system wide recurring course offered to nurses	Difficult to measure what types of patient education interventions are most effective	Pre/Post Course evaluation using a 4-point Likert scale survey immediately after & 3 months post course. Improvements with assessing health literacy and better patient education	Sustainable and can be standardized
Herena, P. Paguio,F. & Pulone, C. (2018, p.450-452) Clinical Research Nurse Education	Experience at an NCI-designated comprehensive cancer center which adopted a CRN education program due to a high percentage of CRN turnover	(N =48) CRNs at a large academic NCI-CCC have completed the course	Level V, A, QIP & expert opinion	Can be generalized to other CRNs around the country	Results reported early & follow up results could have a larger impact/implication of the necessity of intervention	implemented Turnover rate dropped to 5.9%,48 30 of the 48 attendees showed increase in knowledge across 4 domains	Staff shortages of CRNs leaves few with the necessary skill set to cover the jobs of many
Showalter, E., Cline, M., Yungclas, A., Frentz, P., Stafford, K., & Maresh, M. (2017, p. 633-636). Clinical Research Nursing	Development and content of a research nurse residency program	12-months program for new graduates initiated in May 2016, and has had 3 cohorts, (N =24) CRNS in total at an NCI-CCC in Texas.	Level V, A, QIP & expert opinion	Novel approach & provides structure and framework to implement	May not be replicable in smaller institutions Must have leadership support	ORNR has shown that it can provide a sustainable educational infrastructure	CRNs are essential in the coordination of clinical trials and the management of oncology research
Regan, E. (2018, p. E152-E158). Clinical Trials Informed Consent: An educational intervention to improve nurses'	Educational program for nurses to improve knowledge and communication skills used in IC for CCTs	Dana-Farber Cancer Institute (N =26), 22 CRNs, 4 NPs	Level V, A, QI Convenience sample, educational program pre-, & post-, paper surveys	Adapted for local practice or introduced to CCTNs in training programs	May not be generalizable & small sample size is a newly developed tool with evidence of prior	important role of a CRN: Response categories included; patient education (n = 16), patient advocacy and navigation (n = 8), monitoring toxicity (n = 4), and confirmation of eligibility and In-	Teach-back is a an evidenced-based method

knowledge and communication skills			and one-month post-program		use only by original authors QuIC-B, designed for patients, required modification	formed Consent (n = 2). QuIC-B mean score was 61% (SD = 15.96)	
Anderson, K., Leister, M., De Rego, R. (2020, p. 94-103). The 5Ts for Teach Back	Training program with observable components	(N =1300) HCWs in a large academic health care system	Level V A, Single 4-hour training & comprehensive training program	Can be used for training, coaching, and evaluation	Do not retain knowledge of the 5Ts after a single Teach-Back training session	Operationalizes the definition of Teach Back & provides model for training related to the 5-Ts:Take Responsibility, Tell me, Triage, Tools, and Try Again	Teach Back competence increases with reinforcement
Abrams, M., Rita, S., Klurz-Rossi., & Nielsen, G. (2012). Always use teach-back! Toolkit.	Effective oral communication strategies and offer suggestions on how to increase staff awareness as they interact with patients	NA, guidelines	Level V B, Recommend-dations and guidelines	Clear on how to implement into practice	New process implementation in clinical research is challenging	Teach-back is a test of how well you explained the concept & ensure clear communication	Effective communication with pts. ensures safety, self-management, & efficient time
Agency for Healthcare Research and Quality. (2020). Health Literacy Universal Precautions Toolkit	Reduce the complexity of health care, increase patient understanding of health information, and enhance support for patients	NA, guidelines	Level V B, Recommend-dations and guidelines	Clear on how to implement into practice	New process implementation in clinical research is challenging	21 Tools that help improve communication, written communication, self-management and empowerment, & supportive systems & 25 resources such as sample forms, PowerPoint presentations, and worksheets & Quick Start Guide	Clinicians should simplify communication for all pts.
Shoemaker, S, & Brach, C. (2017).	Implementing the AHRQ's training modules for healthcare	NA, guidelines	Level V, B	How leaders and clinicians implement	New process implementation in	Improved IC and policies and practice in 4 hospital systems, QI approach in sequential	Improve pt. safety, decrease liability issues, increase patient-centered care,

Implementation guide for Agency for Healthcare Research and Quality's making informed consent an informed choice training module. #3.	professionals and healthcare leaders		Recommend-dations and guidelines	practice change	clinical research is often challenging	and sustainable steps & importance of guideline implementation	and decrease financial loses
Speros, C. I. (2011, p. 321-333). Promoting health literacy	Define health literacy and provide ways to promote it	NA, expert opinion	Level V, B Recommend-ations and guidelines	Clear on how to implement into practice	New process implementation in clinical research is often challenging	Influenced by individual, cultural, social, and political factors	Fundamental to informed decision-making

Appendix C : Kurt Lewin's Change Management Model Adaptation for this DNP Project



Examine status quo and increase driving forces for change.

The first stage in Lewin's Change Management Model (1947) is *Unfreezing,* which began when the project author recognized the need for nurses to have a standardized process of consent in oncology clinical trials. When questioned, many members of the International Association of Clinical Research Nurses reported no standardized method for their consenting practices, no formalized trainings on the topic, and low confidence with the process. A stakeholder analysis of the professional organization was conducted which revealed the need for a project which increases educational opportunities for its nurses

Take action, make changes, and involve people.

The second stage in Lewin's Change Management Model (1947) is *Move* which is when the construction and implementation of the DNP project commences with the implementation an education program. In this stage, nurses may resolve their uncertainty about the need for change of informed consent processes and accept new ways of practice.

Make changes permanent, establish new way of things, and reward desired outcomes.

The third stage in Lewin's Change Management Model (1947) is *Refreeze.* If the project is successful, the nurses will have more confidence with use of teach-back and will use the method when performing informed consent in oncology clinical trials. Furthermore, this education program could become part of a training session that International Association of Clinical Research Nurses offers on a consistent basis.

Appendix D: SWOT Analysis

Strengths	Weaknesses
Abundant teach-back resources available for use, learning opportunities for nurses The project is congruent with the vision and mission of the International Association of Clinical Research Nurses The project operationalizes Good Clinical Practice by nurses, as it will reinforce how to skillfully communicate alternative treatments to the proposed oncology clinical trials, as well as the relevant risks, benefits, and uncertainties of participation to patients This project empowers nurses to proficiently identify components of the informed consent process for which patients need assistance in understanding and allows patients to clarify misconceptions in real-time	Exclusivity of the education program to International Association of Clinical Research Nurses members only and may reduce the amount of nurses who participate in the program Some nurses who attend may not practice in the oncology specialty as International Association of Clinical Research Nurses is open to all fields of medicine The event will be virtual and this may make it more difficult for the project author to develop a meaningful connection with the attendees This program will only be advertised through IACRN online and virtual platforms
Opportunities	**Threats**
The project may increase nurse confidence with use of the teach-back method when performing informed consent in oncology clinical trials This education program could become part of a training session offered by IACRN on a consistent basis This education program could be replicated at the project author's workplace and in similar oncology clinical trial settings	No one may attend the virtual event This program will only be presented once Despite training, nurses may refuse to use teach-back in their consent practices Nurses may miss the opportunity to attend the education program due to prior commitments, or time constraints related to their current workload Nurses may be unaware of the opportunity

Appendix E: Teaching Plan for Education Program

Methods:
Time allowance for presentation: One hour
Question and answer session: 30 minutes

Education program objectives:
At the end of the presentation and question and answer session, the oncology clinical trial nurses will be able to do the following:
Identify factors that influence patient understanding and promote learning
Define health literacy
Understand and describe steps of the teach-back method
Describe the role and value of the teach-back method
Identify strategies to facilitate the use of teach-back into your cancer clinical trial consenting processes

Education Program Content

Factors that influence patient teaching include not giving patients the opportunity to ask questions, timing of education presentation, no confirmation of comprehension or little follow up (AHRQ, 2020). Ways to promote health literacy include creating a shame free environment, using clear, purposeful, and patient centered communication, and reinforcing and verifying what was taught (Speros, 2011). The Institute of Medicine (2010) defines Health Literacy as: "The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. Health literacy is influenced by individual, cultural, social, and political factors and is fundamental to informed decision-making (Tam et al., 2015; Speros, 2011). Effective communication positively correlates with better patient adherence.

The Agency for Healthcare Research and Quality (2020) defines teach-back as a "communication method used in a respectful way to provide real-time assessment which confirms patient understanding of the complex health related concepts that you tell them (Anderson et al., 2020; Regan, 2018; Dinh et al., 2016; AHRQ, 2020; Nusbaum et al., 2019). The teach-back method helps patients remember and understand more information, raises their satisfaction, helps them feel more relaxed, and helps clinicians garner their patients' trust (Abrams, 2012; AHRQ, 2020). The principles of the teach-back method and 10 observable elements on which it is based remind the nurse to choose the pertinent information for the patient to retain and comprehend, use tools to provide explanations when teaching, verbalize that material presented to the patient is abstruse and that the nurse is the one being tested for how well the concepts were explained, encourage the patient to give an explanation of concepts in their own words, and repeat concepts if the patient does not fully comprehend (Abrams, 2012; AHRQ, 2020; Anderson et al., 2020). An observation tool called "the 5Ts for Teach-Back," proved useful for training, and coaching of teach-back implementation in the clinical setting (Anderson et al., 2020). The Teach-back Observational tool may serve as a script for remembering the 10 elements during the informed consent visit and help to facilitate the use of the teach-back method into practice (Abrams 2012; Anderson et al., 2020; AHRQ 2020).

Some patients perceive clinical trial participation as personal medical care instead of research and are unaware that alternative treatments exist (Pentz et al., 2012; Schumacher et., al, 2017). For patients diagnosed with cancer, teach-back decreases uncertainty related to randomization, significantly improves comprehension of disease knowledge ($p < 0.001$), medication adherence ($p < 0.001$), and self-efficacy ($p = 0.0026$) [Dinh, et al., 2016; Krieger, et al., 2015]. Other factors that contribute to a patient's level of CCT understanding include innovations in clinical trial design, changes in the setting of clinical research delivery for biomedical interventions, first in human studies, an increasing number of procedures per protocol, readability, and length of consent forms (Getz & Campo, 2018; Nathe & Krakow, 2019). Teach-back is an effective method available for use by nurses to communicate complex oncology clinical trial-specific information to patients during the consent process (Lentz et al., 2014; AHRQ, 2020; Speros, 2011). The teach-back method helps nurses facilitate the process and helps them consider the patients' psychosocial situation, family support, and appropriate timing of consent (Nusbaum et al., 2019). Extended contact with healthcare professionals and discussion with a question and answer sessions significantly increase comprehension of a patient's treatment options, the risks and discomforts associated with participation, the research design, and the unproven nature of the trial (Bergenmar et al., 2014; Kass et al., 2015; Nishimura et al., 2013). Patient understanding of IC mediates the relationship between a patient's self-efficacy and decisional conflict to participate in CCTs ($p=0.003$) [Dinh et al., 2016; Miller et al., 2013; Tam et al., 2015]. When tested in four studies, interactive interventions used during consent with teach-back or test/feedback components improved patient comprehension by 100% when compared to standard practices (Glaser et al., 2020).

Knowledge Checks

Question One: What is the most important rationale for using teach-back during the oncology clinical trial informed consent process?

a. To test the patient on his/her ability to repeat the important health information given
b. To give the patient time and opportunity to talk to you
c. To alert you to whether or not your communication was clear
d. To meet all informed consent requirements

Correct answer: C, Teach-back serves as a check to see how well the patient understood what the clinician told him or her.

Question Two: Factors that promote patient teaching are all of the following expect:

a. Timing of education presentation.
b. Social and cultural factors.
c. Not giving your patient the opportunity to ask questions.
d. No confirmation of comprehension.

Correct Answer: B, factors that promote patient teaching are use clear purposeful communication, communicate in a patient centered manner, create a shame free environment, reinforce the spoken word, and verify understanding.

Question Three: Which are examples of open ended questions or inferences which encourage discussion and assess comprehension?

a. Please explain to me what the doctor said you would need to do while you are on the clinical trial.

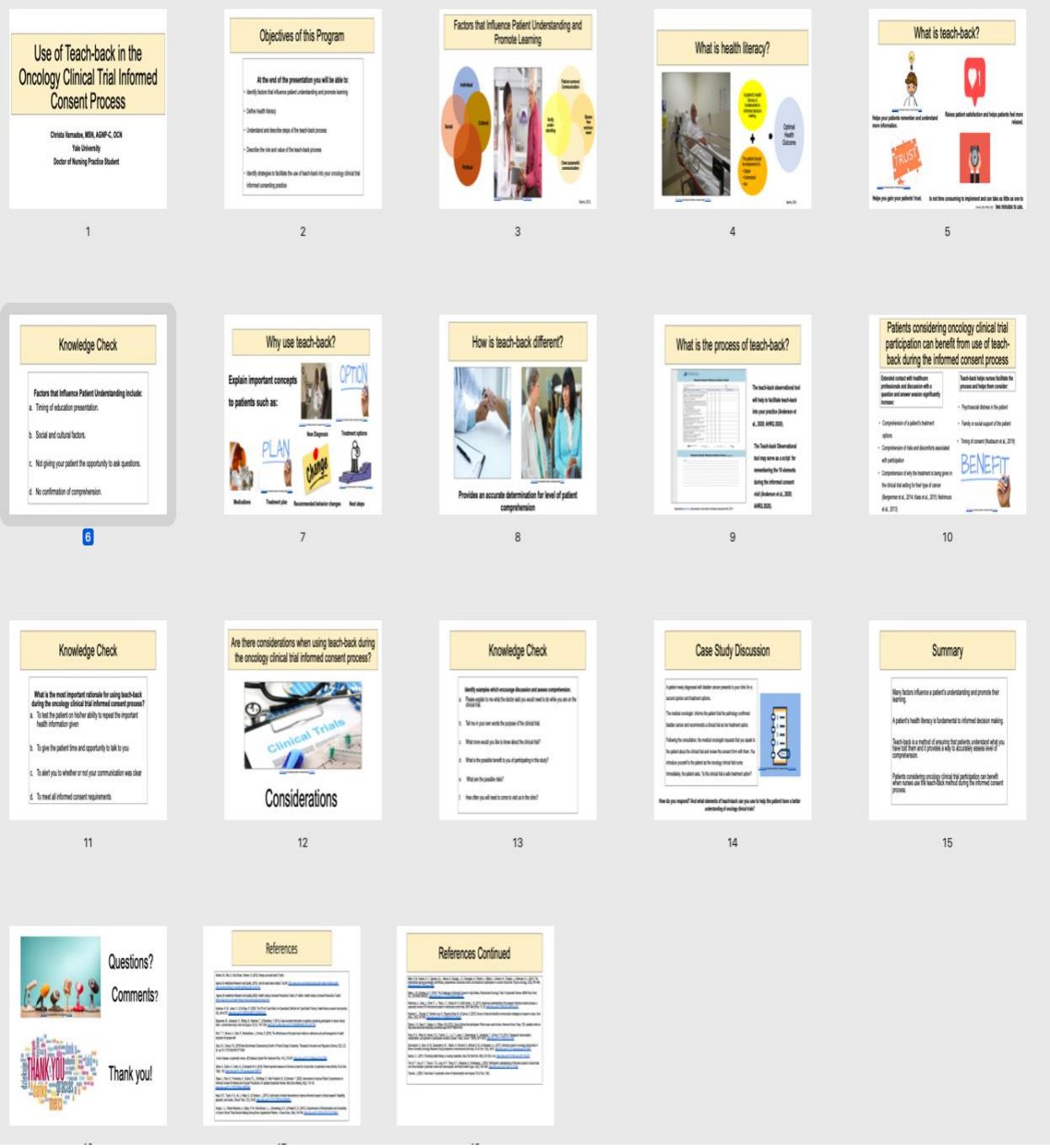
b. Tell me in your own words the purpose of the clinical trial.
c. What more would you like to know about the clinical trial?
d. What is the possible benefit to you of participating in this study?
e. What are the possible risks?
f. How often you will need to come to visit us in the clinic?

Correct Answer: All of the above, Open ended questions encourage discussion and assess comprehension.

Case Study Discussion

A patient newly diagnosed with bladder cancer presents to your clinic for a second opinion and treatment options. The medical oncologist has informed the patient that the pathology from her biopsy was confirmed as bladder cancer by your team of pathologists. The medical oncologist recommends a clinical trial as her treatment option. Once finished with his discussion, the medical oncologist requests that you speak to the patient more about the clinical trial and review the consent form with them. You introduce yourself to the patient as the oncology clinical trial nurse. Immediately, the patient asks, “Is this clinical trial a safe treatment option? ”How do you respond? And what elements of teach-back can you use to help the patient have a better understanding of oncology clinical trials?

Appendix F: Education Program PowerPoint Presentation



Appendix G: Permission to AHRQ Teach-back Toolkit

From: Abrams, Mary Ann <MaryAnn.Abrams@nationwidechildrens.org>
Sent: Tuesday, June 8, 2021 10:57 AM
To: gail.a.nielsen <gail.a.nielsen@gmail.com>; Varnadoe, Christa <christa.roe@yale.edu>
Subject: RE: Permission to use Teach-back conviction and confidence scale

Hello Christa and thank you Gail. Thank you for your interest in the *Always Use Teach-back!* Toolkit.

We created the *Always Use Teach-back!* Toolkit to help individuals and organizations improve their use of teach-back. You are welcome to link to it and use it in your educational offerings. Please note that the Institute for Healthcare Improvement (IHA) hosts the Toolkit in their Health Literacy Solutions Center. It is preferred that the interactive learning module content be used together (not just isolated video clips) since it is intended to be a package. The associated tools (pdfs and videos, including the Observation Tool and the Conviction and Confidence Scale) can be used as needed to supplement your training/project.

When using any of the Toolkit materials, please use this citation: Abrams MA, Rita S, Kurtz-Rossi S, Nielsen G. Always Use Teach-back! Toolkit. 2012. www.teachbacktraining.org.

Thank you and best wishes with your work.

Mary Ann

Mary Ann Abrams, MD, MPH
GME Quality Improvement Medical Director
Ambulatory Pediatrics
614-722-4791
NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.

Appendix H: Permission for implementation

Varnadoe, Christa
Sat 11/20/2021 7:33 PM
To: 'Catherine A Griffith' <cgriffith0@gmail.com>

Christa Varnadoe DNP Propo...
1 MB

Dear Dr. Griffith,

As directed by Sharon Flynn please see my responses to the questions below.

1. What is your time frame for your project?
   - ASAP. My graduation date is May 2022. I originally planned to implement it at a cancer center in New Jersey. However, due to their institution's current staffing level crisis, I had to re-organize my project accordingly. I practice in New York. My college is in Connecticut and due to the NYBOE restrictions, I am unable to implement my project in New York/own place of work. It will be a one-time live webinar presented for any oncology clinical research nurses who wish to attend free of charge.
2. Please send your study objectives, proposal, and pre/post surveys.
3. - My proposal is attached
4. - QI objectives are within my proposal on page 42
5. - Pre/Post surveys are within my proposal on page 50
3. Send the email or written communication from the IRB granting the exemption.
4. - IRB exemption found within the proposal on page 56

Thank you in advance for your consideration and review of my DNP project proposal. I am hopeful that my education program aligns with the mission of IACRN.

Respectfully,

Christa

Christa Varnadoe, MSN, APRN, AGNP-C, OCN
Doctor of Nursing Practice Candidate 2022
American Cancer Society Graduate Scholarship Recipient 2018
Oncology Nursing Society Graduate Scholarship Recipient 2019
Florence Nightingale Award of Excellence Scholar 2019

Yale SCHOOL OF NURSING

Appendix I: Participation Emails

Email Invitation for Participation

Greetings IACRN Member,

Thank you for registering to participate in a quality improvement project conducted by a Doctor of Nursing Practice Student at Yale University. Your participation is voluntary, there are no anticipated risks to your participation, and there are no direct benefits to you taking part in this project. This was approved as a quality improvement project by Yale University's Institutional Review Board. It does not involve human subjects research, and it was determined that reviewed was not required.

The project's purpose is to develop, implement, and evaluate the effects of an evidenced-based education program on nurse confidence with use of the teach-back method during the cancer clinical trial consent process. The project author will present the webinar live over one hour. The Cost to attend is free of charge. At the end of the webinar, I will choose at random a name to receive a $100 USD Amazon gift card for your participation.

Pre-Webinar Survey link:
https://yalesurvey.ca1.qualtrics.com/jfe/form/SV_bfHQChL9utGXPWm

Link for Webinar:
Topic: Use of Teach-back during Informed Consent in Oncology Clinical Trials
Time: Jan 5, 2022 06:30 PM Eastern Time (US and Canada)
Join from PC, Mac, Linux, iOS or Android: https://yale.zoom.us/j/6926914116
Or Telephone : 203-432-9666 (2-ZOOM if on-campus) or 646 568 7788
Meeting ID: 692 691 4116

I look forward to your participation and meeting you this evening.

Sincerely,
Christa Varnadoe, MSN, APRN, AGNP-C, OCN
Yale University Doctor of Nursing Practice Student

Post Participation Email

Dear Participant,

Thank you for taking part in a quality improvement project on January 5, 2022, by a Doctor of Nursing Practice student at Yale University.

As a reminder, the purpose of the project is to develop, implement, and evaluate the effects of an education program on nurse confidence with the use of teach-back during the oncology clinical trial consent process. Now that you have attended, please be sure to complete the post-program survey via the hyperlink below:
https://yalesurvey.ca1.qualtrics.com/jfe/form/SV_aXIkvmRpNg41y6y

Likewise, please find attached additional resources from the program including the Always Use Teach-back toolkit Readings and Resources, the Teach-back Observational Tool, and the slide deck presentation. If you have any questions about this project, please feel free to contact Christa Varnadoe at christa.roe@yale.edu or yaleDNPstudent2022@gmail.com.

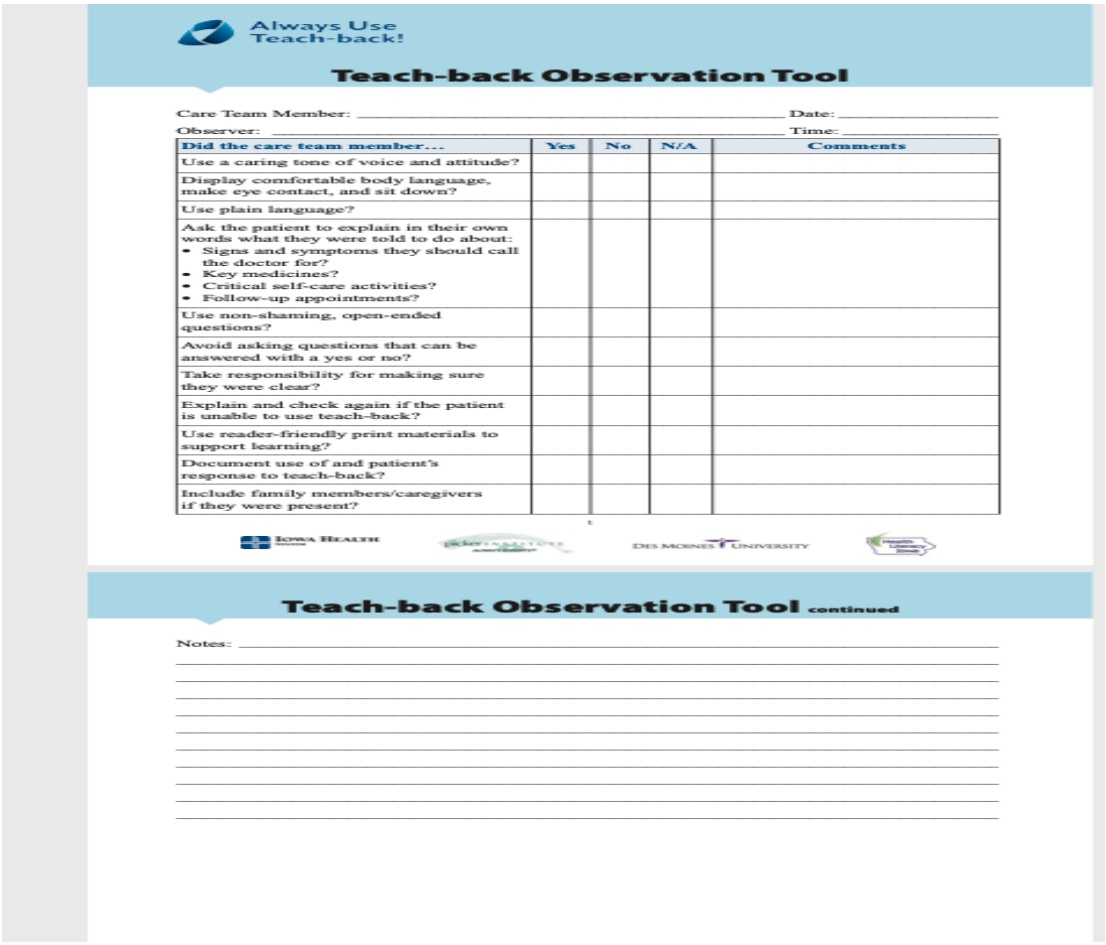
Thank you for your time and participation.

Sincerely,

Christa Varnadoe, MSN, AGNP-C, OCN
Yale University Doctor of Nursing Practice Student

Attachments:
Always Use Teach-back Toolkit Readings and Resources
Teach-back Observational Tool
Slide Deck Presentation

Appendix J: Teach-back Observation Tool



Always Use Teach-back!

Teach-back Observation Tool

Care Team Member: _____ Date: _____

Observer: _____ Time: _____

Did the care team member…	Yes	No	N/A	Comments
Use a caring tone of voice and attitude?				
Display comfortable body language, make eye contact, and sit down?				
Use plain language?				
Ask the patient to explain in their own words what they were told to do about: • Signs and symptoms they should call the doctor for? • Key medicines? • Critical self-care activities? • Follow-up appointments?				
Use non-shaming, open-ended questions?				
Avoid asking questions that can be answered with a yes or no?				
Take responsibility for making sure they were clear?				
Explain and check again if the patient is unable to use teach-back?				
Use reader-friendly print materials to support learning?				
Document use of and patient's response to teach-back?				
Include family members/caregivers if they were present?				

Iowa Health — Des Moines University

Teach-back Observation Tool continued

Notes: _____

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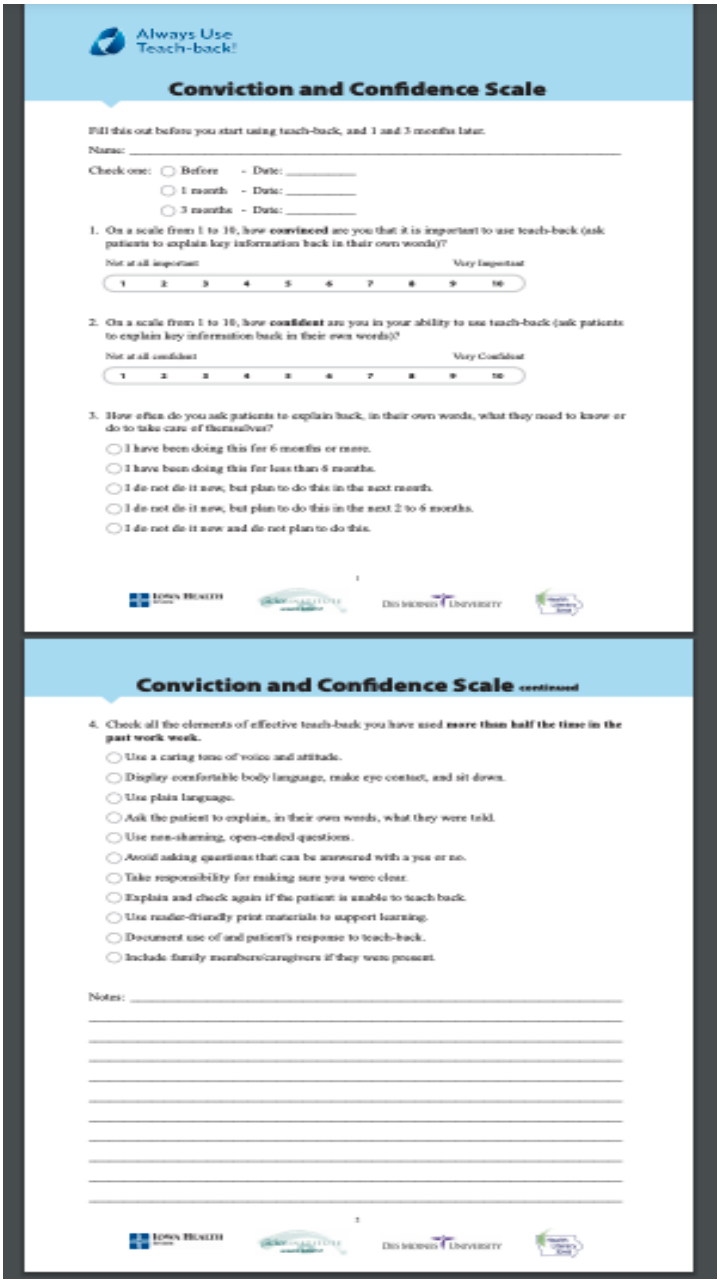
Appendix K: Conviction and Confidence Scale Survey



Always Use Teach-back!

Conviction and Confidence Scale

Fill this out before you start using teach-back, and 1 and 3 months later.

Name: _____

Check one: ◯ Before - Date: _____
◯ 1 month - Date: _____
◯ 3 months - Date: _____

1. On a scale from 1 to 10, how **convinced** are you that it is important to use teach-back (ask patients to explain key information back in their own words)?

Not at all important 1 2 3 4 5 6 7 8 9 10 Very Important

2. On a scale from 1 to 10, how **confident** are you in your ability to use teach-back (ask patients to explain key information back in their own words)?

Not at all confident 1 2 3 4 5 6 7 8 9 10 Very Confident

3. How often do you ask patients to explain back, in their own words, what they need to know or do to take care of themselves?

◯ I have been doing this for 6 months or more.
◯ I have been doing this for less than 6 months.
◯ I do not do it now, but plan to do this in the next month.
◯ I do not do it now, but plan to do this in the next 2 to 6 months.
◯ I do not do it now and do not plan to do this.

Conviction and Confidence Scale continued

4. Check all the elements of effective teach-back you have used **more than half the time in the past work week.**

◯ Use a caring tone of voice and attitude.
◯ Display comfortable body language, make eye contact, and sit down.
◯ Use plain language.
◯ Ask the patient to explain, in their own words, what they were told.
◯ Use non-shaming, open-ended questions.
◯ Avoid asking questions that can be answered with a yes or no.
◯ Take responsibility for making sure you were clear.
◯ Explain and check again if the patient is unable to teach back.
◯ Use reader-friendly print materials to support learning.
◯ Document use of and patient's response to teach-back.
◯ Include family members/caregivers if they were present.

Notes: _____

Appendix L: Pre and Post Program Surveys accessed through Qualtrics Hyperlink

Use of Teach-Back During Informed Consent in Cancer Clinical Trials

Q1 Please choose your age range:

- 18 to 25
- 26-35
- 36-45
- 46-55
- 56+

Q2 Highest Degree? Please provide type of degree

- Associates (1) _____
- Bachelors (2) _____
- Masters (3) _____
- Doctoral (4) _____

Q3 Years experience in a clinical trial setting?

- Less than 1
- 1-2
- 3-4
- 5-6
- 7+

Q4 Have you ever had formalized training on how to perform informed consent in cancer clinical trials?

- No
- Yes

Q5 On a scale from 1 to 10, how convinced are you that it is important to use teach-back (ask patients to explain key information back in their own words)? 1- Not at all important, 10- Very important

Q6 On a scale from 1 to 10, how confident are you in your ability to use teach-back (ask patients to explain key information back in their own words)? 1- Not at all confident, 10- Very confident

Q7 How often do you ask patients to **explain back, in their own words, what they need to know or do to take care of themselves?**

- I have been doing this for 6 months or more.
- I have been doing this for less than 6 months.
- I do not do it now, but plan to do this in the next month.
- I do not do it now, but plan to do this in the next 2 to 6 months.
- I do not do it now and do not plan to do this.

Q8 Check all the elements of effective teach-back you have used more than half the time in the past work week.

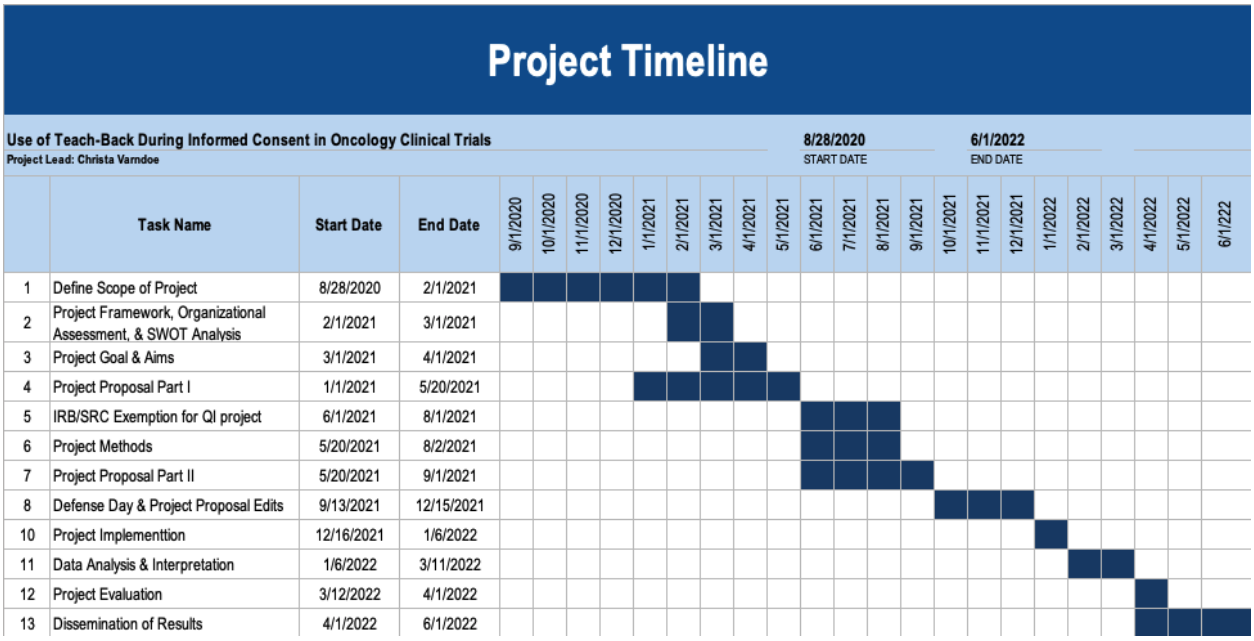
- Use a caring voice and attitude.
- Display comfortable body language, make eye contact, and sit down.
- Use plain language.
- Ask the patient to explain, in their own words, what they were told.
- Use non-shaming, open-ended questions.
- Avoid asking questions that can be answered with a yes or no.
- Take responsibility for making sure you were clear.
- Explain and check again if the patient is unable to teach back.
- Use reader-friendly print materials to support learning.
- Document use of and patient's response to teach-back.
- Include family members/caregivers if they were present.
- and attitude.
- Display comfortable body language, make eye contact, and sit down.
- Use plain language.
- Ask the patient to explain, in their own words, what they were told.
- Use non-shaming, open-ended questions.
- Avoid asking questions that can be answered with a yes or no.
- Take responsibility for making sure you were clear.
- Explain and check again if the patient is unable to teach back.
- Use reader-friendly print materials to support learning.
- Document use of and patient's response to teach-back.
- Include family members/caregivers if they were prese

Appendix M: Stakeholder Analysis

Name	Title/Role	Characteristics/ Interest	Project Engagement	Estimated Priority	Potential Management Strategies
Christa Varnadoe, MSN, AGNP-C, OCN	Operational/Project Leader, Assistant Director, Solid Tumor Oncology Research, Tish Cancer Institute	Role of CCTNs & Improving IC Process High	Leadership	1	Networking will all involved in the project.
Dr. Tish Knobf, PhD, RN, FAAN	Project Sponsor, Internal Academic Advisor, Yale School of Nursing, Co-Chair PhD Program	Provide expert guidance and clarity for project logistics and feasibility High	Leadership	1	Monthly updates on project planning & progress.
Dr. Toby Bressler, PhD, RN, OCN, FAAN	Project Sponsor, External Academic Advisor, Senior Director for Oncology Nursing and Clinical Quality Mount Sinai Hospital	Provide expert guidance and clarity for project logistics and feasibility High	Leadership	1	Monthly updates on project planning & progress.
Andrea Gonzales, MSN, RN	External Advisor, Nurse Manager, Office of Human Research Services at Rutgers Cancer Institute	Increasing opportunities for research nurses to grow in their profession and standardizing CCT IC processes High	Supportive	2	Weekly updates and participation in project planning
Kelly Gleason, MSc, BSN, OCN	External Advisor, Co-founder and Director at Clinfield, Cambridge UK	Seasoned clinical research nurses with international experience and connections High	Supportive	2	As needed consultations
Catherine Griffith, PhD, ANP-BC, FAAN	Director & Founder, Massachusetts General Hospital CRN Collaborative, Chair- IACRN	Key member of IACRN and will promote project to professional organization Low	Supportive	2	Quarterly updates on project development & progress

	Research Committee				
Elizabeth Ness, MS, BSN, RN, CCRP	Director, Office of Education and Compliance, NCI, Center for Cancer Research, Co-author Scope and Standards for CRNS	Key member of IACRN Education Committee, and will promote project to professional organization Low	Supportive	2	Quarterly updates on project development & progress
Clinical Trial Nurses	Members of the International Association of Clinical Research Nurses	Will need their participation in the education program for project to be successfully implemented High	Supportive	1	Monthly updates on project development & progress. Weekly zoom "touch bases."

Appendix N: Gantt Chart



Project Timeline

Use of Teach-Back During Informed Consent in Oncology Clinical Trials
Project Lead: Christa Varndoe

8/28/2020 START DATE
6/1/2022 END DATE

	Task Name	Start Date	End Date
1	Define Scope of Project	8/28/2020	2/1/2021
2	Project Framework, Organizational Assessment, & SWOT Analysis	2/1/2021	3/1/2021
3	Project Goal & Aims	3/1/2021	4/1/2021
4	Project Proposal Part I	1/1/2021	5/20/2021
5	IRB/SRC Exemption for QI project	6/1/2021	8/1/2021
6	Project Methods	5/20/2021	8/2/2021
7	Project Proposal Part II	5/20/2021	9/1/2021
8	Defense Day & Project Proposal Edits	9/13/2021	12/15/2021
10	Project Implementtion	12/16/2021	1/6/2022
11	Data Analysis & Interpretation	1/6/2022	3/11/2022
12	Project Evaluation	3/12/2022	4/1/2022
13	Dissemination of Results	4/1/2022	6/1/2022

9/1/2020, 10/1/2020, 11/1/2020, 12/1/2020, 1/1/2021, 2/1/2021, 3/1/2021, 4/1/2021, 5/1/2021, 6/1/2021, 7/1/2021, 8/1/2021, 9/1/2021, 10/1/2021, 11/1/2021, 12/1/2021, 1/1/2022, 2/1/2022, 3/1/2022, 4/1/2022, 5/1/2022, 6/1/222

Appendix O: Yale University Institutional Review Board Checklist

Yale University Institutional Review Boards Checklist

100 CH.9 Clinical Quality Improvement

Investigators are encouraged to use the "QI Checklist" to help determine whether the proposed activity is considered a Quality Improvement project or whether IRB review is required.

1. Purpose — YES X NO ☐
   - Is the project intended to improve the process/delivery of care while decreasing inefficiencies?

2. Funding — YES X NO ☐
   - Is the project internally funded or externally supported by agencies for direct benefit to existing patients?

3. Project Staff — YES X NO ☐
   - Is the proposed project conducted by the clinicians and staff who provide care or are responsible for the performance quality in the institutions where the project will take place?

4. Project Design — YES X NO ☐
   - Is the project flexible, including rapid and incremental changes such as in a plan-do-study-act (PDSA) cycle?

5. Recruitment — YES X NO ☐
   - Will the project involve a sample of the population (staff or patients) ordinarily seen in the institution where the project will take place?

6. Consent — YES X NO ☐
   - Will the planned activity only require consent that is normally sought in clinical practice and could the activity be considered part of the usual care?

7. Benefits — YES X NO ☐
   - Is it true that most of the current patients at the institution where the planned activity will take place could potentially benefit from the project?

8. Risk — YES X NO ☐
   - A) Is the risk to the participants no greater than what is involved in the care they are already receiving? **OR**
   - B) Can the burden of participating in the activity be considered acceptable or ordinarily expected when reforms are being introduced to the way care is provided?

If the answer to **ALL** of these questions is **YES** then the activity is a QI project and does not involve human subject research. **IRB review is not required.**
If the answer to any of these questions is NO, please consult with the IRB at 785-4688. IRB review may be required.

12-19-12