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Addressing the Psychosocial State of High-Risk Individuals Undergoing Hereditary Cancer Screening by Advanced Practice Registered Nurses (APRNs) in the Community Oncology Setting

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This doctoral project, directed and approved by the candidate's committee, has been accepted by the School of Nursing and College of Graduate and Professional Studies of Abilene Christian University in partial fulfillment of the requirements for the degree

Doctor of Nursing Practice

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A scholarly paper submitted in partial satisfaction

of the requirements for the degree of

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by

Aquilina Kerubo Thompson

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Dedication

I dedicate my DNP project to my parents Paul Magare and Biliah Nyaboke, my dearest and most supportive husband, Kenneth Thompson, my daughter Amber, son Bryce, and my siblings Delila, Pius, and Gregory. They inspired me to pursue this terminal degree in nursing, and I thank each one of them for their complete support and love.

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Abstract

Neoteric advances in genetics make it possible to define genetic risk in cancer, and there should be methods in place to provide comprehensive genomic care with oncology advanced practice registered nurses bridging this gap. The current scope of nursing practice stipulates genetic and genomic literacy; however, there remains a deficit among advanced practice registered nurses in identifying and addressing psychosocial distress during the genetic cancer risk assessment process. Oncology advanced practice registered nurses must be equipped with the knowledge that the genetic cancer risk assessment also involves protecting patients from the psychosocial repercussions of carrying a hereditary cancer gene beyond medical assessment. The goals of this study were to identify psychosocial risk factors in individuals with heightened cancer risk, improve psychosocial management plans, increase shared decision-making referrals based on individual risk factors, and determine the appropriate psychosocial risk tool to utilize in clinical practice. The Genetic Psychosocial Risk Instrument and Supportive Care Screening Questionnaire were implemented in utilizing best practice guidelines at an outpatient community oncology practice in San Antonio, Texas. This three-month project used a quantitative comparative design with a randomized convenience sample who received the Genetic Psychosocial Risk Instrument or Supportive Care Screening Questionnaire. The reconceptualized uncertainty of illness theory was the theoretical framework used to guide this project. Discovering the antecedents of uncertainty provided the advanced practice registered nurses with salient clues about the patient's uncertainty related to the genetic cancer risk assessment process and helped prompt psychosocial referrals. Results revealed that in patients undergoing genetic cancer risk assessment assessments, a certain percentage experienced psychosocial distress, and there is demand for a standardized psychosocial needs identification in this patient population.

Keywords: advanced practice registered nurses, Genetic Psychosocial Risk Instrument, hereditary cancer syndromes, genetic cancer risk assessment, psychosocial distress, previvors

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Chapter 1: Introduction

Recent breakthroughs in genetics have made it feasible to explicate the hereditary risk of some diseases, especially cancer. Increasing access to genetic testing allows health practitioners to identify individuals who have a heightened risk of developing cancer, which prompts genetic cancer risk assessments (GCRA), improves surveillance management, and promotes an awareness of novel targets such as pharmacogenetics in patients who already have a cancer diagnosis. Regardless of the benefits of genetic testing, individuals at high risk for serious illness may become increasingly fearful or distressed about the future (Esplen et al., 2013). Previvors are individuals with a genetic predisposition to develop cancer but as yet have not been diagnosed (Dean & Davidson, 2018). Although genetic testing can decrease a previvor's worries about whether they have a high genetic cancer risk, testing positive often produces negative emotions and long-term uncertainty, thus requiring uncertainty management. Evidence suggests that interest in pursuing genetic testing for cancer syndromes is high, with some reports indicating an 80–90% uptake rate (American Cancer Society, 2020).

Even though resources exist to deliver effective services to those with psychosocial needs in clinical practice, mechanisms are needed to help identify high-risk hereditary cancer patients with psychosocial health needs and link them to appropriate services (Riba et al., 2019). Therefore, it is important to choose tools that are sensitive to evaluate the efficacy of the intervention on psychosocial concerns in high-risk patients undergoing GCRA. The purpose of this study was to compare the Genetic Psychosocial Risk Instrument (GPRI) and the Supportive Care Screening Questionnaire (SCSQ) in their ability to evaluate psychosocial concerns and prompt psychosocial referrals during the GCRA process. There is limited data available; however, with respect to comparing the responsiveness of these two instruments and no

consensus as to which one is superior because no "gold standard" currently exists for psychosocial measurement in high-risk individuals undergoing genetic testing. The GPRI tool has been shown beneficial in determining whether patients need additional psychosocial support in the wake of genetic testing (Esplen et al., 2013). The SCSQ, referenced from the Edmonton Symptom Assessment Scale (ESAS) and Patient Health Questionnaire-2 (PHQ2), is currently utilized in primary investigators' clinical practices but only in patients with a cancer diagnosis.

Statement of the Problem

This evidence-based, scholarly project was designed to identify high-risk individuals undergoing hereditary cancer screening who are liable to experience significant difficulty adjusting to the genetic information and identify high-risk individuals who might benefit from preventative interventions to contain their distress level. Oncology advanced practice registered nurses (APRNs) need to understand that GCRA involves protecting patients from the psychosocial repercussions of carrying a hereditary cancer gene beyond medical assessment. As a result, this project is unique as there are currently no studies investigating the psychosocial impact of GCRA screening by APRNs in the outpatient community setting.

According to the National Cancer Institute, approximately 5–10% of newly diagnosed cancers are genetically inherited (National Cancer Institute [NCI], 2016), and although these statistics are not high, the magnitude of risk conferred by cancer susceptibility genes is often dramatic (Weitzel, 1999). Counseling before and after genetic testing is an integral part of the process to discuss the rationale for any genetic testing, disclose results, define other cancer risks, identify educational needs, and secure referrals, if necessary, for ongoing management (American College of Obstetricians and Gynecologists [ACOG], 2019). What is critical and missing in the GCRA process is the assessment of these high-risk individuals' psychosocial

concerns. Currently, there is no standardized psychosocial screening template for high-risk individuals undergoing GCRA in my clinical practice.

The negative psychosocial impact of genetic testing includes distress (Gritz et al., 2005), more specifically, distress associated with pressure to inform family members of a mutation they may share and isolation from other family members (McInerney-Leo et al., 2005). In addition, other psychosocial impacts might include survivor's guilt if found not to carry the mutation, depression, anxiety disorders, and cancer-related worries after receiving positive mutation results (van Dijk et al., 2006). Qualitatively oriented studies have identified several emotional responses to testing, including sadness, relief, anxiety, and guilt (Cella et al., 2002). Early identification of high-risk individuals who are potentially at higher risk of suffering distress and adverse psychological effects during the GCRA process makes it possible to allocate valuable psychosocial resources (Maheu et al., 2018). In most oncology settings, there are no accepted ways to assess the situation-specific psychosocial concerns in high-risk individuals that have been noted empirically (Cella et al., 2002). Many of these high-risk individuals are often left grappling and dealing with their psychosocial issues alone, leading to nonadherence to treatment or surveillance regimens. This evidence-based project aimed to enhance preventative health delivery in high-risk individuals undergoing GCRA, identify individuals who needed psychosocial interventions, and provide additional psychosocial support as warranted.

Oncology is one of the first subspecialties to experience the full impact of the genomics revolution, and it is now possible to use genomic science in prevention, screening, diagnostics, prognostics, treatment selection, and monitoring (Mahon, 2017). The National Comprehensive Cancer Network (National Comprehensive Cancer Network [NCCN], 2019) advocated for clinical practice guidelines in oncology to include distress management. Psychological

impairments related to the genetic GCRA process can also lead to substantial social problems, such as the inability to work or fulfill other normative social roles (Adler & Page, 2008). For these reasons, the Institute of Medicine mandated that a quality cancer care program must integrate the psychosocial needs in routine cancer care and state that "all cancer care should ensure the provision of appropriate psychosocial health services by identifying each patient's psychosocial health needs and design and implement a plan that links the patient with needed psychosocial care" (Adler & Page, 2008, p. 219). In ensuring centered patient care, the American College of Surgeons (American College of Surgeons [ACoS], 2012) initiated an accreditation standard requiring cancer centers to have an onsite psychosocial program to identify patients and refer them for appropriate care. Nurses have long been aware of the intersection of heredity, lifestyle, and the environment in their assessments of patients and families (Kerber & Ledbetter, 2017). The Oncology Nursing Society (ONS) advocates that part of the APRNs role is to provide genetic and genomic care to individuals in conjunction with expert providers (Mahon, 2017). During the pretesting phase of the hereditary cancer process, APRNs trained in genetics help evaluate risk assessment based on personal and family history, select the best testing strategy and laboratory, and provide research study options. In the postesting phase, the APRN interprets test results, provides recommendations for follow-up, and coordinates appropriate care for other family members.

Purpose of the Study

The overall aim of this Doctor of Nursing Practice (DNP) quality improvement project was to improve psychosocial screening practices, implement and compare two psychosocial screening tools to help identify psychosocial concerns, and increase psychosocial referrals in high-risk individuals undergoing genetic testing at a community outpatient oncology clinic in

Texas. This project had the potential to address the gap between recommendations of available evidence-based literature for best practices. With the advent of APRNs running high-risk cancer clinics, more APRNs are completing specialized training in GCRA, and currently, there is no routine psychosocial screening assessment being conducted during these GCRA visits. Early identification of psychosocial concerns is crucial to developing individualized treatments to improve psychosocial function (Thomas et al., 2019), enhancing preventative health delivery, and impacting cancer morbidity and mortality rates as these high-risk individuals are mode adept in following their treatment or surveillance regimens as prescribed. The American Society of Clinical Oncology's (ASCO) 2003 (as cited in Lu et al., 2014) policy statement on genetic testing recommends testing under three conditions: the patient has a personal history suggesting genetic susceptibility, the test can be adequately interpreted, and test results will influence medical decision-making. To emphasize the importance of counseling, ASCO experts also recommended that testing "only be done in the setting of pre- and posttest counseling (Lu et al., 2014). In this project, I identified psychosocial issues and referrals were made during the pretesting counseling phase of the genetic testing process.

Integral to meeting triple aim initiative goals is aligning incentives for high-risk individuals undergoing GCRA, where the emphasis is on effectively managing and improving individual and population care. The ability to identify the individuals for whom more increased cancer surveillance is warranted may significantly reduce mortality from hereditary cancer syndromes, enable earlier diagnosis, drive treatment choices, and provide aggressive surveillance and prevention. In many cases, these early interventions can significantly reduce human suffering and health care costs (Moore & DeBuono, 2013). Per recommendations from the Institute of Medicine (IOM, as cited in Adler & Page, 2008), ACoS, ASCO, ONS, and NCCN,

the project's objectives included (a) implementing psychosocial screenings with the use of GPRI or SCSQ in high-risk hereditary individuals who presented for GCRA, (b) comparing the number of referrals elicited by both screening tools and choosing a psychosocial screening tool to be utilized during the GCRA process by oncology APRNs in clinical practice, and (c) increasing the number of psychosocial referrals in high-risk patients undergoing GCRA. Data collected from the GPRI and the SCSQ was analyzed inductively to understand better the patient's psychosocial well-being during the GCRA process at a community outpatient cancer care clinic in San Antonio, Texas.

Research Question

This project's primary concern was to implement and evaluate whether the Genetic Psychosocial Risk Instrument (GPRI) or the Supportive Care Screening Questionnaire (SCSQ) could help identify the psychosocial status of high-risk individuals undergoing genetic cancer risk assessments (GCRA) to ascertain which tool was more appropriate in prompting necessary psychosocial referrals. The PICO question was: For APRNs in the oncology setting who provide genetic cancer risk assessments, does the use of the GPRI tool compared to the SCSQ identify psychosocial concerns and prompt psychosocial referrals in high-risk individuals undergoing hereditary cancer screening?

- **P:** high-risk hereditary cancer patients
- **I:** use of the GPRI
- **C:** use of the SCSQ
- **O:** identify psychosocial needs and increase the number of psychosocial referrals

High-risk hereditary individuals were defined as adult individuals diagnosed with cancer, primarily breast, ovarian, colorectal, pancreatic, gastric, prostate, and melanoma cancers.

Individuals who have had multiple cancers occur in the same individual or have had cancer develop in paired organs (both breasts, both ovaries, both kidneys) are also high-risk (Stanislaw et al., 2016). Previvors who have family histories of these cancers, in either first-degree or second-degree relatives, or patients diagnosed with cancer before the age of 50, were also considered high-risk. Individuals with first-degree relatives with known cancer mutations and those who have had multiple individuals in a family who had the same type of cancer were also considered high-risk.

The Genetic Psychosocial Risk Instrument (GPRI) is a brief tool that is reliable and a valid instrument created to screen the psychosocial risk among adults undergoing genetic testing. The GPRI screening tool is designed for genetic testing services and is used to guide clinicians about which patients would benefit from added psychosocial support during the genetic testing process (Esplen et al., 2013). This tool has been validated as a psychological screening instrument for the genetic testing field. Most of the existing psychological screening tools do not consider the risk factors associated with heritable illness or genetic-related stressors (Esplen et al., 2013).

The Supportive Care Screening Questionnaire (SCSQ) is currently utilized at the researcher's clinical site to screen for distress only in patients with an existing cancer diagnosis. The SCSQ is a reliable and validated distress assessment tool that measures the psychometric properties of anger, loss of control, fear, and anxiety, and it pulls its reference from the ESAS and PHQ2 (Maamoun et al., 2013). My clinical site did not offer any psychosocial screening in patients undergoing GCRA. The study's three-month time frame was calculated based on having 30 study participants for the project, given that I typically saw one to three new genetic patients a

week. In three months, there were enough patients enrolled in this evidence-based project to meet the study goals.

Definition of Key Terms

Advanced practice registered nurses. A group of professionals, including nurse practitioners, who treat and diagnose illnesses, advise the public on health issues, manage chronic disease, and engage in continuous education to remain ahead of technological, methodological, or other developments in the field (American Nurses Association, 2020).

Comprehensive cancer risk assessment. A consultative service that includes clinical assessment, genetic testing when appropriate, and risk management recommendations delivered in one or more genetic counseling sessions (NCI, n.d.).

Genetic Psychosocial Risk Instrument. An instrument used to screen for psychosocial risk in individuals undergoing genetic testing for adult-onset hereditary disease (Esplen et al., 2013).

Hereditary cancer syndromes. These are gene changes or mutations that can be passed down from parent to child and increase a person's risk of developing cancer (University of Texas MD Anderson Cancer Center, n.d.).

Previvors. These are individuals with a genetic predisposition to develop cancer who may or may not have been tested for genetic predisposition or diagnosed with cancer (Dean & Davidson, 2018).

Psychosocial distress. This is a broad term that describes acute mental stress resulting from life circumstances or mental illness. Levels of distress are measured based on the severity of the symptoms and their impact on their daily lives (Jacob, 2013).

Supportive Care Screening Questionnaire. A tool designed after pilot testing at Texas Oncology to measure distress and unmet needs in the adult oncology population. It combines a patient's need assessment and the ESAS tool (Texas Oncology, 2020).

Conclusion

The current scope of nursing practice stipulates genetic and genomic literacy; however, there remains a deficit among APRNs identifying and addressing psychosocial distress during GCRA. Despite NCCN guidelines requiring all patients in the oncology setting receive a psychosocial risk assessment, high-risk individuals needing GCRA are not typically assessed. The literature review will reveal that the psychosocial impact of GCRA includes pressure, isolation, survivors' guilt, depression, anxiety, sadness, and cancer-related worries. These psychosocial problems can contribute to poorer adherence, functional impairment, and adverse medical outcomes. Acknowledging the psychosocial issues presented during the GCRA process and assisting patients in getting the help they need is paramount in improving the quality of care and providing comprehensive cancer care.

Chapter 2: Literature Review

This chapter was intended to provide a review of the literature used to guide this practice change project and allot evidence-based support to investigate the problem statement related to the project: Increasing psychosocial assessments in high-risk patients undergoing hereditary cancer screening. The PICO question was: For APRNs in the oncology setting who provide genetic cancer risk assessments, does the use of the GPRI tool compared to the SCSQ identify psychosocial concerns and prompt psychosocial referrals in high-risk individuals undergoing hereditary cancer screening? This study utilized an evidence-based approach to investigate whether the use of the GPRI compared to the SCSQ by APRNs in the oncology setting helped identify high-risk patients with psychosocial issues. The reporting aimed to prompt clinicians to address these patients' psychosocial issues and employ appropriate clinical interventions, which promoted better clinical outcomes.

Literature Search Methods

A search was conducted to find the highest evidence studies related to the PICO question utilizing meta-analysis, systematic reviews, and randomized clinical trials based on the established criteria. Keywords used to organize the search included *Genetic Psychosocial Risk Instruments, risk assessments in cancer and psychosocial state, identifying the psychosocial state in high-risk cancer patients, APRNs role in genetic cancer risk assessments, hereditary cancer syndromes and screening, cancer prevention, psychological distress in genetic screenings, psychological factors related to genetic testing, coping styles in cancer-related threats, uncertainty in hereditary cancer screening, unmet support needs in hereditary cancer screening, cancer genetic risk assessments and distress,* and *advanced practice nurses and genetic testing*. The leading search engines used were PubMed, Cochrane, Google Scholar, and CINAHL.

Current literature within the past 10 years (2010–2020) was sought unless the content included classic works related to conceptual frameworks. Furthermore, exceptions to the 10-year exclusion were limited to meaningful works that provided crucial background information.

Theoretical Framework

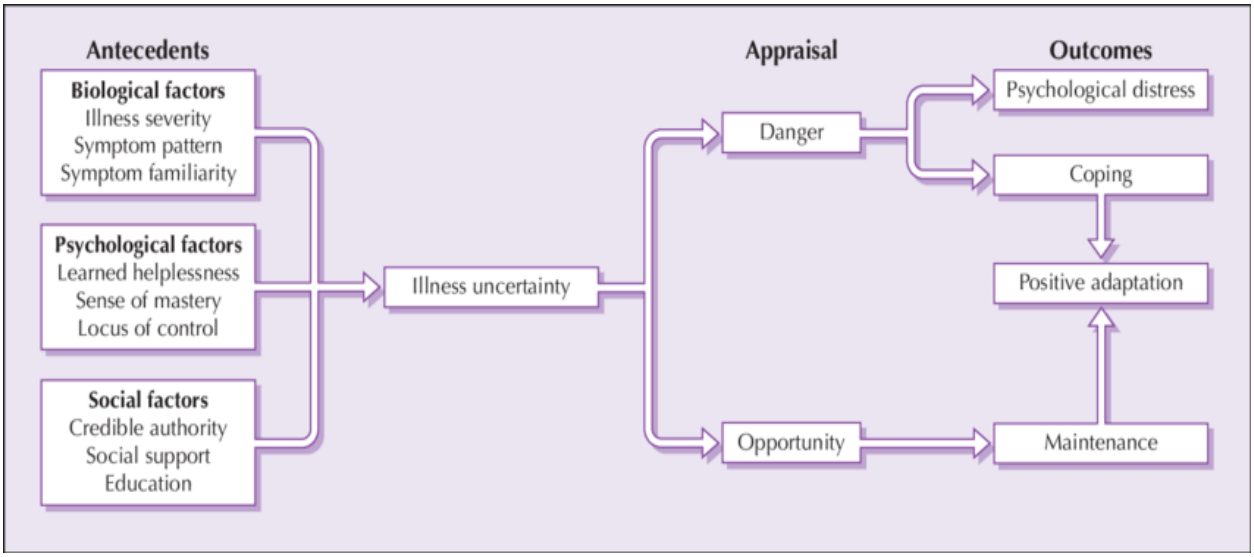
The theoretical framework for this study utilized the reconceptualized uncertainty of illness theory (RUIT) because uncertainty is still recognized as a fundamental construct in studying the patients' responses to coping with genetic testing (Tluczek et al., 2010). Mishel (1988) designed this middle-range theory and defined uncertainty as the "inability to determine the meaning of illness-related events which occurs in situations where the decision-maker is unable to assign definite values to objects and events and cannot accurately predict outcomes because sufficient cues are lacking" (p. 225). Uncertainty can motivate or be a barrier to pursuing genomic cancer testing. Appraisal of uncertainty influences the patient experience of uncertainty, the outcome of uncertainty for patients, and the coping strategies utilized (Bartley et al., 2020), which are critical during the genetic testing process. Mishel's (1990) RUIT furnished us with a theoretical framework explaining how uncertainty is generated and how it affects psychological adjustment to illness (Zhang, 2017). According to Dean and Fisher (2019), the theoretical features of RUIT are pertinent to understanding how uncertainty informs previvors' cancer risk management. The features include:

a. The nature of uncertainty (e.g., sources and antecedents).
b. Appraisals or assessments (and emotional responses) of the uncertainty.
c. Strategies or coping approaches to manage uncertainty (Dean & Fisher, 2019).

The RUIT model clearly indicates these features, as shown in Figure 1, displaying the concepts and their relationships, which form the basis for the theoretical and empirical material.

Figure 1

Antecedents and Outcomes of the Reconceptualized Uncertainty in Illness Theory



Note. Adapted from "The Illness Uncertainty Concept: A Review," by L. J. Wright, N. Afari, & A. Zautra, 2009, *Current Pain and Headache Reports*, *13*(2), p. 134 (https://doi.org/10.1007/s11916-009-0023-z). Copyright © 2009, Current Medicine Group.

Uncertainty in the hereditary cancer screening process can arise when patients contemplate their results, have prospective prophylactic procedures that are recommended if found to have a positive mutation, need subsequent treatments, provided survival chances, and have to relay positive mutations to other close family members. Assessing psychosocial risk during this period of uncertainty is crucial as it helps patients receive appropriate services and help them during this challenging process. The emotional experiences of individuals who receive genetic test results indicating a variant of uncertain clinical significance (a change in the genetic sequence with unknown cancer risks) may be even more complex (Hamilton & Robson, 2019). Bartley et al. (2020) noted that participants who received uncertain genomic results experienced a range of affective reactions to their results, including frustration, shock, regret, sadness, disappointment, and further uncertainty about the future. Patients' uncertainty about management

strategies may be to maintain, increase, reduce, or adjust to that uncertainty (Brashers, 2007). Research informed by RUIT suggested that patients appraising uncertainty as a danger will experience negative emotions and poor health outcomes (Clayton et al., 2018; Kang, 2006), whereas patients appraising uncertainty as an opportunity are likely to self-reflect on the situation and even restructure one's life and priorities. These appraisals inform their uncertainty management decisions (Mishel, 1990; Mishel & Clayton, 2008).

There is a need for nurses to be intricately involved in cancer genetics by targeting their efforts to understand the effect of uncertainty on patient care through teaching (Wallace, 2003). Uncertainty associated with a lack of knowledge about genetic counseling can create barriers to important screening behaviors. Advanced practice registered nurses who provide genetic cancer risk assessments (GCRA) can be instrumental in educating high-risk individuals about the importance, risks, and benefits of adhering to recommendations after testing and should be able to identify and address any psychosocial concerns that can limit adherence. This theoretical framework was chosen for the project because, in oncology, the degree of uncertainty of developing cancer in high-risk individuals is exceptionally high at pretesting because patients often grapple to perceive and understand their chances of developing cancer, especially if they have high-risk hereditary features. The "fear of the unknown" is a significant driving factor in the level of uncertainty before genetic counseling and testing and during the waiting period for results to come in. Mishel's (1990) reconceptualized uncertainty in illness theory suggests that uncertainty evolves, stating that the longer a patient lives with a chronic illness and continual uncertainty, the more positively they appraise their uncertainty. The appraisal of uncertainty as opportunity or danger is supported by RUIT, which states that the experience of uncertainty is neutral until the implications of uncertainty are determined by the patient (Mishel, 1990, p. 258).

Historical Overview

The ultimate goal of hereditary cancer screening is to reduce cancer mortality in individuals with genetic mutations by increasing screening and diagnostic interventions and paving the way for more tailored treatment plans in those who already have cancer. Though most individuals report satisfaction with gaining genetic information about themselves, negative affective consequences, such as anxiety, shock, guilt, and depression, have been reported for those identified as carriers (Evers-Kiebooms et al., 1994; Harris et al., 1996; Jung et al., 1994). Anxiety both during the GCRA visit and immediately after receiving positive carrier results has been reported (Bekker et al., 1994; Harris et al., 1996; Mennie et al., 1993). Although learning one's testing results may promote disease prevention efforts, health experts have expressed concern about potential adverse emotional, cognitive, and behavioral consequences of such knowledge (Lerman & Croyle, 1996; Lerman & Schwartz, 1993). Qualitatively oriented studies have identified several emotional responses to testing, including sadness, depression, relief, anxiety, and guilt (Biesecker et al., 1993). A threat of a genetic condition can elicit feelings and reactions that change family and intimate relations, decisions concerning childbearing and prophylactic surgery, perception of body image, self-esteem, and quality of life (Hutson, 2003).

A study of patients with colorectal cancer undergoing genetic testing for hereditary nonpolyposis colorectal cancer (HNPCC) indicated that the prevalence of depressive symptoms was 24%, as measured on the Center for Epidemiologic Studies Depression Scale (Vernon et al., 1997). The underlying levels of psychological distress in previvors and cancer patients undergoing hereditary cancer screening have been dramatically underestimated, as generalized by Pasacreta (2003), who summarized that available literature challenges a common notion that only individuals with a positive test result will need psychosocial services. Breast cancer patients

diagnosed less than one year ago demonstrated more cancer-specific intrusive thoughts before counseling. This group also had more genetic testing-specific intrusive thoughts before DNA test disclosure (van Roosmalen et al., 2003). It also appeared that women with children and the first family member to pursue genetic testing were more likely to be distressed. In Arver et al.'s (2004) study, there also tended to be higher levels of psychological distress over time in noncarriers than carriers. Cancer-specific distress was found in African American women undergoing BRCA (BReast CAncer gene) counseling and testing, and this distress was elevated with counseling participation regardless of testing participation (Thompson et al., 2002). Studies on previvors from high-risk cancer families who seek cancer genetic testing but are ineligible for it still have high levels of anxiety associated with the hereditary screening process (Meiser, 2005).

Psychosocial Screening in High-Risk Individuals

Assessing the psychosocial impact often provides clues about how the counselee and family may understand and cope with disclosing genetic testing information (Edwards et al., 2008; Pieterse et al., 2005; Pieterse et al., 2007). Individual coping styles, concern for other family members, high levels of distress before testing, a history of depression, having lost a relative to hereditary cancer, and having young children can all affect how well individuals cope with the information they receive after genetic testing (Lodder et al., 2001; Ritvo et al., 1999; van Oostrom et al., 2003; Wang et al., 2005). Research has shown that distress levels after receiving genetic test results depended on the coping style and not just on the positive or negative gene status; however, a prior cancer diagnosis experience can enhance the coping abilities of mutation carriers (Hallowell et al., 2004; Meiser et al., 2002; Tercyak et al., 2001). The researchers noted the need for future nursing research to help identify specific psychosocial

needs among different family members and specific psychosocial needs associated with different types of hereditary cancer syndromes. Other studies, however, have reported no differences in distress level between carriers and noncarriers, as highlighted in a study by Kinney et al. (2005), who noted that the hypothesis that mutation carriers, particularly women who had no personal history of breast carcinoma, were expected to report higher distress than noncarriers was not supported.

A systematic review of controlled trials and prospective studies examining the impact of genetic counseling for breast, ovarian, and colorectal cancer on a more comprehensive range of cognitive, affective, and behavioral outcomes disputed the notion that genetic counseling could lead to adverse psychological sequela (Braithwaite et al., 2006). The increased risk of developing cancer associated with positive genetic testing results may be experienced as traumatic by many patients. However, not all individuals with positive genetic testing results will experience increased distress, and studies should consider specific risk factors to select those who are more likely to need psychological support (Lombardi et al., 2019). Individuals at high risk for gastric cancer perceived a very high personal risk of cancer but reported low cancer worry levels. This paradoxical result may be attributed to participants' high levels of confidence in the effectiveness of screening. These findings highlight the importance for clinicians to discuss realistic risk appraisals and expectations toward screening with unaffected families at risk for gastric cancer to help mitigate anxiety and help with coping (Li et al., 2016).

Several studies have shown that counselees do not experience psychopathological levels of distress after DNA test result disclosure; however, it has not systematically been studied whether the absence of psychopathology also means that counselees do not want to receive help (Vos et al., 2013). In general, genetic counseling for cancer does not have serious adverse

psychological effects, but approximately 25% of counselees experience heightened levels of anxiety, depression, and distress during or after counseling (Eijzenga et al., 2014a). The literature on psychological outcomes of genetic test disclosure is conflicting. Some studies have evidence showing that mutation carriers showed an increased level of psychological distress, specifically, high levels of anxiety and depression, especially in the first months after test disclosure (Ringwald et al., 2016). In 2012, the American College of Surgeons (ACoS) Commission on Cancer (CoC) required accredited cancer centers to integrate psychosocial distress screening into cancer care by the end of 2015 (Ercolano et al., 2018).

Recommendation five of the National Society of Genetic Counselors practice guidelines notes that the genetics consultation should include extensive client resources, including scientific information, psychosocial support, and advocacy. Cancer risk assessments can raise several intellectual and psychosocial issues. High-risk individuals need to contend with an enhanced understanding of their specific cancer risks, potentially difficult decisions for managing their cancer risks, concerns about discrimination, and the worry about possible risks and reactions in their children and other family members (Berliner et al., 2013). Unmanaged psychosocial distress has a strong potential to impact morbidity and mortality negatively and exacerbate other comorbid conditions associated with cancer. Optimal distress screening procedures need to be based on patients' and families' self-report of their rating of psychosocial distress and the problems contributing to the distress (Ercolano et al., 2018).

Current Research Findings

Numerous studies have addressed improved patient outcomes resulting from distress screening in oncology settings, and cancer genetic risk assessment services help reduce distress, improve the accuracy of the perceived risk, and increase knowledge about cancer and genetics

(Garcia et al., 2007; Gentilello et al., 2005; Sivell et al., 2007). The impact of monitoring style on adjustment seems to be moderated not only by the characteristics of the threat (e.g., degree of uncertainty in the genetic context) but also by other personal factors (e.g., optimism), contextual variables (e.g., familial experience with cancer), and interpersonal variables (e.g., monitoring style of partner). Although more work needs to be done in this area, preparatory or psychoeducational interventions seem to improve adjustment and adherence to cancer health threats when the specific demands of the stressful situation are considered (Roussi & Miller, 2014).

Other studies have revealed that cancer risk perception seems to be influenced by cognitive, social, and cultural factors (Godino et al., 2016; Smith et al., 2008). Alternatively, other studies have reported that psychological distress, particularly cancer-specific distress, was significantly associated with refusal or withdrawal from genetic counseling, whether levels of distress were high or low (Cicero et al., 2017). Genetic results typically are either negative, positive, or uncertain, and in affected individuals, inconclusive test results are followed by a range of emotional reactions and misinterpretation of the test results. Individuals who have inconclusive results are considered a vulnerable group since they request counseling to gain certainty yet are left in uncertainty instead of the carriers who said they benefited from having an end to their uncertainty (Schlich-Bakker et al., 2006).

There exists a considerable body of literature on the emotional impact on the BRCA1 and BRCA2 testing results. Research suggested paying particular attention to a subpopulation (nonprobands, disease-free individuals) who, contrary to what is usually believed, may be particularly vulnerable to emotional suffering. Identifying appropriate interventions that target unmet needs among younger women and those with no confidante may reduce distress (Farrelly

et al., 2013; Hirschberg et al., 2015; Mella et al., 2017). In a patient-reported outcome study, Oberguggenberger et al. (2016) noted that certain subgroups of counselees were more vulnerable to distress, including counselees of older age, with a more recent cancer diagnosis or uncertainty regarding decisions. The researchers concluded that a detailed exploration of the strongest risk factors should be integrated into the counseling process and additional psychological support (Oberguggenberger et al., 2016). Recent studies focused on the psychosocial aspects of the hereditary cancer screening process as genetic testing is becoming more mainstream, especially in oncology. However, research regarding the psychosocial implications is new and limited. Comprehensive distress screening allows for the timely identification, evaluation, and management of psychosocial distress over the cancer experience. Distress screening tools and procedures may also result in the discovery of other medical or psychiatric comorbid conditions. This comprehensive support allows for the care of the "whole patient" (Ercolano et al., 2018, p. 492).

Evidence indicates that the use of psychosocial screening instruments among cancer patients results in reductions in emotional distress, increased quality of life, and improved patient-provider communication (Gentilello et al., 2005; Mystakidou et al., 2007; van Scheppingen et al., 2011; Vodermaier et al., 2009). Lammens et al. (2010) were among the first researchers to report the uptake and psychological impact of genetic testing for Li-Fraumeni syndrome (LFS), a hereditary cancer syndrome characterized by a high risk of developing cancer at various sites and ages. The study noted that a substantial minority of individuals exhibit clinically relevant distress levels that may warrant formal psychosocial intervention (Lammens et al., 2010). Several authors have recommended using a screening tool to identify psychosocial

risk in individuals undergoing hereditary screening (Eijzenga et al., 2014b; Esplen et al., 2013; Gopie et al., 2012; Lammens et al., 2010).

Previvors have higher levels of psychological distress than BRCA mutation carriers with breast cancer, nonmutation carriers with breast cancer, and nonmutation carriers without breast cancer (Dagan & Gil, 2005). If left unmanaged, uncertainty can contribute to poor decision-making (Mishel, 1999; Politi & Street, 2011; Wong & Bramwell, 1992) and negative health outcomes (Arora, 2003). Moreover, women who struggle with risk-related uncertainty are more distressed and are at risk of long-term distress (O'Neill et al., 2006). Women at risk for breast cancer face complex risk-related uncertainty for themselves and their families, and while women may have been initially motivated to do genetic testing to reduce their uncertainty about their cancer risk (Bylund et al., 2012), receiving positive BRCA genetic testing results still creates uncertainty coupled with negative emotions that may never dissipate (Dean, 2016; Hoskins & Greene, 2012; Hoskins et al., 2008; Westin et al., 2011).

Bartley et al. (2020) noted that the complexity of genomic testing introduces new scientific, practical, and personal uncertainties specific to this process, and the influence of the type of genomic result and participant uncertainty was mixed. While the quantitative synthesis showed no difference in uncertainty levels between participants who received positive, negative, or uncertain genomic results, the qualitative synthesis found decreases in disease and risk uncertainty for participants who received negative or positive genomic results but increased uncertainty about the future for participants receiving variance of uncertain significance (VUS) results. The researchers inferred that while reducing uncertainty can be a motivator for pursuing genomic testing, results can increase uncertainty.

A systematic review by Ringwald et al. (2016) investigating the psychological distress, anxiety, and depression in affected BRCA 1 or 2 mutation carriers noted that understanding the intermediate and long-term psychological consequences of genetic testing for cancer patients has led to encouraging research. However, a clear consensus of the psychosocial impact and clinical routine for cancer-affected BRCA1 and BRCA2 mutation carriers is still missing. The researchers noted that future studies should implement coping strategies, specific personality structures, the impact of genetic testing, supportive care needs, and disease management behaviors to screen for the possible intermediate- and long-term psychological impact of a positive test disclosure (Ringwald et al., 2016).

The Genetic Psychosocial Risk Instrument

The Genetic Psychosocial Risk Instrument (GPRI) is a validated tool used during hereditary cancer screenings. When developed and validated, researchers noted that the final 20-item GPRI had high reliability and Cronbach was 0.81. A high correlation supported construct validity. With a cutoff score of 50, the GPRI identified 84% of participants who displayed distress post genetic testing results, supporting its potential usefulness in a clinical setting (Esplen et al., 2013). The GPRI was developed to identify individuals liable to experience significant difficulty adjusting to the genetic information they receive. As such, the GPRI appears to be a better choice at face value than general anxiety measures for clinicians who wish to determine whether clients need additional professional support in the wake of genetic testing (Esplen et al., 2013). The tool was designed to be completed within 10 minutes.

The Supportive Care Screening Questionnaire

The supportive care screening questionnaire was created in 2015 by my clinical organization’s social workers and APRNs to address the Oncology Care Model (OCM)

requirement of the IOM care plan. It is a reliable, validated distress assessment tool that measures the psychometric properties of anger, loss of control, fear, and anxiety in the oncology setting. The tool was designed to be completed within 10 minutes.

Chapter Summary

Advanced practice registered nurses proved to be equally effective in providing education about genetic testing compared to genetic counselors (Bernhardt et al., 2000). Public genomic literacy levels are increasing, in part due to celebrity-driven attention to genetic conditions, increased use of social media, direct-to-consumer marketing of genetic testing, and the promise of personalized medicine and targeted therapies for a variety of conditions (King & Smith, 2020). Genetic tests should be proposed along with proper psychological support and counseling focused on users' genetic health literacy, perception of risk, beliefs about disease controllability, and foster fruitful medical decisions (Oliveri et al., 2018). Referral to psychosocial professionals may be improved by discussing psychopathology during genetic counseling sessions and other needs and existential concerns (Vos et al., 2013). Consideration of coping strategies, the impact of genetic testing, or disease management behavior should be implemented in clinical practice to clear screen for the possible intermediate- and long-term impact of a positive test disclosure status. Much of what is known about cancer patients' psychosocial issues related to genetic or genomic testing is from an overrepresented female and breast cancer perspective. Similarly, most research investigating patient uncertainty concerning cancer genomic has focused on females with a personal or family history of breast cancer, highlighting a bias in the literature and a need for future research to include a more diverse range of cancer patients (Dean & Fisher, 2019).

In patients undergoing cancer risk assessments, there seems to be a certain percentage within this group that experience heightened anxiety, depression, or distress during or after

counseling. However, this literature review was conflicting as some studies evidenced that mutation carriers showed an increased level of psychological distress, categorically, high levels of anxiety, and depression, while other studies refute that claim. Distress screenings by APRNs working in oncology in patients undergoing genetic counseling and testing are paramount in treating the patient holistically as it allows for the timely identification, evaluation, and management of psychosocial distress during the risk assessment and evaluation period. Evidence indicated that using psychosocial screening instruments in high-risk individuals resulted in reduced emotional distress, increased quality of life, and improved patient-provider communication (Cunningham et al., 2018). Unmanaged psychosocial distress has strong potential to impact both morbidity and mortality resulting from nonadherence to treatment or surveillance regimens and poor decision-making, as studies have highlighted adversely.

Chapter 3: Research Method

This chapter introduces the research methodology used in this quantitative study using the Genetic Psychosocial Risk Instrument (GPRI) and the Supportive Care Screening Questionnaire (SCSQ) in identifying high-risk hereditary patients needing psychosocial support while undergoing genetic counseling and screening. The study utilized an evidence-based initiative by implementing either the GPRI or SCSQ tools to evaluate whether these tools could help identify the psychosocial needs in high-risk patients undergoing genetic cancer risk assessments (GCRA) by APRNs in the outpatient oncology setting. The project's main goal was to identify high-risk individuals who needed psychosocial screening and refer them appropriately by implementing either the GPRI or SCSQ. The applicability of this quantitative approach for this study is discussed in-depth in this chapter. The research plan, including the methodology, study participants, procedures, and analysis method, is also a primary component of this chapter. The research question was: For APRNs in the oncology setting who provide genetic cancer risk assessments, does the use of the GPRI tool compared to the SCSQ identify psychosocial concerns and prompt psychosocial referrals in high-risk individuals undergoing hereditary cancer screening?

Purpose

This evidence-based project's goals were to (a) identify psychosocial issues while screening in high-risk individuals, (b) align genetic cancer screening recommendations in high-risk individuals by improving psychosocial management plans, (c) implement and compare two psychosocial screening tools (GPRI and SCSQ) to determine the appropriate tool to utilize in this population, and (d) increase shared decision-making referrals based on individual risk factors. Outcome measures were reflected (a) based on the number of study participants who had

identifiable psychosocial needs and (b) on the increase in the number of psychosocial referrals in high-risk individuals undergoing GCRA at a community oncology care clinic in a major city in Texas. Because this study was designed to examine the use of the GPRI tool or the SCSQ concerning the number of psychosocial referrals in individuals undergoing genetic screening, a quantitative approach was the most appropriate choice. The single reality this study assumed was that those high-risk patients undergoing hereditary cancer screening who needed psychosocial services had to be identified and referred appropriately during the screening process.

Project Design

This evidence-based project utilized a quantitative comparative design with a convenience sample. Once high-risk individuals were self-referred or were referred for GCRA, the clinic schedulers notified me, and I determined if any of these patients met study criteria by assessing their medical records. If they met the criteria, I would notify the schedulers, who then made the GCRA appointment and emailed a genetic testing packet. The packet included a patient welcome letter, family health questionnaire, frequently asked questions (FAQ) sheet, family fact sheet, force brochure (asking the question, Is the cancer in your family hereditary?), and the Genetic Information Nondiscrimination Act (GINA) and You information sheet. For this DNP project, the packet also included a cover letter on the purpose of the research study (see Appendix A), my name, how the information was going to be used, any potential benefits or harm the participant could expect, what would happen with the information they shared, and the informed consent form (see Appendix B). When the high-risk patients came in for their GCRA visit, I reviewed their consent, asked if they had any questions, and explained the study's purpose before signing the consent form. The GPRI (see Appendix C) or SCSQ (see Appendix D) was

then administered. Based on their GPRI score or SCSQ needs, I referred them appropriately to a social worker, chaplain, counselor, psychologist, or psychiatrist.

The first unit of analysis included findings from an audit on all study participant charts and the results of their psychosocial screenings. Demographic data collected included age, race, gender, education, and a known cancer diagnosis. The second unit of analysis included data from the GPRI questionnaire. The validated GPRI questionnaire had 20 questions, with 19 of these questions having assigned scores. If the score was 50 or greater and question 19 was positive, a psychosocial referral was recommended (Esplen et al., 2013). The third unit of analysis included data from the SCSQ, which had two parts. Part A addressed the emotional, social, practical concerns, and Part B addressed depression symptoms. There were two indicators used to measure the outcomes of the project from the identified participants. The first measure was the number of referrals generated from the GPRI tool, and the second measure was the number of psychosocial referrals elicited from the SCSQ tool during GCRA.

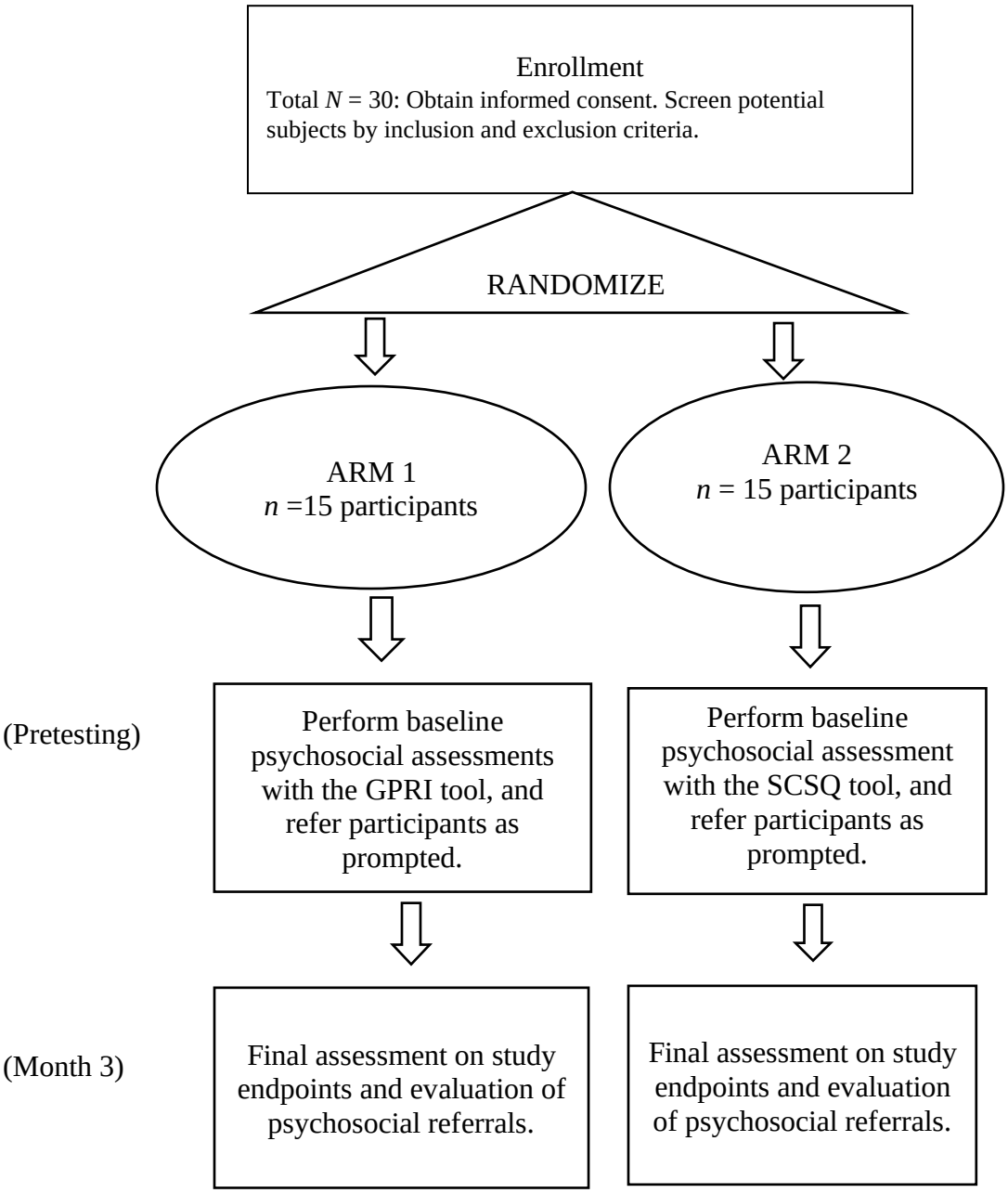
Once the institutional review board (IRB) applications were approved by Abilene Christian University (ACU; see Appendix E), clinic (see Appendix F), and the project chair, Dr. Aboul-Enein, work began by screening potential study participants from the GCRA referrals. I assumed responsibility for these project activities, which entailed educating the front desk and medical assistants and scheduling staff on study objectives, attaining participants' consents, executing quantitative measurement scales, and disseminating the results into practice. Key stakeholders for this project at this community oncology clinic included the four practice medical oncologists, the region practice manager, the regional nursing manager, I the APRN and the administrative manager.

Since the project utilized convenience sampling, every prescreened potential GCRA referral participant who met study criteria was again informed of the study's purpose and had all their questions answered before consent. Once consent was obtained, the GPRI or SCSQ was administered to the study participants in the privacy of the examining room by me during the pretesting GCRA phase. Any participant whose score was greater than 50 on the GPRI questionnaire and any participant who expressed interest in talking with a counselor about their psychosocial concerns was referred appropriately. On the SCSQ, any participant interested in getting supportive care was also referred to a social worker, counselor, psychologist, or psychiatrist.

I collected and compiled data at baseline and utilized a face-to-face interview at the pretesting phase of the GCRA visit. Three months after study implementation, data obtained from both tools was reviewed and analyzed to disseminate results. This data included (a) the total number of patients screened using the GPRI and the total number of patients screened with the SCSQ, (b) the total number of patients who required additional psychosocial services based on the screenings with either the GPRI or SCSQ, and (c) the total number of patients who received psychosocial referrals (see Figure 2). Additional data was also collected, including patient age, gender, ethnicity, education, and whether the patient was a previvor or had an existing cancer diagnosis.

Figure 2

Study Design Schema



Methodology Appropriateness

This evidence-based project measured the key indicator: the number of referrals generated from either the GPRI or the SCSQ tools. A systematic probability convenience

sampling, which was randomized, was utilized in this study. The project design had two arms. Study participants in arm one had their psychosocial status assessed utilizing the GPRI tool, and those in arm two were assessed with the SCSQ tool. To meet the study objectives, data from this project was quantified based on the interpretive research approach, a quantitative research method best suited for this project. Confounding variables included the subject's negative perception of the referral process if psychosocial issues were identified. Data collection in this evidence-based project was collected via a nonprobability sampling because of feasibility issues related to time.

Feasibility and Appropriateness

I currently practice in an outpatient oncology clinic in a major city in Texas. The clinical site participates in the Genetic Risk Evaluation and Testing (GREAT) program, which provides in-depth cancer risk evaluations by trained APRNs. In the current clinical setting, psychosocial concerns are not addressed in high-risk individuals undergoing genetic testing. Participants were self-referred or provider referred for genetic counseling services under the GREAT program. The GREAT program was implemented in January 2019 at the investigator's outpatient oncology clinic, which sees an average of 15 new high-risk hereditary patients each month. Since program implementation, I have seen 154 high-risk hereditary cancer patients and has established a high-risk cancer clinic. Outcome achievability was obtainable through the applications of a statistical approach that validated the use of quantitative measurements. There were no associated financial costs obligated to the organization for the support of this project.

IRB Approval and Process

The IRB board of ACU and the IRB board at my clinical site granted permission to conduct this DNP project titled "Assessing Psychosocial State in High-Risk Individuals

Undergoing Genetic Screening." Dr. Faisal Aboul-Enein (chairperson) supervised me. ACU's training process included the National Institutes of Health (NIH) Protecting of Human Subjects and Research Participants Training and Ethics completed within the preceding months before initiating the project. The date of completion was September 8, 2020 (see Appendix G). The good clinical practice and human subjects training was required by my clinic and completed on November 21, 2019 (see Appendix H). A comprehensive introduction to ethics and human subject protection course offered by the association of clinical research professionals (ACRP) was completed on February 4, 2021 (see Appendix I) as part of my clinic's IRB approval requirement. Data from all participants was anonymized, and no participants were identified by name or any other manner during or after the study.

Interprofessional Collaboration

Consultation with scholarly authors was obtained during this project with permission from Dr. Mary Jane Esplen, whose GPRI tool was utilized, and Dr. [redacted] (see Appendix J), registered nurses who helped develop the SCSQ for my clinical practice. Collaboration with psychologists and counselors at the San Antonio Counseling and Behavioral Center (SACB), licensed social worker Rebecca Clinton MSW, LCSW, and psychiatrist Dr. Mark Drogin. Collaboration with this interdisciplinary team was crucial in coordinating and developing this project.

Practice Setting

This project's study and implementation were completed at a community clinic in Texas. The clinic is an outpatient cancer center with four medical oncologists and two APRNs. The clinic offers a robust array of leading-edge treatment options in cancer care, including chemotherapy and immunotherapy treatments. The APRNs perform all treatment review and

coordination (TRC), advance care planning (ACP), survivorship visits, and genetic cancer risk assessments (GCRA). The clinic is part of a larger physician-led network and has 210 locations throughout Texas and Southeastern Oklahoma, with 500 physicians across Texas and 162 mid-level providers. One hundred four of the mid-level providers participate in the GREAT program. The regional practice director granted permission to utilize this clinic for the proposed project (see Appendix K).

Target Population

The target population included high-risk individuals diagnosed with cancer, primarily breast, ovarian, colorectal, pancreatic, gastric, prostate, and melanoma cancers. The participants included previvors who had family histories of these cancers in either first-degree or second-degree relatives, patients and their previvors diagnosed with cancer before the age of 50, and patients who had family members with first-degree relatives with known cancer mutations. High-risk individuals also included previvors with multiple individuals in a family who had the same cancer, patients or those who have had cancer develop in paired organs (both breasts, both ovaries, both kidneys), and patients who have had multiple cancers occur in the same individual. Subject diversity was preferred. Patient participants were limited to those who were English speaking only. Exclusion criteria included current oncology patients who did not have primarily breast, ovarian, endometrial, colorectal, pancreatic, gastric, prostate, and melanoma cancers, patients with mental disorders, and patients referred for post GCRA visits without pretesting by a trained genetics APRN.

Risks and Benefits

There were minimal anticipated risks associated with this study's implementation, from consent procedures, data collection, data measurements, evidence dissemination, and translations

into practice. There were no preconceived benefits, including no monetary compensation or rewards for participating in the study. Research participants remained anonymous and only identifiable with a unique identification number given at the study initiation. All ethical principles were maintained. There were no identified conflicts of interest in this study. This study's limitations included unforeseen time constraints, small population size, patient mortality, and individuals who had been referred for post counseling results without pretest. The sample population was a convenience sample, potentially weakening the internal and external validity of the study. The sample population was small, potentially affecting the significance of the findings.

Instruments and Measurement Tools

Demographic data for study participants included age, ethnicity, gender, education, and cancer diagnosis. I administered to each study arm the GPRI and the SCSQ at the end of the GCRA visit. The demographic data, GPRI score, SCSQ information, and data of kind of referral placed were then inserted in a data analysis tool in Microsoft Excel. After the three-month study period, a review on the number of psychosocial referrals elicited by each tool was made. I chose this measurement tool because it is a nonintrusive strategy for collecting data and speed of review. The tool is also practical, inexpensive, and effective.

Data Collection

During the project timeline and implementation (see Table 1), personal identifiers, including gender, ethnicity, age, race, type of cancer, and cancer treatment type, were documented. There was no preintervention data on the psychosocial referrals as psychosocial assessments were not currently conducted for high-risk individuals undergoing GCRA with the APRNs. The GPRI has 20 questions, the SCSQ has two parts, and I administered either questionnaire during the pretesting GCRA visit. Appropriate referrals were ordered in the

IKnowMed G2 system based on elicited answers, and data was accessible in real-time. Postintervention data points included the total number of high-risk individuals seen by the investigator for three months, the total number of GPRI and SCSQ administered, the total number of positive psychosocial screenings, and the total number of referrals elicited by each tool for a total of three months of data collection.

Table 1

Project Timeline

Scholarly project milestone(s) completed	Month/year completed
Letter of support received from the Practice Site	05/2020
PICO developed and completed	06/2020
Theoretical framework paper completed	06/2020
Chair/committee members secured for the project	06/2020
Mini proposal approved	07/2020
EBP tool (GPRI) permission email received from the author	08/2020
Chapters 1–3 revisions completed, reviewed by chair and committee members	10/2020
Proposal defense	11/2020
IRB proposal for Abilene Christian University	01/2021
IRB proposal for clincal site	02/2021
Secured IRB proposal	02/2021
Project implementation (three months)	03/2021
Project analysis for Chapters 4–5	07/2021
Chapters 4–5 revisions completed, reviewed by chair and committee members	09/2021
Final project defense	09/2021

Participants' privacy was protected, and any identifying information was redacted from the recordings. The identified data collected during this project was stored in a secure university password-protected drive under the researcher's name. The university will own data in case access is needed at a future date. This storage system was provided by the online graduate school for doctoral student research data and supported by the university's information technology (IT) department for security purposes and kept for the minimum required time according to IRB guidelines. Outcomes were measured by determining the number of referrals to other health care providers as needed, including social workers, psychiatrists, psychologists, or counselors.

Analysis Plan

The Statistical Package for the Social Sciences (SPSS) was used to perform a descriptive analysis of the data, and the Pearson chi-square was chosen to determine whether there were any variances between the two groups being compared (high-risk patients subjected to the GPRI screening tool versus high-risk patients subjected to the SCSQ tool). Data was transferred directly from an Excel spreadsheet into the SPSS software. The null and the alternative hypothesis were:

H*0*: There will be no difference in the number of referrals made to social workers, psychiatrists, psychologists, or chaplains in high-risk individuals subjected to the GPRI versus those subjected to the SCSQ tools.

H*1*: The GPRI screening tool will identify more psychosocial concerns compared to the SCSQ in high-risk individuals undergoing hereditary cancer screening, which will prompt more referrals to social workers, psychiatrists, psychologists, or chaplains.

The Pearson chi-square test was utilized with an alpha of 0.005, as I determined whether there is an association between the choice of the screening tool and the number of referrals generated using a bivariate table. Cross-tabulation presented the distributions of the GPRI and SCSQ with three variable intersections of "accepted referral, declined referral, or did not need a referral." Recording of study data was recorded on an Excel spreadsheet with both variables identified by the investigator. A nonprobability sample was chosen because of feasibility issues related to time and costs to obtain a random sample at this oncology clinic. The sample size depended on the availability of newly referred and current patients, but the aim was about 15 participants total in both groups. The G*Power to conduct a priori power analysis to calculate sample size was computed. For a power of 0.80 with an alpha of 0.005 and a moderate effect

size, it was determined that a sample of 30 patients was needed. An additional 10% was added to account for attrition for patients who declined participation, bringing the total sample required to 30 patients. A unique participant identification number was allocated at baseline.

Chapter Summary

The role of the DNP defined by Essential II of the Essentials of Doctoral Education for Advanced Nursing Practice requires proficiency "in quality improvement strategies and in creating and sustaining changes at the organizational and policy levels" (American Association of Colleges of Nursing, 2006, p. 10). This study tried to ascertain whether the GPRI tool in high-risk individuals undergoing hereditary cancer screening would help identify those patients needing psychosocial services. The study participants had been referred to undergo genetic counseling and testing services at an outpatient community cancer center in a major city in Texas. Inclusion and exclusion criteria were applied, and the quantitative analysis project design supported the study methodology. No time constraints were identified with the project development, and all requirements were met before IRB approval. The estimated timeline for completion was three months.

Chapter 4: Findings

This chapter presents the results of the data analysis, including the quantitative survey results. This evidence-based project utilized a quantitative comparative design. It evaluated the efficacy of the Genetic Psychosocial Risk Instrument (GPRI) and the Supportive Care Screening Questionnaire (SCSQ) in identifying the psychosocial needs of high-risk individuals undergoing genetic cancer risk assessments (GCRA) by advanced practice registered nurses (APRNs) in the community oncology setting. This research design was more desirable as I) tried to ascertain a linear relationship between the two quantitative variables (GPRI or SCSQ) in psychosocial risk identification. The research study fulfilled the two assumptions required to analyze data with the Pearson chi-square test in that both questionnaires (independent variables) and the number of psychosocial referrals (dependent variable) were measured at a nominal level. Secondly, both the independent and dependent variables had two or more independent groups. The independent variable groups that met this criterion were the use of the GPRI or the SCSQ tools, and the dependent group that met this criterion was the number of study participants who either accepted, declined, or did not need a psychosocial referral.

The study utilized a systematic convenience sample of 30 participants randomized in two arms to receive either the GPRI or SCSQ. The number of psychosocial referrals elicited by the GPRI or SCSQ was tabulated at the end of the three-month study period. The demographics are described, and key findings are highlighted. The project data was collected from March 12, 2021, to June 24, 2021. Forty-two participants were screened, and 33 potential study participants met the study criteria, with three declining participation.

Purpose of the Project

This DNP quality improvement project's overall aim was to improve psychosocial screening practices, implement and compare two psychosocial screening tools to help identify psychosocial concerns, and increase psychosocial referrals in high-risk individuals undergoing genetic testing at a community outpatient oncology clinic in Texas.

The goals of this study were:

a. to identify psychosocial risk factors in individuals with heightened cancer risk;
b. to improve psychosocial management plans and increase shared decision-making referrals based on individual risk factors; and
c. to determine the appropriate psychosocial risk tool to utilize in the community oncology setting.

Administering either the GPRI or SCSQ psychosocial risk assessment tools at the initial GCRA visit by the APRN helped identify study participants who needed additional psychosocial support. These patients were then referred to a social worker, counselor, psychologist, or APRN for advanced care planning or psychiatrist based on their scores on the GPRI or answers on the SCSQ. The psychosocial concerns noted on the SCSQ were fear, worry, anxiety, sadness, feeling like a burden to others, support for children and teens, support for the caregiver, insurance, needed help with advanced care planning (ACP), and guidance with social security. On the other hand, the psychosocial concerns that the GPRI tool identified in this study included guilt, sadness, nervousness, anxiety, relationship worries about potential genetic results, worries about children, worries about professional careers, daily mood, guilt about passing on disease risk to children, and problems in life arising from genetic results. Study outcomes were observed after

administering the two questionnaires and included the results from the total number of study participants who needed psychosocial referrals in both the GPRI and SCSQ groups.

Demographics

From March 2021 through July 2021, 42 participants referred for genetic counseling were screened, and 30 of them met the criteria for study participation. The participants' ages ranged between 22 and 78 that were referred for GCRA with me.. The median age of the participants was 47. The sample size included 30 patients, of which 16.7% were male, and 83.3% were female. The participants were 10% African American, 53.3% Caucasian, and 36.7% Hispanic. With respect to scholarship, 16.7% of the study participants had a high school diploma, 13.3% had a certificate, 10% had an associate's degree, 36.7% had a bachelor's degree, and 23.3% had a master's degree. Previvors comprised 56.7% of the study participants, and 43.3% had a cancer diagnosis. Of the 43.3% who had a cancer diagnosis, 15.3% had colon cancer, 23% had rectal cancer, 7.6% had testicular cancer, 23% had breast cancer, and 7.6% had a history of Hodgkin's lymphoma. Twenty-three percent of the study participants comprised one male and two females who had more than one cancer diagnosis. The first female had breast and pancreatic cancer, the second female had breast, uterine, and pancreatic cancers, and the male participant had prostate and pancreatic cancers.

The targeted facility was an outpatient oncology clinic in a major city in Texas and the project was conducted during regular clinic hours, Monday through Friday. The reason for choosing this site was that the study group consisted of high-risk individuals who were either self-referred or referred by other health care providers based on their type of cancer or family history. The project implementer was her own support service, explaining and obtaining the informed consent, administering the questionnaire, and analyzing the data.

Data Analysis

I utilized the SPSS version 20.0 software program for statistical analysis and obtained frequencies, percentages, mean and standard deviation (SD) to describe the sociodemographic and clinical characteristics. A dichotomous variable was generated for the GPRI and the SCSQ screening tools, grouping "accepted referral, declined referral, or no referral needed" categories. The Pearson chi-square analysis was employed to determine and compare any relationship between the variables of the two instruments simultaneously. The Pearson chi-square was used in this study because (a) the independent variable (questionnaire) and dependent variable (psychosocial referrals) were measured using a nominal scale, and (b) both the independent and dependent variables had two more categorical independent groups. In this study, the independent variable, which was the use of the questionnaire, contained either the GPRI or SCSQ group. The dependent variable was the psychosocial referrals that had grouped variables as "accepted referral," "declined referral," or "no referrals needed." Since fewer than five expected cases were in the 2x2 cells, Fisher's exact test was used (Plichta & Kelvin, 2015).

Questionnaire comparison revealed that the GPRI detected 10 patients with psychosocial needs, four of whom declined psychosocial referral compared to 11 identified patients in the SCSQ arm, five of whom declined psychosocial referrals. However, an equal number of patients, 40% in both the GPRI and SCSQ arms, accepted psychosocial referrals to social workers, counselors, and psychiatrists. One-third of those in the SCSQ arm declined referrals even when clinically appropriate compared to 26.7% in the GPRI arm. One-third in the GPRI arm did not need referrals compared to 26.7% in the SCSQ arm. Pearson chi-square analysis revealed χ (1) = 1.222, p = .895, so there was no statistically significant association between referrals and assessment tools.

Table 2 represents the association between the use of the GPRI or SCSQ and the referral the tools elicited. The number of psychosocial referrals increased from 0%–40% during this project implementation phase in high-risk individuals subjected to the GPRI versus those subjected to the SCSQ tools. Counselors and social workers received the most referrals out of all specialty resources personnel.

Table 2

Referral and Questionnaire Cross-Tabulation

Referral type	Count	Questionnaire		Total
		GPRI	SCSQ	
Accepted Referral	Count	6	6	12
	Expected Count	6.0	6.0	12.0
	% within Questionnaire	40.0	40.0	40.0
Declined Referral	Count	4	5	9
	Expected Count	4.5	4.5	9.0
	% within Questionnaire	26.7	33.3	30.0
No Referral	Count	5	4	9
	Expected Count	4.5	4.5	9.0
	% within Questionnaire	33.3	26.7	30.0
Total	Count	15	15	30
	Expected Count	15.0	15.0	30.0
	% within Questionnaire	100.0	100.0	100.0

Table 3 represented the descriptive analysis with the Pearson chi-square analysis, which revealed $\chi(1) = 1.222$, $p = .895$. There was no statistically significant association between referrals and assessment tools. The null hypothesis was accepted as the *p*-value (.895) and was greater than the alpha (.005). The null hypothesis noted that there would be no difference in the number of referrals made to social workers, psychiatrists, psychologists, or chaplains.

Table 3

Descriptive Statistics: Chi-Square Tests

Variable	Value	*df*	Asymptotic Significance (2-sided)
Pearson Chi-Square	.222[a]	2	.895
Likelihood Ratio	.223	2	.895
Linear-by-Linear Association	.047	1	.829
N of Valid Cases	30		

Note. a. Four cells (66.7%) have expected count less than 5. The minimum expected count is 4.50.

Reliability and Validity

I personally applied the two instruments utilized in this project during the first appointment. The time required to complete the evaluation was 10 minutes for each instrument. With a cut-off score of 50, the 20-item GPRI has good reliability and validity as it identified 66.6% of study participants who had psychosocial risk factors who needed psychosocial referrals. These findings supported the GPRI's potential usefulness in the outpatient clinical setting. The SCSQ two-part questionnaire with 22 items based on six factors also had good reliability and validity. It identified 73.3% of study participants who had psychosocial risks and needed psychosocial referrals.

Chapter Summary

The current scope of nursing practice stipulates genetic and genomic literacy. In the advent of APRN-run high-risk hereditary cancer clinics, APRNs play a crucial role in evaluating individuals who have an increased risk of developing cancer, providing comprehensive health education, and importantly individualizing recommendations based on risk. This study's findings

revealed that in high-risk individuals undergoing GCRA, 70% needed additional psychosocial support beyond a medical assessment. Advanced practice registered nurses play a crucial role in screening and addressing the psychosocial issues associated with GCRA and must evaluate these needs and make appropriate referrals as needed. According to Pasacreta (2003) and Voorwinden and Jaspers (2016), approximately 10%–25% of counselees experienced heightened levels of distress during and after the genetic counseling process, but genetic counselors often failed to recognize and address these issues since they tend to be more focused on gathering and giving medical information (Meiser et al., 2008). They also lacked the appropriate tools to assess the specific psychosocial problems and distress levels experienced by counselees.

Among the adverse psychological responses identified in this study, the most frequent included worry about the possibility of having a genetic mutation, worry about passing the genes to their children, stress about personal relationships, sadness, fear, guilt, depression, anxiety, and uncertainty. Forty percent of patients accepted their psychosocial referrals to counselors, psychologists, and psychiatrists, indicating a need to correctly identify these patients and refer them appropriately in the community oncology setting. Secondly, engaging patients in decision-making, particularly on their psychosocial concerns as it relates to the GCRA process, is essential as it helps these patients have possible psychosocial benefits such as relief from uncertainty, a satisfaction of curiosity, relief of guilt, improved family supports, and optimistic empowerment (Wade, 2019). It is well understood that effectively engaging patients in their care is essential to improve health outcomes, improve satisfaction with the care experience, reduce costs, and even benefit the clinician experience (Krist et al., 2017). Both the SCSQ and GPRI questionnaires effectively identified the psychosocial needs in this high-risk patient population. Chapter 5 includes a discussion of the interpretations, inferences, and implications of the study

findings. Recommendations for APRNs who provide high-risk hereditary cancer screening services and recommendations for future research will also be addressed.

Chapter 5: Discussion of Findings

The purpose of this project was to evaluate psychosocial risks in high-risk hereditary cancer patients undergoing genetic cancer risk assessments (GCRA) by oncology APRNs in the outpatient community setting. Genetic screening for inherited cancer risk is an uncomplicated test in its execution, but it holds compelling information for individuals and their families regarding health and illness across the lifespan. Indeed, the psychosocial issues that arise from genetic testing interact with elements of individual personalities and cognitive capacity affecting relationships with others, striking at the core of an individual's identity (Wasserman, n.d.). The Genetic Psychosocial Risk Instrument (GPRI) and the Supportive Care Screening Questionnaire (SCSQ) were utilized as psychosocial assessment tools in this study. This chapter discusses the interpretation and inference of the findings and implications of the analysis for leaders relevant to the study results. Recommendations are presented for APRNs who provide high-risk hereditary cancer screening services and recommendations for future research.

This project determined that in high-risk individuals undergoing GCRA, 70% had identifiable psychosocial needs, and 43% of these patients were willing to get additional psychosocial support to address these needs. It has been reported that low social support and a personal or familial history of cancer are risk factors for anxiety (Eijzenga et al., 2014a). This is important because anxiety levels have been associated with decision-making, compliance to screening methods, and risk-reduction measures (Hart et al., 2012). As a result, oncology APRNs who perform GCRA must identify the psychosocial needs of all individuals participating in high-risk hereditary cancer screening, including making appropriate support referrals when identified. The literature review revealed that individuals undergoing GCRA had been shown to benefit

from additional psychosocial support as it helps reduce treatment nonadherence or surveillance regimens and improved decision-making.

Currently, there are only two validated psychosocial screening tools specific for hereditary cancer screening: the Genetic Psychosocial Risk Instrument (GPRI) and Psychosocial Aspects of Hereditary Cancer (PAHC) questionnaire. To measure study outcomes, the SCSQ was selected for this study because it is a supportive screening questionnaire that pulls reference from the validated Edmonton Symptom Assessment Scale (ESAS) and validated Patient Health Questionnaire-2 (PHQ2). Also, the SCSQ is currently being utilized at the clinical site and systemwide at [redacted] to assess psychosocial needs in patients undergoing cancer treatment only. It is not utilized in GCRA visits. The second instrument, GPRI, was chosen because it is a validated tool and the first reported psychosocial screening instrument used for adult-onset hereditary disease (Esplen et al., 2013). Another validated tool for use in this study was the Psychosocial Aspects of Hereditary Cancer (PAHC) questionnaire developed by Eijzenga et al. (2014b). This questionnaire was considered but not chosen because the authors had recommended that it be used in combination with the distress thermometer. Most of the psychosocial screening tools like the Patient Health Questionnaire-9 (PDQ9), Hamilton Depression (HAM-D) rating scale, and Hamilton Anxiety (HAM-A) scale were not specific to GCRA and were not oncology or high-risk cancer screening specific.

Interpretation and Inference of Findings

This project showed that a certain percentage of patients undergoing hereditary cancer risk assessments experienced heightened anxiety, depression, guilt, worry about the risk of disease and passing down genes to their children, fear about illness if positive, relationship worries, or distress during or after genetic counseling. This is important because it has been

demonstrated that the application of either the SCSQ or the GPRI questionnaires provides greater understanding and sensitivity to identify psychosocial alterations in high-risk individuals undergoing hereditary cancer screening. It has been reported that low social support and a personal or familial history of cancer are risk factors for anxiety (Eijzenga et al., 2014a). Anxiety levels have been associated with decision-making, compliance to screening methods, and risk-reduction measures (Hart et al., 2012). The high-risk hereditary cancer population has been shown to benefit significantly from additional psychosocial support referrals as needed during this process. Therefore, oncology APRNs who perform hereditary cancer risk assessments must identify the psychosocial needs of all individuals participating in high-risk hereditary cancer screening, including making appropriate support referrals when identified.

There was a correlation between the variables evaluated by the GPRI and SCSQ, and study results suggest that cancer-related worries, guilt, anxiety, and depressive symptomatology affect the well-being of these high-risk individuals. These results suggest that either tool can be applied to identify participants who would require psychosocial support during the hereditary cancer screening process by APRNs in the outpatient community oncology setting. Since there is no "gold standard" in the choice of psychosocial screening tools, the tools utilized will typically be APRN-subjective as this study proves that both screening questionnaires were adequate in prompting psychosocial referrals as needed. However, the SCSQ identified more patients who needed referrals and will be implemented in all the 210 clinical sites with APRNs providing high-risk GCRA services. The clinical site's psychosocial referrals went from 0% to 70% during the study implementation phase, which is relevant as it highlights an identifiable gap in care that needs to be continually addressed. The use of psychosocial screening tools resulted in detecting

other medical or psychiatric comorbid conditions, which prompted psychosocial referrals to the appropriate clinicians and, most importantly, improved patient-provider communication.

The significant findings and points that relate to the overall purpose of this project included identifying psychosocial concerns in high-risk hereditary cancer patients who came in for their GCRA visits with the APRN. Forty-three percent of these patients accepted their psychosocial referrals. These study findings assist the APRN in providing a comprehensive cancer risk assessment as stipulated by the NCCN guidelines, which advocates for the need for patients and families to be informed that distress management is an integral part of total medical care and that they are provided appropriate information on the psychosocial services. One of the goals of this study was to implement a psychosocial screening tool that can be utilized in clinical practice by APRNs conducting genetic counseling visits following the standards of care (SOC) stipulated by NCCN. Two of the NCCN's SOC prescribe that the quality of distress management programs or services should be included in institutional continuous quality improvement (CQI) projects and that interdisciplinary institutional committees should be formed to implement standards for distress management (NCCN, 2020).

The study's findings revealed that in a certain percentage of patients, and this case, that 70% of the patients had identifiable psychosocial risk factors, and 43% of those patients accepted psychosocial referrals to counselors, APRNs, social workers, counselors, psychologists, and psychiatrists. Studies investigating distress screening, referral, and acceptance of professional support services found low correspondence between emotional distress and uptake. Some studies found that patients who reported a higher burden of emotional symptoms were more likely to access services than those who reported a lower burden of symptoms (Zwahlen et al., 2017).

The reasons provided by patients about not wanting to see a psychosocial interdisciplinary team member were time constraints, not sure if insurance would cover counseling services, and wanting to wait on their genetic results before considering a psychosocial assessment by another health provider. Most of the patients felt that they could self-manage symptoms and that they did not feel distressed enough. They also felt that they did receive adequate support from friends and family. There was an increase in shared decision-making between me and the study participants, and more importantly collaboration with other disciplines. Understanding these new findings presented in this project helps add to the current nursing body of knowledge about high-risk individuals undergoing GCRA by APRNs, including assessing these individuals' psychosocial needs, addressing these needs, and tailoring individualized treatment plans. These treatment plans help address these patients' uncertainties, improve psychosocial function, and allocate valuable psychosocial resources that promote surveillance and treatment adherence. Early identification of these high-risk individuals at a potentially higher risk of suffering distress and adverse psychological effects during GCRA enhances preventative health delivery, which helps improve decision-making, preserves adherence to treatment and surveillance regimens, and impacts cancer morbidity and mortality rates.

Recently, there has been increasing debate over the lack of appropriate measures for psychosocial impact in genetic or genomic medicine, with some authors highlighting a need to use cancer-specific scales. However, there is currently limited research assessing the long-term psychological outcomes of genomic cancer testing (Yanes et al., 2019). Oncology APRNs who have been trained in GCRA must identify any psychosocial needs in high-risk individuals and

during the hereditary screening process and facilitate psychosocial resources that can help these individuals cope with their psychosocial concerns and needs.

Limitations

Limitations associated with the project included issues related to self-reporting because the study participants filled out the assessment tools. In addition, a small sample size was used due to the three-month study time frame and dependence on incoming and clinical referrals, affecting the statistical significance level. A larger sample size would have provided greater power in detecting any difference between the two psychosocial risk assessment tools.

Implications for Leaders

Genomic testing is expeditiously being integrated into clinical settings to direct population screening programs and testing of tumor cells to guide cancer treatment. At the clinical site, there was demonstrated need for standardized identification of psychosocial support. It is essential that oncology APRNs advocate, initiate psychosocial screening measures, and ensure the delivery of high-quality care by ensuring these high-risk individuals receive the care and support they need during the high-risk hereditary screening process. Advanced practice registered nurses in the oncology setting are ideal health care providers to assess patients' psychosocial needs, provide guidance, and make psychosocial referrals and recommendations. Targeting screening to high-risk populations is likely to have significant benefits in health care by making allocated resources more efficient and reducing the burden of routine care for those at the lowest risk (Yanes et al., 2019). As noted with this study findings, a significant amount of high-risk hereditary cancer patients reported higher levels of anxiety, depression, worry, negative mood, and genetic risk perception, thus being at risk for psychological discomfort during the counseling process. Therefore, resources and programs should be put in place to accommodate

psychosocial referrals within the interdisciplinary context in inpatient, outpatient, and community settings.

With a growing need for oncology nurses to integrate genetic and genomic information in every aspect of oncology nursing care, this research has generated new information for oncology APRNs by providing a frame of reference on how some high-risk individuals undergoing hereditary cancer screening and testing need their psychosocial needs assessed. This is important because oncology APRNs play an evaluative role in identifying psychosocial risk factors in this patient population that can impact mental health, adherence to surveillance, or treatment plans as recommended. Improving cognizance among oncology APRNs working in the outpatient community setting and encouraging the development or expansion of an interdisciplinary network comprising social workers, counselors, chaplains, psychologists, and psychiatrists can help improve continuity of care and provide comprehensive cancer care to these high-risk individuals. The results from this DNP project conclusively indicated that high-risk individuals undergoing GCRA identified the need for additional psychosocial support. Positive results were produced from this project as evidence revealed that both psychosocial risk assessment tools utilized could identify psychosocial needs prompting psychosocial referrals.

In congruence with the Institute of Health (IHI) Triple Aim Initiative, nurse leaders and especially DNP-prepared nurses are called to improve the patient experience of care. This project highlights the need for utilizing a psychosocial screening tool to help identify psychosocial needs in high-risk individuals undergoing GCRA and refer them appropriately, which helps improve health quality and patient satisfaction. Secondly, the GCRA process by oncology APRNs helps identify individuals at risk for developing cancer and helps minimize these risks by promoting early-detection education and strategies to help lower this risk. This notion aligns with the

second triple aim initiative of improving population health as genetic or genomic literacy is available to individuals, communities, and diverse populations. The third triple aim initiative calls for reducing the cost of health care, and the early detection of elevated cancer risk and early detection of psychosocial risk in high-risk individuals helps reduce the cost of health care. In cancer patients undergoing GCRA, this testing allows the sparing of unnecessary use of costly procedures or treatments as the presence of specific genomic markers paves the way for targeted, individualized therapy, saving health care dollars. Also, in previvors, the presence of a genetic mutation that can lead to cancer, a very costly disease, can be reduced by prophylactic surgeries or increased diagnostic screening, which reduces the individual's financial cost and saves their lives. A systematic review conducted by Jansen et al. (2016) on cost-effectiveness and cost-utility of psychosocial care in oncology noted that psychosocial care is likely to be cost-effective at different, potentially acceptable, willingness-to-pay thresholds.

Outcomes from this DNP project indicated that oncology APRNs and especially those trained in providing GCRA services should work with other health care providers to provide comprehensive, individualized cancer genetic and genomic care, including assessing psychosocial risk. The results produced several implications for nursing practice according to the eight DNP Essentials and the Essentials of the Doctoral Education for Advanced Nursing Education Practice (American Association of Colleges of Nursing, 2006) for APRNs, which will be discussed further.

Essentials of Doctoral Education for Advanced Practice Nurses

Essential 1: Scientific Underpinnings for Practice

Psychosocial distress in high-risk individuals undergoing hereditary cancer screening is evident in some of these individuals who report worry, guilt, anxiety, depression, fear, and risk-

related uncertainty. The literature review helped support the benefits of identifying and addressing psychosocial concerns in these individuals. The literature review and this study findings could provide a basis for generalizing and assimilating this intervention in the outpatient oncology setting and wherever high-risk individuals present for hereditary cancer screening. With the recent advent of APRN-run high-risk cancer clinics and more APRNs getting training in providing genomic counseling and testing, measures should be put in place to treat these high-risk individuals comprehensively or by focusing on an individual as a whole. The DNP allows for the homogenization of nursing science from knowledge derived from psychosocial science in this project, which also reinforces nursing science concepts.

The theoretical framework guiding this research project was the reconceptualized uncertainty in illness theory (RUIT) by Mishel (1990). The theory reinforces that in the GCRA process, uncertainty and risk management is an ongoing, distressful chronic experience, which is characterized by emotional and psychological distress and inevitably tied to an individual's ongoing risk-related uncertainty (Dean & Fisher, 2019). Research informed by RUIT suggests that patients appraising uncertainty as a danger will experience negative emotions and poor health outcomes (Clayton et al., 2018; Kang, 2006). Any uncertainty must be assessed throughout the hereditary cancer screening process by oncology APRNs providing this service. Some nursing interventions informed by RUIT that can help high-risk individuals undergoing hereditary cancer screening are using an appropriate psychosocial screening tool that addresses emotional concerns and assessing and referring these individuals appropriately to help them explore the emotional and social conditions from which meaning of the disclosed event is attained. Reconceptualized uncertainty in illness theory can be applied in any clinical setting where GCRA services are being provided. It serves as a suitable framework to disseminate

information that helps advance foundational nursing interventions for practice change and health promotion, which helps develop the DNP provider as a nursing scientist.

Essential 2: Organizational and Systems Leadership for Quality Improvement and Systems Thinking

There is an identifiable need to evaluate psychosocial status in high-risk individuals undergoing hereditary cancer screening as most of these individuals endorse having psychosocial concerns associated with the hereditary screening process. Since genetics is a recognized nursing specialty and genetic testing services are now being offered by trained APRNs as a contemporary nursing science, the development of new care delivery models to meet the needs of this patient population based on this study's findings can help promote the quality of care and excellence in practice. Systemic organization arrangements should be put in place to ensure that psychosocial screening services are incorporated during the GCRA process and must include an interdisciplinary network of counselors, social workers, chaplains, psychologists, and psychiatrists for patients who have been identified as needing psychosocial services. Practice policies that affect clinical flow during the hereditary screening process should be updated to include psychosocial screening at each pre GCRA visit by the APRN. Integrating an electronic psychosocial referral system into the interdisciplinary team is vital to the success of this practice change.

Essential 3: Clinical Scholarship and Analytical Methods for Evidence-Based Practice

Assessing the need for psychosocial screening in high-risk individuals undergoing hereditary cancer screening by oncology APRNs in the research practice revealed that some of these individuals had psychosocial needs that required an interdisciplinary team approach to manage clinical outcomes. As it is known, risks associated with genetic testing include emotional

distress, psychological harm, and potential insurance and employment discrimination (Smith et al., 2004). Integration across disciplines, including social work, psychology, hospitality, and psychiatry, has been shown to address these psychosocial issues related to the hereditary screening process. Genetic tests should be proposed along with proper psychological support and counseling focused on users' genetic health literacy, perception of risk, and beliefs about disease controllability to foster fruitful medical decisions (Oliveri et al., 2018).

The two survey instruments utilized in this project included the Genetic Psychosocial Risk Instrument (GPRI) and the Supportive Care Screening Questionnaire (SCSQ). The SCSQ identified more patients in this project with psychosocial issues and was an easy, expeditious, and effective tool to assess and address the high-risk individuals' feelings and concerns about the GCRA and genetic results. The APRN can implement this survey at the pregenetic counseling phase of GCRA and prompt psychosocial referrals if warranted. As a practice that is part one of the nation's largest networks of integrated, community-based oncology practices and with 118 APRNs trained in genetics through the Genetic Risk Evaluation and Testing (GREAT) program, this quality improvement project's results will be translated into practice with the use of the evidence-based intervention (SCSQ) assessment as part of the hereditary screening process by APRNs in clinical practice.

Essential 4: Information Systems or Technology and Patient Care Technology for the Improvement and Transformation of Health Care

The use of information technology in the oncology practice setting permitted the transmittal of study information to study participants and assisted in data organization during this research project. The translation of research findings into evidence-based findings in high-risk individuals undergoing hereditary cancer screening was made possible using SPSS version 20.0.

Study limitations included a small sample size of 30 participants and the three-month study duration. The SCSQ could essentially be incorporated into the electronic health record (EHR) as part of the genetic packet emailed to patients during the scheduling phase. If the APRN identifies psychosocial needs during the GCRA pretesting visit, a thorough assessment and evaluation of needs will be completed, and appropriate psychosocial referrals will be made via the EHR ordering system. I hope to incorporate this protocol into my clinical practice as an assessment tool for high-risk individuals seeking hereditary screening services. In January 2022, I hope to meet with the GREAT program director Gayle Patel, Certified Genetic Counselor (CGC), and senior manager for clinical services for McKesson, Lori Lindsey FNP-BC, to design a protocol utilized in all clinical sites providing GCRA services (McKesson Specialty Health supports the U.S. Oncology Network).

Essential 5: Health Care Policy for Advocacy in Health Care

Genetics has revolutionized how cancer risk is assessed in previvors, and it also impacts treatment decisions in patients who have a cancer diagnosis. However, numerous negative implications and challenges are associated with hereditary cancer screening. Advanced practice registered nurses trained in providing GCRA services should be aware of these implications and treat the patient holistically, assessing for and addressing psychosocial concerns. Organizational standards can be improved with the DNP's engagement in policy development related to standardizing psychosocial health assessments in the outpatient oncology setting for all high-risk individuals presenting for GCRA. Promoting clinical awareness and perceptions of APRNs involved in genetics on the psychosocial issues that are associated with GCRA can help the DNP design and implement health care policies that promote quality of care in oncology, which can include building a robust psychosocial referral system and a psychosocial interdisciplinary team

for any identified high-risk individual. Early identification of psychosocial needs in this patient population is an important starting point for a practical clinical application of genetic testing and to organize personalized care plans, which can drive patients to self-determination of a healthy lifestyle and to make appropriate clinical decisions for their health (Oliveri et al., 2018). On the local and national landscape, the DNP is equipped to provide public awareness programs that highlight the psychosocial issues related to hereditary cancer screening as it becomes more mainstream and accessible.

Essential 6: Interprofessional Collaboration for Improving Patient and Population Health Outcomes

Collaborative skills are essential in implementing psychosocial treatment plans that include interprofessional practice. The APRN should address identified psychosocial needs and appropriate clinical referrals made. The DNP plays a crucial role in establishing and leading a network of other clinicians trained to address psychosocial concerns in this high-risk hereditary cancer population. The DNP will also employ effective communication strategies with these high-risk individuals, office staff, social workers, and mental health providers to provide comprehensive and excellent patient-centered care. In implementing new practice guidelines and standards of care in the hereditary cancer screening arena, the DNP utilizes collaborative and communication skills with the GREAT program director and the five regional genetic counselors who are responsible for providing educational support to all the APRNs in practice and operational support throughout the GREAT program.

Essential 7: Clinical Prevention and Population Health for Improving the Nation's Health

Nurses are positioned to contribute to and lead the transformative changes that are occurring in health care by being fully contributing members of the interprofessional team as

they shift from episodic, provider-based, fee-for-service care to team-based, patient-centered care across the continuum that provides seamless, affordable, and quality care (Salmond & Echevarria, 2017). In the oncology research setting, providing evidence-based data to oncology APRNs on the clinical utility of assessing the psychosocial status of high-risk individuals undergoing hereditary cancer screening is instrumental in promoting high-quality holistic nursing care.

According to the RUIT theory, APRNs can help high-risk individuals manage their uncertainty about the cause of their disease if they have cancer or if they are previvors in the likelihood of developing cancer by helping them gain knowledge, solve problems, and perceive health issues as manageable. Discovering the antecedents of uncertainty provides the APRN with salient clues about the patient's uncertainty, and the psychosocial interventions aimed at managing uncertainty are based on understanding the individual's view about the situation and defining the characteristics of uncertainty (Taş Bora & Buldukoğlu, 2020). According to the National Cancer Institute (n.d.), many individuals at risk for cancer lack access to genetic screening and preventative approaches due to cost, geographical location, or lack of understanding about these strategies. By improving the availability and uptake of these tests by individuals and families at high risk for cancer, significant improvements can be made to prevent and treat inherited cancer syndromes early (NCI, n.d.). With the shortage of trained genetic counselors in the United States, oncology APRNs are bridging this health care gap, implementing evidence-based strategies to identify those at risk and implementing appropriate clinical management, which improves population health.

Health care systems are integrating cancer risk assessment services into their settings to improve services, differentiate themselves from other practices, and provide overall better care

for the communities they serve, and many APRNs have been asked to participate in or lead these new initiatives (King & Smith, 2020). Psychosocial and behavioral outcomes of genetic testing in oncology are well known, and the implementation of a clinical initiative that addresses these concerns is vital in helping improve the overall health status of the population of the United States.

Essential 8: Advanced Nursing Practice

The specialization and subspecialization in nursing have enabled APRNs to work in distinctly complex areas of practice. With the expanding role of the APRN in genomic practice, there have been two distinct pathways. First, APRNs are now offering cancer risk assessment services in a consultative arena where the APRNs engage in risk assessment and develop a plan of care meant to be provided by the patient's referring provider. Secondly, other APRN-led GCRA programs provide a more comprehensive cancer risk assessment, develop and implement plans of care, and monitor high-risk patients long-term (King & Smith, 2020). As a nurse practitioner in oncology who provides hereditary cancer screening services, it is essential to explore therapeutic interventions such as assessing psychosocial status in high-risk individuals and appropriately referring them as this is based on evidence in the literature.

Advanced practice registered nurses are adept at developing collaborative relations with many members of the health care organization. This research project highlighted the fact that the APRN can advance and support therapeutic partnerships with patients, their families, and other professionals to facilitate patient outcomes and optimal care. It is efficacious that oncology APRNs running high-risk hereditary cancer clinics collaborate through a referral system with other APRNs in different specialties like primary care, obstetrics/gynecology, gastroenterology, urology, dermatology, endocrinology, neurology, genetics, and nephrology with the main aim of

improving population health outcomes. This DNP project demonstrated a systematic health assessment in high-risk individuals and the evaluation of evidence-based care to improve these patient outcomes in hereditary cancer screening.

Recommendations for Future Research

The assessment of psychosocial risk in high-risk individuals undergoing hereditary cancer screening by APRNs in the community setting must be assimilated in the pregenetic counseling visit because it can help identify patients who may need additional psychosocial support. Given the rapid advancement of genomic medicine, understanding the evidence based on the psychosocial impact of genomic testing is imperatively needed to help provide adequate support in high-risk individuals. Utilizing a psychosocial screening tool such as the GPRI or SCSQ has been shown to help identify individuals who need additional psychosocial support services. However, this study did not reveal any significant difference in the percentage of referrals between the two tools, and future research can be aimed at a head-to-head comparison of the two validated screening tools used in GCRA, namely the Genetic Psychosocial Risk Instrument (GPRI) and Psychosocial Aspects of Hereditary Cancer (PAHC) questionnaire. Addressing these psychosocial concerns allows patients to participate in their plan of care and make informed medical decisions and enables providers to understand the impact of psychosocial distress during the hereditary screening process. Further nursing research is needed to help identify specific psychosocial needs after positive hereditary cancer results disclosure. Moreover, research that could assist in identifying specific psychosocial needs among different family members during the GCRA process is also important to explore.

Additional research utilizing a larger sample size with an extended study duration is essential to further improve psychosocial screening practices in different settings and establish a

gold standard for psychosocial measurement in the hereditary screening arena. A small sample size can affect the reliability and variability, which may lead to bias. Larger sample sizes have been shown to provide more accurate mean values and identify outliers that could skew the data. The variability of utilizing different clinical settings that offer hereditary cancer screening ranging from outpatient, inpatient, urban, rural, and teaching hospitals can significantly strengthen the assessment of psychosocial risk factors in the broader variation of these high-risk individuals. Additionally, future studies could highlight the long-term psychosocial impact of the hereditary cancer screening process by utilizing a prospective, longitudinal study design. Also, psychosocial assessments during the posttesting phase can provide information about the changes in knowledge, cancer worries, distress, and risk perception. Advanced practice registered nurses could enhance their high-risk hereditary cancer clinics by improving their psychosocial screening practices by creating an interdisciplinary network that addresses any identified psychosocial needs.

Conclusion

It has been shown that psychosocial challenges can transpire throughout the hereditary cancer screening process, ranging from discussions about referrals for testing to medical decisions based on results. This project evaluated the need for psychosocial screening services utilizing a psychosocial assessment tool in high-risk individuals undergoing GCRA by oncology APRNs in the community setting. This study's findings ascertained that a certain percentage of the study participants experienced heightened anxiety, depression, guilt, worry about disease risk and passing down genes to their children, fear about illness if positive, relationship worries, or distress during the GCRA process. Thus, it is indispensable to systematically evaluate and detail the psychosocial variables during the GCRA process and appropriately refer these patients for

psychosocial interventions. The study's findings also revealed that the use of the SCSQ identified one patient more who needed a psychosocial referral compared to the GPRI. However, it is important to note that not all study participants accepted psychosocial referrals even when a need was identified. Thus, there was no statistically significant association between referral and assessment tools, and the null hypothesis could not be rejected. There was also an overall improvement in the number of study participants referred for additional psychosocial support during this study.

The findings revealed that psychosocial risk assessments needed to be assessed at the precounseling and postcounseling phases of the GCRA, and a viable psychosocial risk assessment tool are critical to implementing routinely. It is imperative to assess the high-risk individual's perception of their psychosocial needs associated with the hereditary screening process, refer them appropriately, and provide them information on the availability of these services. The dissemination of this evidence-based research project can help APRNs tailor the way they deliver genetic and genomic information and holistically address any psychosocial concerns that may arise during the hereditary screening process. It can also assist in changing current clinical practice by improving health outcomes and patient care. Dissemination of this evidence should not be limited to [redacted] only but should be shared nationally and with the public to help address the psychosocial issues that arise during the hereditary cancer screening process.

Precision medicine calls for APRNs involved in genetic and genomics to tailor medical treatment based on each patients' individual characteristics, and aside from performing a nursing assessment, identify hereditary risk, provide patient counseling, order testing, interpret testing, and make appropriate clinical recommendations, the APRN should provide additional

psychosocial support as needed. The pathways to disseminate this evidence-based research include presenting this study's findings in oncology nursing journals, roundtable discussions, and oral presentations. Diversification of oncology nurse practitioner practice to include GCRA has resulted from the limited number of adequately trained health care providers, time constraints of busy practicing clinicians, and failure to obtain and update family cancer history. The emergence of alternate practice models that have evolved to extend these genetic cancer risk assessment services outside of the traditional academic genetics model into a community-based approach using APRNs has been successful (King & Smith, 2020). Doctors of Nursing Practice trained in genetics are called to fulfill the demands of the high-risk population undergoing hereditary cancer screening as they are equipped with advanced assessment skills and can view the high-risk individuals holistically while tailoring individualized care plans. The APRNs also have higher educational training in interdisciplinary collaboration, leadership, and evidence-based practice as they can continually adapt to the rapidly evolving world of clinical genetics.

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Appendix A: Participant Information Sheet

Hello,

My name is Lina Thompson and I am conducting research for my doctoral degree at Abilene Christian University. My study is on the assessment of psychosocial status during the genetic screening process. I would like to invite you to participate in my research.

In order to be included in this study you must meet the following criteria:

- Over the age of 18.
- Be a patient with no cancer history but who has a family history of the following cancers in either 1st or 2nd degree relatives: Breast, ovarian, endometrial, colorectal, pancreatic, gastric, prostate, and melanoma.
- Be a patient with no cancer history but a family history of family members who have diagnosed with cancer before the age of 50.
- Be a patient with no cancer history but have family members with known cancer mutations.
- Be a patient with no cancer history but have family members with who have had cancer develop in paired organs such as both breasts, both ovaries or both kidneys.
- Be a newly diagnosed cancer patient with the following cancers: Breast, ovarian, endometrial, colorectal, pancreatic, gastric, prostate, and melanoma, referred in for genetic counseling and testing.
- Be a patient who has had multiple cancers occur in the same individual.

You cannot participate if:

- You have a mental health diagnosis.
- You have been referred in for post genetic counseling without a pre testing by one of our nurse practitioners.

If you participate in this research, you will be asked to:

- Complete either a 6 part questionnaire OR a 20 part questionnaire.
- Complete a pre-testing genetic counseling session with one of the Nurse Practitioners.

If you have questions for me, please email me at [redacted] You can also call me at [redacted]

Appendix B: Research Study Consent Form

STUDY TITLE: Implementation of a Clinical Practice Guideline Recommendation to Address the Psychosocial State of High-Risk Individuals Undergoing Hereditary Cancer Screening: A Practice Change in Oncology Care

PRINCIPAL INVESTIGATOR: Aquilina Thompson AOCNP, FNP-BC

INTRODUCTION:

This is a research study and it includes research participants who choose to take part and who meet the criteria for inclusion in the study. This form provides important information about that study, including the risks and benefits to you as a potential participant. Please read this form carefully and ask the researcher any questions that you may have about the study. You can ask about research activities and any risks or benefits you may experience. You may also wish to discuss your participation with other people, such as your family doctor or a family member.

Your participation in this research is entirely voluntary. You may refuse to participate or stop your participation at any time and for any reason without any penalty or loss of benefits to which you are otherwise entitled.

WHY IS THIS STUDY BEING DONE?

The purpose of this quality improvement project is to identify and implement an evidence-based screening tool in high-risk individuals undergoing genetic testing in the oncology setting. The study hopes to properly identify psychosocial concerns in high-risk individuals undergoing genetic testing and provide appropriate referrals as needed.

If selected for participation, you will be asked to attend one visit with the study staff at your pre-genetic counseling visit to complete either a questionnaire (20 questions) or a two section questionnaire that collects information about your psychosocial status. These questionnaire's will take about 10 minutes of your time to complete.

HOW MANY RESEARCH PARTICIPANTS WILL TAKE PART IN THIS STUDY?

Around 30 participants will take part in this study.

WHAT ARE THE RISKS AND BENEFITS TO TAKING PART IN THE STUDY?

There are minimal anticipated risks associated with this study's implementation, starting from consent procedures, data collection, data measurements, evidence dissemination, and translations into practice.

However, there is a risk of breach of confidentiality, and accidental disclosure which exists in all studies.

There are potential benefits to participating in this study. Such benefits may include identifying psychosocial issues that may prompt referrals to social workers, psychiatrists, psychologists, or chaplains as needed. Even if you do not benefit, we hope the information learned form this study will benefit other high risk individuals undergoing genetic testing in the future.

The researchers cannot guarantee that you will experience any personal benefits from participating in this study.

WHAT ABOUT PRIVACY & CONFIDENTIALITY?

Any information you provide will be confidential to the extent allowable by law. Some identifiable data may have to be shared with individuals outside of the study team, such as members of the ACU Institutional Review Board and [redacted] Otherwise, your confidentiality will be protected all identified data collected during this project will be stored in a secure university password protected drive under the project researcher's name. The university will own data in case access is needed at a future date. This storage system is provided by the online graduate school for doctoral student research data and supported by the university's IT department for security purposes and kept for three years.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

Aquilina Thompson, AOCNP, FNP-BC at ([redacted] or Email [redacted]

If you are unable to reach the lead researcher, or wish to speak to someone other than the lead researcher, you may contact:

Dr. Faisal Aboul-Enein, DrPH, MSN, RN, FNP-BC, FACHE at [redacted]

If you have concerns about this study, believe you may have been injured because of this study, or have general questions about your rights as a research participant, you may contact ACU's Chair of the Institutional Review Board and Executive Director of Research:

Dr. Megan Roth, Ph.D. at (

Email :

328 Hardin Administration Bldg., ACU Box 29103

Abilene, TX 79699

HIPAA AUTHORIZATION:

Authorization to Release Protected Health Information for Research Purposes.

Your health information is protected by a law called the Health Insurance Portability and Accountability Act (HIPAA) is a federal law passed to protect the privacy of your Protected Health Information (PHI). PHI is any information about you that could tell someone who you are. The following information will explain how we will use and disclose your PHI for this study: If you agree to participate in the research, the researcher will collect and retain data from your medical record including: age, gender, race, education, and cancer diagnosis if applicable. These data will be used for the conduct and oversight of this study. Identifiers will be replaced with a code, and the key will be retained for 3 years. You have a right to refuse authorization or revoke authorization at any time. However, you will not be able to participate in the research if you do. Once the key has been destroyed, we may not be able to remove your data set if you revoke authorization after that time. There is a risk of accidental disclosure, though the PI is taking steps to protect your privacy, as described in the Privacy & Confidentiality section.

Your personal information will not be disclosed without your written authorization except where permitted by state and federal laws or required by law. Results of this study may be published in a scientific journal after all identifying data has been removed. Organizations that may review your medical information for quality assurance and data analysis as required under the guidelines of the Health Insurance Portability and Accountability

Act (HIPAA), Abilene Christian University Institutional Review Board, and US Oncology Institutional Review Board. These groups will be permitted to review information contained in your medical record that includes your name, inspect and /or copy records kept prior to and related to your participation in this study and any of the data generated by the study.

ADDITIONAL INFORMATION

HOW LONG WILL YOU BE IN THE STUDY?

The study consists of one study visit.

CAN YOU CHANGE YOUR MIND ABOUT PARTICIPATING?

Yes, you can agree to be in the study now and change your mind at any time and for any reason. You can withdraw from the study and your decision will not change your regular medical care. You can talk to study staff first before making this decision.

WHAT OTHER OPTIONS ARE THERE?

Taking part in a study is voluntary and is not part of your regular health care. There are no treatments or benefits that are conditional on authorization to participate in this study. Your participation may be ended early by the researcher for certain reasons. For example, we may end your participation if you no longer meet study requirements, the researchers believe it is no longer in your best interest to continue participating, you do not follow the instructions provided by the researchers, or the study is ended. You will be contacted by the researchers and given further instructions in the event that you are removed from the study.

WHAT ARE THE COSTS?

There is not additional cost burden to you for being in this study. Because this study is collecting information only, there is no change to your usual medical care. You will not be paid for taking part in this study.

WHAT ARE THE RIGHTS AS A PARTICIPANT?

Before you sign this document, you should ask questions about anything that you do not understand. You do not give up any legal rights by signing this consent form and you may withdraw from the study at any time.

SIGNATURE PAGE

Please sign this form if you voluntarily agree to participate in this study and allow the use of associated protected health information (PHI) as described above. Sign only after you have read all of the information provided and your questions have been answered to your satisfaction. You understand this study is voluntary and you can withdraw at any time. You are signing this consent form prior to participation in any research activities. You do not waive any legal rights by signing this form. You will be given a signed and dated copy of this informed consent to keep.

Printed Name of Participant	Signature of Participant	Date

Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

Appendix C: Genetic Psychosocial Risk Instrument

Appendix A Genetic Psychosocial Risk Instrument (GPRI)

The purpose of this questionnaire is to help identify individuals who may need additional support while going through genetic testing. The questions are about your life experiences and feelings about the disease for which you are receiving genetic testing/counseling. Please note that whenever the word "disease" is used, it is referring to the disease for which you are having genetic testing and/or counseling. Please read each statement carefully, then respond by placing a firm checkmark in the most appropriate space.

Name:	Date (dd / mm / yyyy):

1. I have/had a personal diagnosis of the disease for which I am receiving counseling/testing	(5) Yes	(1) No
2. I have taken care of a very ill parent or another close family member (e.g. sibling)	(0) Yes	(1) No
If yes, the illness was related to the condition for which I am receiving counseling/testing	(5) Yes	(3) No
3. I lost a close family member (e.g. parent/sibling) to the disease for which I am receiving counseling/testing	(5) Yes	(1) No
If yes, please indicate who the family member was who died (check all that apply): (0) a parent (0) a sibling (0) other (specify)_____		

	Strongly agree	Somewhat agree	Neither agree/disagree	Somewhat disagree	Strongly disagree	Not applicable
4. If I learn that I have a genetic mutation, I believe that:						
a. I will have more problems in my life	5	4	3	2	1	0
b. I will change plans for my career/ profession	5	4	3	2	1	3
c. I will have difficulties in my family relationships	5	4	3	2	1	3
5. The disease for which I am at risk is currently causing a significant disruption in my family life	5	4	3	2	1	3
6. I am worried that my test result will impact on my relationship with my significant other (or future partner)	5	4	3	2	1	3
7. I am worried about talking to my children (young or adult) about the heritable nature of the disease for which I'm being tested	5	4	3	2	1	3
8. My worries about the disease affect my daily mood	5	4	3	2	1	3
9. I worry often about my risk of getting the disease	5	4	3	2	1	3
10. I am concerned about my risk of getting the disease	5	4	3	2	1	3
11. I feel guilty that I might pass on the disease risk to my children	5	4	3	2	1	3

	Almost all of the time	Often	Sometimes	Hardly ever	Not at all
12. I have generally felt sad in the past month	5	4	3	2	1
13. I have generally felt nervous and anxious in the past month	5	4	3	2	1

14. I have had emotional problems in the past	(5) Yes	(1) No
15. I have had counseling with a counselor and/or a mental health professional in the past	(5) Yes	(1) No
16. I have been diagnosed with a depressive or anxiety disorder in the past	(5) Yes	(1) No
17. I have had emotional problems that led me to have thoughts about suicide	(5) Yes	(1) No
18. I am now seeing a counselor for one or more of these emotional concerns	(5) Yes	(1) No

19. I am interested in talking with a counsellor about one or more of these concerns	(0) Yes	(0) No

Instruction to the user: Item #19 is for referral purpose only, no score is assigned. The remaining items all have assigned scores. Because item #4 has three sub-statements, a total of 20 statements/items are included in the scoring.

Appendix D: Supportive Care Screening Questionnaire

Today's Date: _____

Patient Name: _____ **Date of Birth:** _____ **MR#:** _____

Part A

Your overall well-being is important to us. Below are some common concerns to many patients. Please take a few moments to complete the following questions so that we can understand your concerns and support you.

Emotional Concerns (check all that apply)

☐ Fear / Worry / Anxiety ☐ Guilt ☐ Changes in Appearance
☐ Sadness ☐ Loneliness ☐ Intimacy / Sexuality

Social / Family Concerns (check all that apply)

☐ Feeling a burden to others ☐ Safety concerns ☐ Support for Caregiver
☐ Support for Children / Teens ☐ Communicating with my Healthcare Team ☐ Help at Home
☐ Relationship Difficulties

Practical Concerns (check all that apply)

☐ Insurance / Financial ☐ Advance Care Planning (Medical Power of Attorney / Living Will) ☐ Transportation
☐ Guidance on Social Security / Disability ☐ Employment Concerns

Are there any additional services you require? _____

Would you like to be contacted regarding these concerns at this time? ☐ Yes ☐ No

Part B

Over the last 2 weeks, how often have you been bothered by any of the following problems? (Circle number that applies)

Circle number that applies	Not at all	2-3 days	4-5 days	Every day
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed or hopeless	0	1	2	3

Appendix E: IRB Approval Letter: ACU

ABILENE CHRISTIAN UNIVERSITY
Educating Students for Christian Service and Leadership Throughout the World

Office of Research and Sponsored Programs
320 Hardin Administration Building, ACU Box 29103, Abilene, Texas 79699-9103
325-674-2885

January 28, 2021

Aquilina Thompson
Department of Nursing
Abilene Christian University

Dear Lina,

On behalf of the Institutional Review Board, I am pleased to inform you that your project titled "Addressing the Psychosocial State of High-Risk Individuals Undergoing Hereditary Cancer Screening by APRNs in the Community Oncology Setting",

(IRB# 21-004)is exempt from review under Federal Policy for the Protection of Human Subjects.

If at any time the details of this project change, please resubmit to the IRB so the committee can determine whether or not the exempt status is still applicable.

I wish you well with your work.

Sincerely,

Megan Roth

Megan Roth, Ph.D.
Director of Research and Sponsored Programs

Appendix F: IRB Approval Letter: Study Site

Date: 2/22/2021

Principal Investigator: Lina Thompson, FNP-BC

Department: Medical Oncology

Title: Implementation of a Clinical Practice Guideline Recommendation to Address the Psychosocial State of High-Risk Individuals Undergoing Hereditary Cancer Screening: A Practice Change in Oncology Care

Re: **Privacy Board Initial Approval for Protocol Number NF** – 2101a

Dear Lina Thompson,

In accordance with the Federal Regulations, the [redacted] Privacy Board reviewed the above reference research study and found it met the requirements for approval under the Texas Advisory board noted below. The study is approved for the following time frame: **2/22/2021 to 2/21/2022**. Approval ends at 12 a.m. midnight on approval end date. If the research will be conducted at more than one site, you may initiate research at any site from which you have a letter granting you permission to conduct the research. Retain a copy of this letter in your files.

Research category of approval:

☒ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
Note: some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

☐ Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Note: summer search in this category may be exempt from the HHS regulations for the protection of human subjects. 45CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.

☐ Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device or not generally eligible for expedited review, including studies of cleared medical devices for new indications).

Examples:

a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy.
b) Weighing or testing sensory acuity.

c) Magnetic resonance imaging.
d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radio activity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography.
e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing were appropriate given the age, weight, and health of the individual.

Use the attached approved informed consent documents.

You have been granted a waiver of documentation of consent according to 45 CFR 46.117 and/or 21 CFR 56.109(c)(1).

You have been granted a waiver of informed consent according to 45 CFR 46.116(d).

Responsibilities of the Principal Investigator:

1. Report immediately to the Privacy Board any unanticipated problems;
2. Submit for review and approval by the Privacy Board all modifications to the protocol or consent forms. Ensure the proposed changes in the approved research or not applied without prior Privacy Board review and approval, except when necessary to eliminate apparent immediate hazard to the subject. Changes in approved research implemented without Privacy Board review and approval initiated to eliminate apparent immediate hazard to the subject must be properly reported to the Privacy Board and will be reviewed under the unanticipated problems policy to determine whether the change was consistent with ensuring the subjects continued welfare;
3. Report any significant findings to become known during the research that might affect the willingness of subjects to continue to participate;
4. Ensure that only persons formally approved for the Privacy Board and enroll subjects;
5. Use only a currently approved consent form, if applicable.
   Note: Approval period for 12 months or less;
6. Protect the confidentiality of all persons and personally identifiable data and train your staff and collaborators on policies and procedures for ensuring the privacy and confidentiality of subjects and their information;
7. Submit a continuing review application for continuing review by the Privacy Board. Federal regulations require Privacy Board review of on-going projects no less than once a year a reminder letter will be sent to you two (2) months before your expiration date. If a reminder is not received from the [redacted] Privacy Board about your upcoming continuing review, you're still the primary responsibility of the principal investigator not to conduct research activities on or after the expiration date. The continuing review application must be submitted, reviewed and approved before the expiration date;
8. Upon completion of the research study, a closure report must be submitted to the [redacted] Privacy Board; and
9. Include the [redacted] Privacy Board study number on all future correspondence relating to this protocol.

If you have any questions, contact the [redacted] Privacy Board via SharePoint and/or via email at [redacted]

Sincerely,

/s/ [redacted] PhD

[redacted] PhD, RN, ACNS- BC
Privacy Board Chair
Director, Research Support & Privacy Board Operations
[redacted]

Appendix G: Protecting Human Research Participants Certificate of Completion

CERTIFICATE

OF COMPLETION

PHRP Online Training, Inc. certifies that

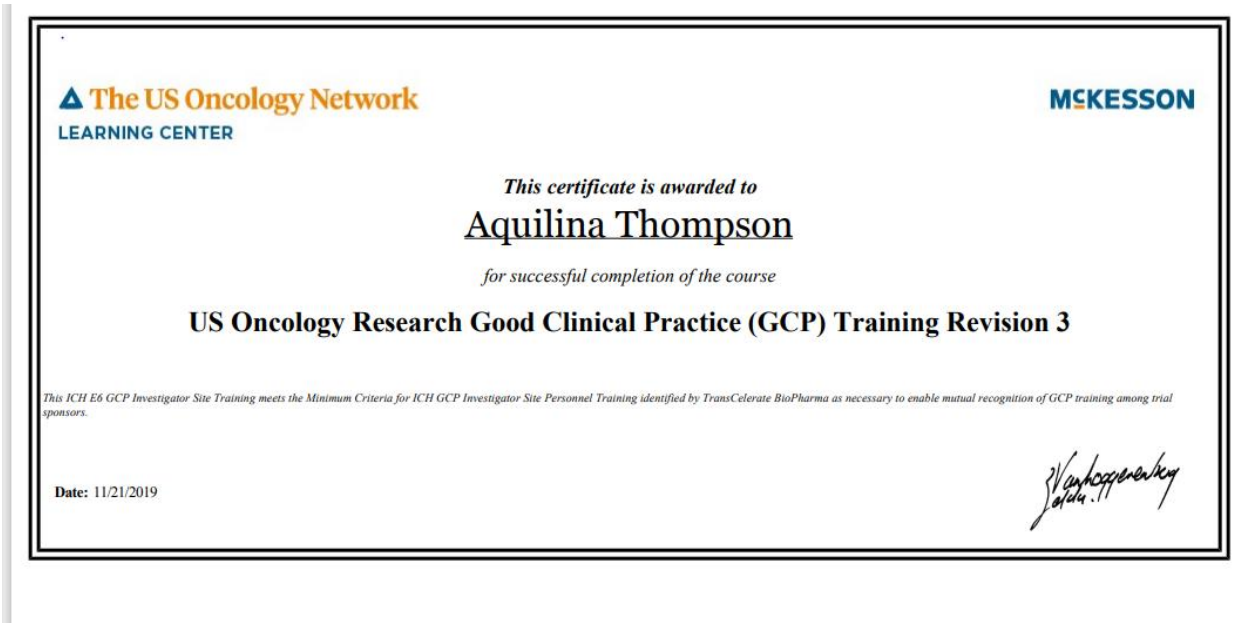
aquilina thompson

has successfully completed the web-based course "Protecting Human Research Participants Online Training."

Date Completed: 2020-09-08 Certification Number: 2856753

PHRP
Protecting Human
Research Participants
Online Training

Appendix H: Good Clinical Practice Certificate



The US Oncology Network
LEARNING CENTER

McKESSON

This certificate is awarded to

Aquilina Thompson

for successful completion of the course

US Oncology Research Good Clinical Practice (GCP) Training Revision 3

This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

Date: 11/21/2019

Appendix I: Ethics and Human Subject Protection Certificate

ACRP

FOR LEARNING · FOR LISTENING · FOR LIFE

Certificate of Completion

Association of Clinical Research Professionals certifies that

Aquilina Thompson

has successfully completed

Ethics and Human Subject Protection: A Comprehensive Introduction

Version: Jan 2020

Date of completion: Feb 4, 2021

Jim Kremidas — Executive Director

ACRP

Appendix J: Measurement Tool Permission Letter

Permission to use the GPRI for DNP Project

Report message - Block user

Aquilina Thompson 22 hours ago

Good Afternoon Dr. Esplen,

I am a DNP student at Abilene Christian University and currently in the beginning stages of my DNP project titled "Implementation Of A Clinical Practice Guideline Recommendation To Address The Psychosocial State of High-Risk Individuals Undergoing Hereditary Cancer Screening: A Practice Change in Oncology Care."

I would like to request your permission to use the GPRI instrument for my research study and I will not sell or use it with any compensated or curriculum development activities. I will include the copyright statement on all copies of the instrument. I will send a copy of my completed research study to your attention upon completion of the study.

Expected length of project is about 8-12m from now.

Thank you so much for all you have done in this field and you can email me your permission at

Sincerely,
Aquilina Thompson, AOCNP, FNP-BC

Mary Jane Esplen to you 45 minutes ago

Dear Aquilina,
Thank you for reaching out and asking for permission. Yes, by all means please feel free to use the instrument. And, thank you for considering our work in your research. All the best to you with your research and I'd be interested in hearing about your findings. You have the paper and tool ? It is in the public domain and published.
Best,
Mary Jane Esplen

Appendix K: Facility Support Letter

February 1, 2021

[redacted] Ph.D.
Chair, [redacted] Privacy Board
[redacted]

Dear Dr. [redacted]

The purpose of this letter is to grant Aquilina Thompson a graduate student at Abilene Christian University permission to conduct research at [redacted]. The project,
"Addressing the Psychosocial State of High-Risk Individuals Undergoing Hereditary Cancer Screening by APRNs in the Community Oncology Setting" entails:

1. Once a genetic referral is received at the clinic, the PI will review the medical record prior to consent to determine patient eligibility and prior to emailing or mailing the genetics packet to patients who meet study criteria. For this study, the genetic packet will also include, a copy of the recruitment flyer, consent form for those who wish to participate.
2. The target population will include high-risk individuals over 18 years of age, who have been diagnosed with cancers of the: breast, ovarian, colorectal, pancreatic, gastric, prostate, and melanoma cancers. They will also include previvors who have family histories of these cancers in either first degree or second - degree relatives of patients who have been diagnosed with cancer before the age of 50 and patients with first degree relatives with known cancer mutations. High-risk individuals will also include previvors who have multiple individuals in a family who have the same cancer, patients or those who have

had cancer develop in paired organs (both breasts, both ovaries, both kidneys), and patients who have had multiple cancers occur in the same individual.

3. The target population will include patients who have been scheduled to come into the clinic for their face-to-face pre-testing genetic visit with the nurse practitioner which includes a phlebotomy in clinic for genetic testing. Based on the participants history and clinicals, the PI typically decides the appropriate genetic panel labs that is drawn the same day patient is at the clinic for their pre-testing visit.
4. Following both [redacted]nd ACU patient visit Covid-19 guidelines, all participant will be screened by the schedulers for any potential exposure and respiratory symptoms before setting up the face-to-face pre-testing genetic visit including with the PI. Screening will include determinirg if the person has traveled to an outbreak area, has come in contact with someone who has tested positive, or who is exhibiting symptoms of respiratory illness.
5. The PI will be symptom-free without known exposure and will have had her both doses of her COVID-19 vaccine by the time the study commences, and additional safeguards include: The pre-genetic testing visit will occur in the clinic exam rooms where hand-washing facilities, and hand sanitizer is available. The PI will maintain proper distance, will have a maximum of two individuals in the exam room at a time.
6. Once patients are in the clinic for their pre-genetic testing visit and labs and have agreed to be study participants, the PI will review the consent with the patient and will provide either the GPRI or SCSQ screening surveys.
7. Demographic data that will be collected include age, race, gender and education of all the participants. A systematic probability convenience sampling which is randomized will be utilized in this study. The project design will have two arms. Study participants in arm one will have their psychosocial status assessed utilizing the GPRI tool, and those in arm two will be assessed with the SCSQ tool.
8. To meet the study objectives, data from this project needs to be quantified and based on the interpretive research approach.
9. Participant's privacy will be protected, and any identifying information will be redacted from recordings. The identified data collected during this project will be stored in a secure university password protected drive under the project

researcher's name. The university will own data in case access is needed at a future date. This storage system is provided by the online graduate school for doctoral student research data and supported by the university's IT department for security purposes and kept for security purposes and will be kept for a period of three years following the completion of the study, and then destroyed.

The number of subjects for this study will be 30 and the purpose of this study is to identify the appropriate psychosocial assessment tool that can be utilized in the outpatient oncology setting in high risk individuals undergoing genetic counseling and testing.

[redacted] was selected because the PI is currently employed and has been working there for 4.5 years now and the PI offers Genetic counseling services. Once the study has been completed in December, 2021, the results will be shared with [redacted] in the spring of 2022. Results findings will also be disseminated through the doctoral project repository.

I, [redacted], do hereby grant permission for Aquilina Thompson to conduct "Addressing the Psychosocial State of High-Risk Individuals Undergoing Hereditary Cancer Screening by APRNs in the Community Oncology Setting" at [redacted]

Sincerely,

[redacted]