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The Effect of Implementing an Evidence-Based Family History Screening Tool in the Primary Care Setting to Increase the Identification of Patients at Risk for Hereditary Breast and Ovarian Cancer Syndrome A Quality Improvement Project

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The Effect of Implementing an Evidence-Based Family History Screening Tool in the Primary Care Setting to Increase the Identification of Patients at Risk for Hereditary Breast and Ovarian Cancer Syndrome

A Quality Improvement Project

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By

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Contents

Abstract

Improvement of identification and education of Hereditary Breast and Ovarian Cancer Syndrome (HBOC) among primary care providers was the focus of this quality improvement project. The development of a pre-implementation and post-implementation survey along with the distribution of a family history screening tool and the Evidence-Based Practice Guidelines provided by the Centers for Disease Control was introduced for the intervention. The anonymous surveys were distributed to primary care providers at the University of Miami in Miami-Dade County locations. Participants recruited for this quality improvement project included Doctors (MD, DO), Nurse practitioners, and Physician assistants currently practicing in primary care.

The quality improvement project included two surveys using clinical scenarios to assess primary care providers' knowledge in identifying patients at an increased risk for HBOC. The providers willing to participate began by taking a pre-implantation survey to assess their baseline knowledge. The providers then received the Evidence-based Practice Guidelines Supporting Genetic Susceptibility Testing for Hereditary Breast and Ovarian Cancer Syndrome and the seven-question family history screening tool. They were then asked to review and implement these tools into their practice for 6 weeks. After the completion of the 6 weeks, the providers were then asked to complete a second survey using the provided family history screening tool to answer clinical scenario questions.

Family history and screening tools were designed to identify at-risk patients for HBOC. On average, the post-implementation clinical scenario questions while utilizing the family history screening tool showed an increase in the identification of patients at risk for HBOC in comparison to the pre-implantation clinical scenario questions where no family history screening tool was used. While this project cannot make final conclusions due to its sample size, it can

open opportunities for further validation of this theory and bring further evidence to translate research into changing clinical practice to better serve the community.

Introduction

Hereditary Breast and Ovarian Cancer Syndrome (HBOC) is a genetic condition associated with an increased risk for breast, ovarian, pancreatic, prostate, and melanoma cancers. This genetic condition is associated with a gene mutation in the genes BRCA 1 and BRCA 2. While HBOC only accounts for 5-10% of breast and 15% of ovarian cancer cases, people who inherit these gene mutations have a greater risk of developing these cancers (Owens et al., 2019). On average, a woman's lifetime risk of developing breast cancer and ovarian cancer is 13% and 1.2% (National Cancer Institute, 2014). While patients with a gene mutation in BRCA1 increase the risk of developing breast cancer to 55-72% and a gene mutation in BRCA2 increase the risk to 45%-69%. While the risk for ovarian cancer in a gene mutation in BRCA1 is 39%-44% and BRCA2 is 11%-17% (National Cancer Institute, 2014). These numbers are significant in comparison to the general population. Patients at an increased risk for HBOC should be identified and offered increased screening, and prevention strategies. Primary care providers are the gatekeepers of patients' health. Their priorities in practice should be to identify patients' risk for disease and promote their prevention. The US Preventive Services Task Force (USPSTF) makes recommendations for disease processes based on evidence and the benefits and harm that can come from screening patients (Owens et al., 2019). The USPSTF currently recommends that primary care providers assess their patients for BRCA1/2 with a family risk assessment tool. Patients with a positive result should be referred for genetic counseling (Owens et al., 2019). The current family risk assessment tools approved by the USPSTF for screening are the Ontario Family History Assessment Tool, Manchester Scoring System, Referral Screening Tool, Pedigree Assessment Tool, Seven-Question Family History Screening, and the International Breast Cancer Intervention Study Model (Owens et al., 2019). According to the USPTSF, these

tools are useful predictors in identifying patients with HBOC to be referred for genetic counseling with a 77%-100% predictor rate (Owens et al., 2019). The issues in question are; do primary care physicians know how to identify HBOC and what are the knowledge gaps, tools, and current practices for identifying patients at increased risk for HBOC?

Background

Primary care providers (PCP) are the gatekeepers of their patients' health. They are the frontline in identifying patients' risk factors and when it is appropriate to refer patients for further evaluations. PCPs can aid patient care and prevention of HBOC related cancers by identifying at-risk patients and referring them to genetic counseling for further evaluations. The current issue when it comes to identifying patients at risk for HBOC is that many primary care providers are not well versed in the genetic principles that are needed to identify patients with an increased risk for HBOC (Nair et al., 2017). A systematic review conducted by Hamilton et al. (2016) revealed that PCPs noted their limitations in their knowledge of genetics and collecting and interpreting family history data (Hamilton et al., 2016). Hamilton et al. (2016), also revealed one study that implemented a multicomponent cancer genetics toolkit in order to improve knowledge of PCP providers in a women's primary care clinic at a Veterans Administration Medical Center. The use of this toolkit improved the knowledge of cancer genetics in PCPs from 59% to 73% post-implementation of the toolkit (Hamilton et al., 2016). The more knowledge and confidence PCPs have with identifying risk factors, or "red flags" associated with HBOC, such as early age of onset of breast cancer diagnosis (younger than 50 years old), bilateral breast cancer, male breast cancer, ovarian cancer, multiple affected relatives with the same cancer, Ashkenazi Jewish decent in their patient or patients' family history, the more confident they will be in referring patients for genetic testing and counseling. Genetic testing and counseling for hereditary cancer

syndrome such as HBOC allow for patients to understand their personal risk for developing HBOC related cancers. Being referred to genetics for testing and counseling also provides patients the opportunity to understand their options for screening, prevention, and managing their risk for HBOC related cancers. It is imperative that PCPs be confident in identifying red flags in their patients for HBOC related cancer in order for patients to have these important conversations with the appropriate specialist and increase their surveillance as indicated.

Scope of the Problem

According to the American Cancer Society in the year 2022, 19,880 women will have a new diagnosis of ovarian cancer, and 12,810 women will die from ovarian cancer (American Cancer Society, 2022). The 5-year survival rate for ovarian cancer is 49.1% (National Cancer Institute SEER, 2018a). This poor prognosis is due to the fact that there are difficulties in detecting ovarian cancer early. For example, ovarian tumors are not palpable on routine exams unless they are large and by this time it is usually not a good sign. If PCPs could identify patients with "red flags" and refer them for genetic testing and counseling, then patients could have a better understanding of their risks and have the necessary conversations of risk, and prevention strategies. In comparison, breast cancer has a 5-year survival rate of 90.3 % (National Cancer Institute SEER, 2018b). This is in part due because there is better screening, imaging, and early detection rates for breast cancer. As noted, in comparing breast cancer survival rates and ovarian cancer survival rates, we can identify that early detection and screening are crucial to patient outcomes. One thing to note, in HBOC is a risk for other cancers to develop that fall within this cancer syndrome such as prostate cancer. A man with a BRCA 1 or BRCA 2 mutation has an elevated risk with up to an approximately 20% chance of developing prostate cancer (Li et al., 2013) in comparison with general population who have a risk of 6% (Petrucelli et al., 2016).

Pancreatic cancer risk is as much as 1-3% with BRCA 1 and between 3-5% for BRCA 2, in comparison to the general population risk which is 0.5% (Petrucelli et al., 2016). Risk for male breast cancer in the general population is 0.1%, a man with a BRCA 1 pathogenic variant has a 1-2% risk and BRCA 2 pathogenic variant has a risk of between 6-8% (Petrucelli et al., 2016). The risk for melanoma is also increased. Though the risk of these other cancers developing is lower in comparison to breast and ovarian cancer, they are still cancers that are a part and related to this syndrome and bring individuals at a greater risk for this diseases in comparison to the general populations risk. Again, PCPs are the gatekeepers and at the frontline of identifying risk factors for their patients. Helping PCPs to better understand and build confidence in identifying patient's female and male who are at increased risk for HBOC could potentially allow their patients to have better screening and risk management/treatment in relation to the cancers in this syndrome.

Consequences of the Problem

As previously mentioned, ovarian cancer is the gynecologic cancer with the worst survival rates and outcomes, due to difficulties in early identification. It has been noted that the earlier a disease or condition is identified, the better the outcome and survival rate for the patient is. Unfortunately, women with ovarian cancer or a family history of ovarian cancer are not receiving genetic testing or counseling and thus missing important information for themselves and implications for their families. As noted by one study published by Kurian et al., (2019), in the Journal of Clinical Oncology found that in the timeline between 2013 and 2014 only one-quarter of patients with breast cancer and one-third of patients with ovarian cancer had genetic testing done. 7.8% of patients diagnosed with breast cancer who had genetic testing done were found to have a pathogenic variant. Conversely, for the patients diagnosed with ovarian cancer

who had genetic testing done, 14.5% of those patients were found to have a pathogenic variant. These pathogenic variants that were found warranted change in these patients' care such as a need for an increase in breast cancer screening, earlier colonoscopy, or risk-reducing surgeries such as mastectomy, or oophorectomy (Kurian et al., 2019). The consequence of missing patients with “red flags” for HBOC is the missed opportunity for these high-risk patients to have these increase in screenings, earlier screenings, or prophylactic risk-reducing surgeries. In addition to missing one individual at risk, a generation or family could be at risk as these genes can be passed on from parents and generations before.

Knowledge Gaps

PCPs' knowledge and confidence in referring women with ovarian cancer to genetic testing and counseling are lacking. As discussed in a cross-sectional study done by Hann et al. (2017) the authors studied the attitudes of healthcare professionals toward genetic testing and risk reduction management for ovarian cancer alone. In this study, it was noted that general practitioners had a large difference in knowledge of ovarian cancer as compared to the other specialist in this study (Hann et al., 2017). The specialties surveyed in this study included oncologist, genetics clinicians, general practitioners, gynecologist, and nurses (Hann et al., 2017). General practitioners scored significantly lower than other disciplines in conducting cancer risk counseling and knowledge of genetics (Hann et al., 2017). Out of the 10 questions that were presented in the survey in relation to ovarian cancer and genetics knowledge, general practitioners median score was 4/10. Versus other subspecialties such as clinical genetics and oncologist scored in the median ranges of 8/10 and 7/10. These results do not come as a surprise as general practitioners deal with many health conditions and diseases while the other disciplines in this study such as genetic clinicians, oncologists, and gynecologists are specialized in the

disease and genetic process of ovarian cancer. In the study published by the authors Nair et al. (2017), they sought to see the knowledge of primary care providers as it relates to the identification of high-risk patients for HBOC. In their study, they noted that there were knowledge gaps for primary care providers in identifying patients and their families at risk for HBOC (Nair et al., 2017). They further concluded that PCPs are a critical part of identifying patients at risk for HBOC and ensuring referral for genetic testing and counseling (Nair et al., 2017). PCPs should have basic understanding of HBOC and genetics. The understanding and importance of a patient's family history, and risk factors that account for their patient's risk of HBOC. The goal in identifying patients at risk is to give patients the option of appropriate consultation with experts in order to have the conversations needed to assess what risk-reducing screening and or procedure is appropriate for them. The goal of screening and identification of high-risk patients is prevention.

Literature Search

The literature search identified a total of 109 articles, 6 articles were identified from CINHAL database, 53 were identified from the PubMed database, and 50 articles were identified from the Embase database. A total of 1 article was removed before screening due to duplication giving a total of 108 articles screened. A combination of the words used for this search was hereditary breast and ovarian cancer syndrome, primary care or primary healthcare, or primary health care. A total of 32 records were excluded for being older than 10 years, 20 records were excluded due to publication type. Inclusion criteria for publication type included clinical trials, meta-analysis, randomized controlled trials, systematic reviews. All other articles were excluded. A total of 21 articles were excluded due to being the wrong population/disease type. Inclusion criteria by disease included hereditary breast and ovarian cancer syndrome, breast cancer, or

ovarian cancer. All other diseases or cancer syndromes were excluded such as Lynch syndrome, Li-Fraumeni, Cowden, Peutz-Jeghers, etc. to keep the focus of this literature review on HBOC and BRCA1/2. 32 articles were screened and excluded by their title or abstract due to being either the wrong intervention or population such as articles that reviewed preimplantation testing and experience of risk-reducing surgeries after identification of BRCA mutations. After the application of inclusion, exclusion, and screening of title and abstracts of articles, 3 articles were chosen in this method to include in the literature review. 3 articles were identified through other methods such as citation searching within articles and assessed and included in reviews, giving a total of 7 studies in this literature review. Figure 1 shows the PRISMA flow diagram process

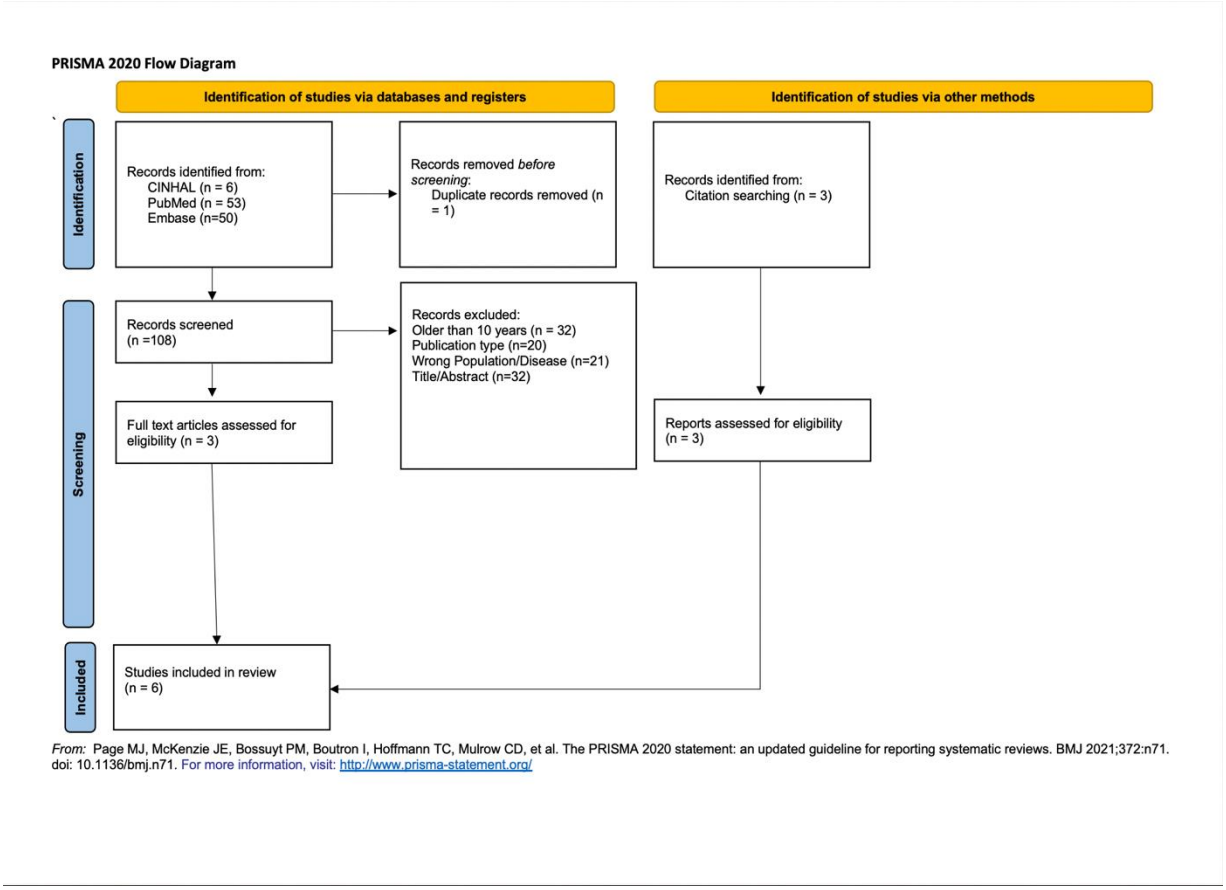

Figure 1. PRISMA flow diagram (Page et al., 2020).

Summary of the Literature

Within the scope of this literature review, it can be noted that genetics is a subspecialty that most providers during their training do not have the opportunity to fully learn and properly incorporate into their practice. As noted in the literature, providers with a greater time in practice had more knowledge and experience with HBOC than those with less experience. These knowledge gaps can be closed by providers in their continued effort to seek continuing education and incorporate the use of guidelines such as those recommended by the USPSTF. These guidelines can potentially allow for providers to screen and identify patients at high risk for HBOC. The first step in closing this gap though is educating primary care providers on HBOC, the importance of a detailed personal and family history intake, and the interpretation of the family history in order to accurately use guidelines to help identify patients at risk for HBOC. The studies included in this review revealed that there are not many studies that analyzed large cohorts of participants, thus potentially skewing, and not accurately portraying general results. Though these studies were of small cohorts across the U.S similar patterns and results were revealed in each study. Future studies should also focus on whether providers have heard of these guidelines and based on the guidelines if they are able to correctly screen and identify these high-risk patients (Bellcross et al., 2011). There are still gaps and concepts to be understood in this topic, but a consensus can be made that there is a potential knowledge deficit in the primary care setting with regard to HBOC, and patients at high risk are not being identified, thus causing potential harm to patients and their families who should be receiving increased screening or further evaluation.

Literature Review

Knowledge Deficit in Primary Care

One of the themes revealed in the literature review is that of a knowledge deficit in primary care providers in identifying patients at an increased risk for HBOC. The study published in the Journal of Cancer Education by authors Nair et al. (2017), aimed to assess and evaluate Georgia primary care providers' knowledge of HBOC (Nair et al., 2017). This study was able to do so in providing surveys to primary care providers across Georgia. The survey questions assessed primary care providers knowledge of HBOC, BRCA gene mutation inheritance pattern, referral pattern to genetics in their practice, and clinical scenarios for the primary care providers to identify what family history pattern or patient is at the highest risk for HBOC (Nair et al., 2017). Consequently, 44% of providers reported referring patients to genetic counseling but 92.1% failed to recognize ovarian cancer at any age as a risk factor for HBOC (Nair et al., 2017). Of the two basic knowledge questions asked with regard to inheritance patterns and first-degree relative risk 53.4 and 39% of primary care providers correctly answered these questions (Nair et al., 2017). For the last two questions that assessed clinical application for high-risk patients there was a 37.1% and a 3.9% correct response rate (Nair et al., 2017). The limitations identified were that this study was limited to only providers in the state of Georgia. These results do not reflect the knowledge and consensus of all primary care providers in Georgia, let alone across the country. Another limitation noted was the study sampling size. Again, this cohort of participants in this study only represents less than 1% of all primary care providers in the state of Georgia (Nair et al., 2017). Though this study has limitations, it did provide many details and insight into the knowledge of primary care providers and HBOC. This study helped to suggest that primary care providers are not properly recognizing patients at risk for HBOC and that screening tools implemented into the primary care setting can help to improve the identification of patients at high risk. Correspondingly, a more recent study

published in the Journal of Genetic Counseling by authors Dekanek et al. (2019) also conducted a study of primary care providers' knowledge and confidence in regard to HBOC. In this study, a questionnaire was designed to assess the knowledge of primary care providers about BRCA1/2, including inheritance patterns, indications for testing, and confidence in communicating result interpretations (Dekanek et al., 2019). The surveys revealed that among the primary care providers, there were several gaps identified for BRCA1/2 knowledge (Dekanek et al., 2019). The average score to correct answers to knowledge questions for BRCA1/2 was 73%. In the surveys conducted, they also revealed that participants were not confident in their abilities to counsel or test patients for BRCA1/2 about 50% of participants revealed that they felt confident in counseling or discussing testing with patients about BRCA1/2. (Dekanek et al., 2019). Limitations to this study included that the participants in this study were from a large academic hospital with more than half of the participants having 15 years or more experience as clinicians. The study population is not representative of all primary care providers as many do not work in large academic hospitals with resources to geneticists or genetic counselors (Dekanek et al., 2019). With that being mentioned, it still conveys the need for more education of primary care providers, and the possibility of incorporation of tools to aid clinicians in any setting. In comparison, the study published by authors Trivers et al. (2011) also conducted a vignette survey study amongst primary care providers across the United States that sought to investigate primary care providers adherence to referring patients to genetic counseling based on their risk for ovarian and breast cancer (Trivers et al., 2011). In this vignette study, 41% of primary care providers failed to identify patients at high risk for ovarian and breast cancer, while 74% mislabeled average risk patients as high-risk patients while only 65% of clinicians were able to correctly identify patients as high risk for breast or ovarian cancer (Trivers et al., 2011). These

numbers are concerning because real patients could be missed or looked over because the healthcare provider cannot properly identify patients at an increased risk. This study had its limitations in that it was a vignette-based study it does not necessarily reflect a health care provider's practice (Trivers et al., 2011). It is also uncertain of the guidelines these health care providers were following when analyzing the vignette-based surveys. For example, the USPSTF recommends the use of family history screening tools such as the ones mentioned earlier in this review. Another study published in the American Journal of Preventative Medicine by authors Bellcross et al. (2011) also analyzed the knowledge and awareness of BRCA amongst primary care providers in the U.S. (Bellcross et al., 2011). This study included 4 scenarios for primary care providers to identify whether it was considered an increased risk, or low risk for HBOC based on family history pattern in relation to the USPSTF guidelines. The participants were also asked if they were aware of the BRCA testing and if they had ever ordered BRCA testing for their patients. Of the 1,500 primary care providers who participated, 87% were aware of the BRCA testing and 25% reported to have ordered BRCA testing in the last year, (Bellcross et al., 2011). It was noted in this study that providers who were aware of testing and had ordered BRCA testing were more likely to recognize a high-risk scenario than the providers who answered that they were aware of testing but had never ordered BRCA testing (Bellcross et al., 2011). This study suggests that many providers do not recognize patients at risk for HBOC through family history as suggested by the USPSTF guidelines (Bellcross et al., 2011). This study had its limitations in that it does not fully represent all primary care provider's practices in the U.S., and it did not seek to ask if providers were aware of the USPSTF guidelines and recommendations for patients at risk for HBOC. Amongst the literature, it can be noted that there is a knowledge gap amongst primary care providers and identifying patients at an increased risk

for HBOC. Guidelines that are set in place such as those recommended by the USPSTF allow for providers to properly screen and identify at-risk patients.

Prevalence of Referral

For patients to be referred to genetics for counseling, they must first be identified by their primary care providers. The following study conducted by authors Quillin et al. (2014), sought to analyze the prevalence of referrals to genetic counseling for patients at risk for HBOC. The participants in this study were asked to complete a survey that included questions about their personal and family history of breast and ovarian cancer. The participants were then categorized as high risk by the USPSTF guidelines for BRCA referral for counseling and testing and then asked if they had ever met with a genetic counselor or had been referred for testing (Quillin et al., 2014). Of the 486 participants, 22 participants met the criteria for BRCA counseling and testing with only one participant stating they met with a genetic counselor. However, this participant did not undergo genetic testing (Quillin et al., 2014). The results from this study suggested that 1:22 patients in a primary care setting qualify for referral to genetics-based on current guidelines (Quillin et al., 2014). The limitations in this study included that family history was self-reported and not verified. This study was also only conducted in a single institution and does not reflect the general population. Family history is an important implication for identifying patients based on USPSTF guidelines. Primary care providers are at the forefront of proper and detailed patient family histories in order to identify at-risk patients when using guidelines such as those recommended by the USPSTF. In an earlier study conducted by Bellcross et al. (2013) they also assessed the prevalence of patients meeting USPSTF guidelines for increased risk of HBOC and whether these patients were referred to genetics for counseling or testing. In this study, the participants' family history was collected and assessed for increased risk as determined by

USPSTF guidelines. They were divided into groups of patients with a personal history of cancer, and no personal history of cancer. Roughly 90% of participants in this study who met USPSTF guidelines for referral had a conversation with their primary care providers about their family history. It was revealed in this study though, that only 20% of the participants had been referred to genetics for counseling (Bellcross et al., 2013). Mirroring similar results as the study conducted by Quillin et al. (2014). In the literature, it is noted that though patients are having conversations with their primary care providers about their family history, patients at high risk for HBOC are not being identified and referred to genetics for counseling.

PICO Clinical Question

P- In patients at risk for hereditary breast and ovarian cancer syndrome (HBOC)

I- Does the use of an evidence-based family history screening tool in the primary care setting

C- N/A

O- Increase the identification of patients at risk for hereditary breast and ovarian cancer syndrome?

Primary DNP Project Goal

The primary goal of this quality improvement project is to understand the effects of implementing an evidenced-based family history screening tool in the primary care setting in order to increase the identification of patients at risk for hereditary breast and ovarian cancer syndrome. By achieving this project goal, the knowledge and confidence of primary care providers in identifying patients at risk for hereditary breast and ovarian cancer syndrome (HBOC) can be further understood. Implementing an evidence-based family history screening

tool into the primary care setting can further provide primary care providers with the appropriate tools needed to identify and increase the identification rate of patients at risk for HBOC. Identification of these patients at risk for HBOC and referral to genetic care can potentially detect genetic mutations in these patients that have preventative screening and guidelines. Currently, at the University of Miami where the quality improvement project is taking place, there is no policy in place in relation to hereditary breast and ovarian cancer syndrome screening. For example, the University of Miami has a policy in place that provides guidelines for referral to the Lung Cancer Screening Program, screening criteria, screening procedures, and pulmonary nodule management through the recommendation for lung cancer screening according to the USPSTF and National Comprehensive Cancer Network (NCCN) guidelines. No policy or procedures exist at the University of Miami for hereditary breast and ovarian cancer syndrome. In the University of Miami's electronic health record that is utilized, family history intake and a pedigree can be taken and created, but once the information is put into the electronic health record, there is no alert or clinical decision support functionality. The provider is left to interrupt the data and information that has been collected on the patient.

As noted in the literature, primary care providers lack the knowledge and confidence in identifying patients at an increased risk for HBOC. As revealed in the study conducted by Nair et al. (2017) Primary care providers have limited knowledge of HBOC. Including knowledge deficits in inheritance patterns, and failure to recognize the significance of personal and family history as it relates to HBOC. This study suggested that patients at risk for HBOC may not be regularly identified (Nair et al., 2017). As also published by Childers et al. (2017), revealed the national estimates of genetic testing in women with a history of breast or ovarian cancer noted that less than one in five individuals with a history of breast cancer or ovarian cancer met the

criteria for genetic testing under NCCN guidelines underwent genetic testing (Childers et al., 2017). In identifying these knowledge deficits and lack of referral to genetics in the primary care setting through the literature, as well as no current policy or procedure in the immersion site, this project aims to increase provider awareness, confidence and increase the identification of patients at risk for HBOC through the use of evidence-based guidelines screening tools

Objectives

"SMART" is an acronym that stands for specific, measurable, attainable, realistic, and timely objectives. This acronym is used to identify the objectives and activities needed to accomplish the goals of a project (Centers for Disease Control and Prevention, 2021c). The SMART Goal Form provided by the Centers for Disease Control and Prevention will be used to understand the process of developing SMART goals. The SMART goals for this quality improvement project are shown in Table 1.

Table 1.

Not-so-SMART objective: Increase the knowledge and identification rate of patients at risk for hereditary breast and ovarian cancer syndrome in the primary care setting.	
Key Component	**Objective**
Specific - What is the specific task?	To increase the knowledge and provide primary health care providers with educational materials and an evidence-based family history screening tool to use in practice in order to help providers easily identify patients at risk for HBOC.
Measurable - What are the standards or parameters?	Surveys/questionnaires will be provided to primary care providers after approval by the Internal Review Board (IRB) of UM and FIU. Data will be collected and interpreted using REDcap.
Achievable - Is the task feasible?	The project is feasible secondary to the availability of primary care providers willing to participate in this project.
Realistic - Are sufficient resources available?	The University of Miami is a research and teaching facility, and the recruitment of primary care providers will facilitate data collection. This project will provide insight into patient screening and

	promote the increase of knowledge and identification of patients at an increased risk for HBOC.
Time-Bound - What are the start and end dates?	The project will be implemented and completed between July of 2022 and October of 2022.
SMART objective 1: From July of 2022 through October of 2022, implementation, and the use of educational and evidence-based family history screening tools into primary care providers practice will be used with the initiative of increasing the knowledge of providers and identification of patients at risk for HBOC.	

(Centers for Disease Control and Prevention, 2021c).

Definition of Terms

Hereditary breast and ovarian cancer syndrome (HBOC): is a genetic conditions that increases the likely hood of a person to develop breast, ovarian and other forms of cancer (Centers for Disease Control and Prevention, 2021a).

Hereditary: received or capable of passing from an ancestor to an offspring (Merriam-Webster Dictionary, 2019).

Gene mutation: a variation or change in the DNA sequence of a gene.

Pathogenic variant: a gene mutation known to cause and increase the likely hood of disease.

Genetic counseling: the processes of assisting affected or at-risk individuals in understanding their disease risk and risk management options (National Cancer Institute, 2012).

Genetic counselor: healthcare professional with a graduate education and training in genetics.

Conceptual Underpinning and Theoretical Framework

The Donabedian model will be utilized as the conceptual underpinning for this quality improvement project. The Donabedian model is the standard approach for assessing quality in healthcare. The model includes three categories: structure, process, and outcome (Howell & Stevens, 2020). The structure includes evaluating the characteristics of the healthcare system.

The process encompasses the specific and measurable actions that are theorized to have an impact on the outcome measures, and the outcome includes the goal or the impact on patient care (Howell & Stevens, 2020). In using this model, the structure of the healthcare system creates the process of care, in this scenario the primary care providers in this institution do not have a policy or procedure to identify patients at high risk for HBOC (Howell & Stevens, 2020). No family history screening tools or policies and procedures to identify patients at risk for HBOC results in patients at increased risk are being missed and there is a missed opportunity for increased screening or measures for patients to take in preventing their cancer risk (Howell & Stevens, 2020). The purpose of this quality improvement project and in using this model is to increase primary care providers' knowledge and provide healthcare providers with the necessary evidence-based screening tools to identify and refer patients at risk for HBOC. Lewin's Change theory will be utilized as the theoretic framework to guide this quality improvement project. Lewin's Change Theory is a three-step model with the proposition that behavior is a dynamic balance of forces working in opposition (Gorbunoff et al., 2014). These driving forces encourage change by driving participants in the desired direction and inhibiting forces that could impede change (Gorbunoff et al., 2014). In this three-step model theory, the first step of altering behavior and "unfreezing" begins with analyzing the current organization and its current practices. In doing so, the primary care providers of the organization can become aware of current practice guidelines, education, and tools that are available to aid in the practice and identify patients at an increased risk for HBOC as compared to their current practice. The second step involves the change and so-called "movement" needed to achieve the change in current practice. This will include providing primary care providers with the necessary educational handouts and family history screening tools needed to be successful in identifying patients at

increased risk for HBOC. These educative hand out's and family history screening tools will allow for providers to understand the reasoning and rationale of which patients are at an increased risk and help to identify patients at an increased risk. Lastly, the third step in the theory involves "refreezing," which includes reinforcing this new change in practice. Reinforcing the importance of identification of patients at increased risk for HBOC by using evidence-based guidelines will help to change the cultural norm of the organization. The proposed quality improvement project "The Effect of Implementing an Evidence-Based Family History Screening Tool in the Primary Care Setting to Increase the Identification of Patients at Risk for Hereditary Breast and Ovarian Cancer Syndrome" will address the current clinical practice and create a cultural norm and improve the clinical practice of primary care providers in using evidence-based guidelines to identify patients at an increased risk for HBOC.

Methodology

Setting, Participants and Description of Approach and Project Procedures

This project was conducted through the use of surveys. Potential participants were identified from the healthcare provider staff lists at the University of Miami Primary Care Provider website. This staff list is public information and gives the name of each health care provider that works at each site. The health care providers emails are listed on the University of Miami people directory website which is also public information. Potential participants were invited to participate in the quality improvement project by email. Physicians (MD/DO) who specialize in internal medicine, family medicine, currently practicing in a primary care setting, Nurse Practitioners currently practicing in a primary care setting, Physician Assistants currently practicing in a primary care setting at the University of Miami sites were identified and asked to participate via email. The questionnaires were conducted via a digital survey using REDcap.

REDcap web application is a secure web application used for building and managing online surveys and databases. The initial survey includes clinical scenario questions to assess the healthcare providers knowledge in identifying patients at risk for HBOC according to USPSTF guideline family history screening tool "Seven-Question Family History Screening (U.S Preventative Services Task Force, 2019)." The initial questionnaire is presented in table 3. Once the knowledge assessment was completed by the provider, they received a copy of the "Evidence-based practice guidelines supporting genetic susceptibility testing for hereditary breast and ovarian cancer syndrome tool (Centers for Disease Control and Prevention, 2021b)." This tool can be found and is provided by the Centers for Disease Control and Prevention and is intended to assist primary care providers with the information and evidence-based guidelines set forth by USPSTF recommendations. The full supplemental tool can be found in appendix B. The primary care providers participating in this quality improvement project were also provided with a copy of the Seven-Question Family History Screening tool to implement into their daily practice. This tool is provided in table 4. The goal of this project was to provide primary care providers with the tools and guidelines needed to identify patients at risk for HBOC. The providers had 6 weeks to review and incorporated the tools into their practice. After the 6 weeks, the providers were asked to complete a second digital REDcap survey assessing their knowledge and confidence in identifying increased risk for HBOC via clinical scenarios. The post-assessment questionnaire is presented in table 5. This quality improvement project was dependent on primary care provider's willingness to participate. It was also dependent on the provider's willingness to read and update their knowledge on the current guidelines that were provided. It is important for providers to understand the importance of family history screening as it relates to their patient's health history and indication for screening or referrals.

SWOT Analysis

A SWOT analysis is a method that can be used to evaluate the strength, weaknesses, opportunities, and threats that can have an effect on achieving the project goal (Centers for Disease Control and Prevention, 2021d). The University of Miami is a large teaching and research hospital, which gives to its providers and patient population an opportunity to learn and experience new research and advances in medicine. Strengths to take into consideration for this quality improvement project also include the many disciplinaries and specialties that are within the health care system. Allowing for any provider in this system to have access to specialists and referrals for their patients. It can be noted that at the start of a new quality improvement project there will be a need to recruit and retain participants for said project. This attrition can be seen as a threat and weakness that can affect the quality improvement project. Other weaknesses and threats identified for the project included acceptance of changes in providers' practices. The full SWOT analysis is provided in Table 2.

Table 2. SWOT Analysis

Internal Factors	
Strengths	**Weaknesses**
• Research and teaching hospital • Many disciplinary and specialties at hand for primary care providers and outreach for support • Experienced staff	• No current policy or procedure in place for identification of HBOC • Recruitment of primary care providers to participate in project • Retention of primary care providers to continue with project
External Factors	

Opportunities	Threats
• Participants of the project are all within the University of Miami health care system • Incentive for primary care providers to increase their knowledge on HBOC	• Acceptance of change and implementation of screening tool to practice • Increase in time it takes to collect and analyze family history • Continuation and maintenance of the project after it has been implemented

Protection Of Human Subjects

The proposed quality improvement project qualified as exempt research according to the U.S Department of Health and Human Services Office for Human Research Protections pursuant to 45 CFR 46.104:

> (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
>
> (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
>
> (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

Participants for this quality improvement project were recruited through email; potential participants were those who are currently specialized in family medicine or internal medicine, practicing primary care. Including Nurse Practitioners, Physician Assistants, Doctor of Medicine (MD), or Doctors of Osteopathic Medicine (DO). The information and data obtained during this project was in a manner that did not identify the participants.

Participants responses were not linked to their identity. (No identifying information was included on the surveys and the documents were not coded and linked to the individual's identity.) The researchers were able to track who had responded to the surveys via a participant list that contains email addresses, but the researchers did not know which individual survey belonged to which respondent/participant. All surveys completed by participants did not ask for participants name or identifying information. All electronic data was maintained on an encrypted device requiring a password for access. Surveys were completed through the University of Miami REDCap web portal program, which is password protected and only the student researcher involved in the study had access to the study survey within the REDCap system. The topic addressed would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

The consent process was initiated with study participants prior to starting any research procedures. Participants were given ample time to consider their agreement. Consent was obtained voluntarily prior to initiating any study procedures: Potential participants were asked to complete consent and acknowledgment of participation in the research project through electronic consent using the University of Miami REDcap web platform. Consent was provided to reassure potential participants that their participation is voluntary, no personal information will be asked or disclosed, and there are no negative consequences to not taking place in the project, participating in the project involves no risk. Benefits to participating in the quality improvement project include primary care providers increasing their knowledge of HBOC and the use of screening tools to identify patients at risk for HBOC. While others involved may benefit from the knowledge obtained from this research quality improvement project.

This study was approved by the IRB at The University of Miami, Miami, FL and Florida International University, Miami, Florida.

Data Collection

The collection of data was acquired from the Pre-Implementation Primary Care Provider Assessment and from the Post-Implementation Primary Care Provider Assessment surveys. These surveys were anonymous and completed through the University of Miami's REDcap survey application. A web link was sent to agreeing participants via email for access to both surveys. Once completed, the providers were provided with the Seven-Question Family History Screening Tool which can be found in table 4 and the Evidence-based Practice Guidelines Supporting Genetic Susceptibility Testing for Hereditary Breast and Ovarian Cancer Syndrome guideline, which can be found in Appendix B. Participants' knowledge and confidence in HBOC, and identification of at-risk patients were assessed. This was achieved by utilizing clinical scenario questions that included assessing knowledge of inheritance patterns, and current clinical practice. After the providers reviewed and utilized the family history screening tool in their practice for 6 weeks, they were then asked to complete a second and final post-implementation primary care provider's assessment survey. The post-implementation survey assessed the provider's knowledge and confidence in identifying patients at an increased risk for HBOC after reviewing and utilizing the family history screening tool and guideline. Knowledge and confidence were once again assessed through utilizing patient scenarios, self-reporting of confidence, and the self-reported numbers of patients that were identified as the increased risk through the use of the screening tool. The pre- and post-implementation surveys can be found in Tables 3 and 5.

Table 3. Pre-implementation Primary Care Provider Assessment

Clinical Scenario	USPSTF Recommendations/ Rationale for question
As a primary care provide which title would best describe you? MD DO PA NP	Assessing how many participants fall in what healthcare provider category
How many years have you been practicing in Primary care? 1-3 years 3-6years 6-9 years 10+ years	This question will assess how many years of experience the participant has in practicing in a primary care setting.
How confident do you feel in identifying patients at risk for HBOC? Very confident Somewhat confident Not at all confident	Assessing providers self confidence in identifying patients at risk for HBOC.
On average how many patients do you identify at risk for HBOC and refer to genetics for counseling per month? 0-3 5-10 10-20	Assessing how often providers are identifying and referring patients to genetics for counseling.
Do you currently use a screening tool to assess patients at an increased risk for HBOC? Yes No	Assessing if provider currently uses any screening tool or guide in practice to identify HBOC.
A patient can inherit a BRCA 1 or BRCA 2 pathogenic variant from:	Assessing Providers knowledge of inheritance patterns.

Their mother only *Either parent Their Father only	
Which of the following patient scenarios is at an increased risk for HBOC? Patient with a family history of their mother diagnosed with cervical cancer at the age of 50. Patient with a family history of their father diagnosed with lung cancer at the age of 70. *Patient with a family history of a maternal aunt diagnosed with breast cancer at the age of 45.	In utilizing the Seven-Question Family History screening tool: Any patient with a family history of a women with a breast cancer diagnosis before the age of 50 should initiate a referral for genetic counseling.
Which of the following patient scenarios is at an increased risk for HBOC? *Patient with a family history of their paternal grandmother diagnosed with breast cancer at the age of 60 and their paternal aunt diagnosed with breast cancer at the age of 65. Patient with a family history of their father diagnosed with basal cell carcinoma at the age 65 and their mother diagnosed with basal cell carcinoma at the age 60. Patient with a family history of a maternal cousin who was diagnosed with cervical cancer diagnosed at the age of 50.	In utilizing the Seven-Question Family History screening tool: Any patient with a family history of 2 or more relatives with a diagnosis of breast cancer should initiate referral for genetic counseling.

Which of the following patient scenarios is at an increased risk for HBOC? Patient with a family history of their mother diagnosed with cervical cancer at the age of 50 *Patient with a family history of their sister diagnosed with breast cancer at the age of 60 Patient with a family history of their father diagnosed with lung cancer at the age of 70	In utilizing the Seven-Question Family History screening tool: Any first degree relative with a history of breast cancer should initiate referral for genetic counseling.
Which of the following patient scenarios is at an increased risk for HBOC? *Patient with a family history of a paternal grandmother diagnosed with bilateral breast cancer at the age of 60 Patient with a family history of a maternal cousin diagnosed with breast cancer at the age of 70 Patient with a family history of a paternal aunt diagnosed with cervical cancer at the age of 50.	In utilizing the Seven-Question Family History screening tool: any relative with a diagnosis of bilateral breast cancer should initiate a referral for genetic counseling.
*Indicates correct answer	

Table 4. Post-implementation Primary Care Provider Assessment

Questions	Rationale
Was the screening tool helpful in your everyday practice in identifying patients at an increased risk for HBOC?	Assessing providers opinion on helpfulness of using screening tool in practice.

Very helpful Somewhat helpful Not at all helpful	
How confident are you in identifying patients at an increased risk for HBOC while using the screening tool? Very confident Somewhat confident Not at all confident	Assessing primary care providers confidence in identifying patients at increased risk for HBOC post implementation of screening tool.
On average how many patients were identified at increased risk for HBOC after implementation of the screening tool? 0-3 5-10 10-20	Assessing how often providers are identifying and referring patients to genetics for counseling after implementation of screening tool.
A patient can inherit a BRCA 1 or BRCA 2 pathogenic variant from: Their mother only *Either parent Their Father only	Assessing Providers knowledge of inheritance patterns.
In using the screening tool: Which of the following patient scenarios is at an increased risk for HBOC? Patient with a family history of their mother diagnosed with cervical cancer at the age of 50. Patient with a family history of their father diagnosed with lung cancer at the age of 70. *Patient with a family history of a maternal aunt diagnosed with breast cancer at the age of 45.	Assessing the usability in identifying patients at risk for HBOC with family history screening tool. Will compare Pre-implementation answers VS Post-implementation answers. In utilizing the Seven-Question Family History screening tool: Any patient with a family history of a women with a breast cancer diagnosis before the age of 50 should initiate a referral for genetic counseling.

In using the screening tool: Which of the following patient scenarios is at an increased risk for HBOC? Patient with a family history of their mother diagnosed with cervical cancer at the age of 50 *Patient with a family history of their sister diagnosed with breast cancer at the age of 60 Patient with a family history of their father diagnosed with lung cancer at the age of 70 .	Assessing the usability in identifying patients at risk for HBOC with family history screening tool. Will compare Pre-implementation answers VS Post-implementation answers. In utilizing the Seven-Question Family History screening tool: Any first degree relative with a history of breast cancer should initiate referral for genetic counseling.
In using the screening tool: Which of the following patient scenarios is at an increased risk for HBOC? *Patient with a family history of their paternal grandmother diagnosed with breast cancer at the age of 60 and their paternal aunt diagnosed with breast cancer at the age of 65. Patient with a family history of their father diagnosed with basal cell carcinoma at the age 65 and their mother diagnosed with basal cell carcinoma at the age 60. Patient with a family history of a maternal cousin who was diagnosed with cervical cancer diagnosed at the age of 50.	Assessing the usability in identifying patients at risk for HBOC with family history screening tool. Will compare Pre-implementation answers VS Post-implementation answers. In utilizing the Seven-Question Family History screening tool: Any patient with a family history of 2 or more relatives with a diagnosis of breast cancer should initiate referral for genetic counseling.
In using the screening tool: Which of the following patient scenarios is at an increased risk for HBOC?	Assessing the usability in identifying patients at risk for HBOC with family history screening tool. Will compare Pre-implementation answers VS Post-implementation answers.

*Patient with a family history of a paternal grandmother diagnosed with bilateral breast cancer at the age of 60 Patient with a family history of a maternal cousin diagnosed with breast cancer at the age of 70 Patient with a family history of a paternal aunt diagnosed with cervical cancer at the age of 50.	In utilizing the Seven-Question Family History screening tool: any relative with a diagnosis of bilateral breast cancer should initiate a referral for genetic counseling.
*Indicates correct answer	

Educational Resources/ Family History Screening Tool

Table 5. Seven-Question Family History Screening Tool

No.	Questions
1	Did any of your first-degree relatives have breast *or* ovarian cancer?
2	Did any of your relatives have bilateral breast cancer?
3	Did any man in your family have breast cancer?
4	Did any woman in your family have breast *and* ovarian cancer?
5	Did any woman in your family have breast cancer before age 50 y?
6	Do you have 2 or more relatives with breast *and/or* ovarian cancer?
7	Do you have 2 or more relatives with breast *and/or* bowel cancer?

*One positive response initiates referral (U.S Preventative Services Task Force, 2019)

Data Management

The collection of consents was done electronically through REDcap. The collection of survey data was also done through REDcap, which is a secure web platform for building and managing online databases and surveys. Data collection and consents were stored through this platform and is password protected. Only researchers invited to participate in this project on REDcap were able to access or view the data. The information in this web platform will not be linked to the participant's identity secondary to the implementation of anonymous surveys. No personal information was asked of the participants during the surveys and of individuals who did

not agree to participate in this project. Data analysis was performed by the quality improvement team members after the completion of data collection through the ability to export data from Redcap into a CSV file.

Discussion

Limitations

The delayed launch of this quality improvement project was impacted by the Internal Review Boards at the University, and at the clinical site. Despite submitting protocols early, the quality improvement project approval was given by the University in July 2022, while the clinical site approval was received in August 2022.

The project length and implementation of the project was originally proposed to begin in June 2022 and to be implemented for 12 weeks. The project was reduced to 6 weeks due to this delay in approval. Thus, our time for recruitment was also reduced. Despite reaching out to those identified as potential participants for participation (n=41) the response rate to the initial survey was low (n=5) bringing the total response rate to 12.2%. While post-implementation response rate was decreased (n=3) as participants were lost to attrition. Though the sample size is considered small for research standards, this project can reveal the potential knowledge gaps and bring interest to bigger studies on this topic. As this quality improvement project has taken place in only one institution, the results of this project would not reflect the standard of practice for all primary care providers or for the providers within this institution. More research on the topic of the knowledge deficit of primary care providers in relation to HBOC is needed, but this project can open the discussion and further add to the literature.

Results

As noted from previous studies, the literature has demonstrated that primary care providers have shown to have a knowledge deficit when it comes to HBOC. The literature has also demonstrated that in primary care providers not being able to identify at-risk patients for HBOC there is a decrease in referral rates to genetics for appropriate counseling.

A paired sample t-test was performed to determine the statistical significance. Participants average scores were compared pre-implementation and post-implementation of the use of a family history screening tool. On average, pre-implementation clinical questions scores were worse (M=75, SD= 43.30) than compared to post-implementation where the use of the family history screening tool implementation was used (M=86.66, SD= 23.09). This improvement though of 11.66, was not statistically significant, $t(2)= 3.46$, $p =.762$. Though at this time there is no statistical significance, an inference can be made that if a larger population was used the hypothesis can be accepted as it was noted that average scores pre-implementation and post-implementation improved.

Results from the pre-implementation survey revealed that 40% of participants identified themselves as MD, 40% of providers identified themselves as NP and 20% of providers identified themselves as DO. On average, 60% of providers identified as having 10+ of year's experience, 20% had 6-9 years of work experience, and 20 percent of providers had 3-6 years of experience. 40% of providers rated themselves as very confident in identifying patients at risk for HBOC, while 40 percent reported no confidence at all, and 20% reported being somewhat confident. On average, 80% of providers reported 0-3 patients per month that they identified at-risk patients for HBOC and refer to genetics for counseling. While 20% reported 5-10 patients per month identified and referred to genetics for counseling 100% of providers participating in

these surveys reported not using a screening tool to assess patients at an increased risk for HBOC.

The pre-implementation knowledge questions showed that all providers scored an average of 65% on the clinical situational knowledge questions. Providers with 3-9 years of experience who felt very confident in identifying patients at risk for HBOC scored an average of 100% on the clinical scenario knowledge questions. Providers with 10+ years of experience who felt very confident in identifying patients at risk for HBOC scored an average of 50 % on the clinical scenario knowledge questions. Providers with 10 + years of experience who felt somewhat confident in identifying patients at risk for HBOC scored an average of 100% on the clinical scenario knowledge questions and providers with 10+ years of experience who felt not at all confident in identifying patients at risk for HBOC scored an average of 37.5%. As this cohort of participants is small, it does not reflect the national average PCP knowledge nor does this quality improvement project reflect the standard or average knowledge of PCPs at the University of Miami. Though these results do reflect what has been noted in the literature. As predicted, the PCPs involved in this project have a variable range of knowledge of HBOC. The findings suggest that clinical knowledge is independent of experience or confidence. Providers with 3-9 years of experience who felt very confident in identifying patients at risk for HBOC scored an average of 100% on the clinical scenario knowledge questions, Whereas Providers with 10+ years of experience who felt very confident in identifying patients at risk for HBOC scored an average 50 % on the clinical scenario knowledge questions.

Post implementation, survey results showed that 100% of participants found the family history screening tool helpful in identifying patients at an increased risk for HBOC. An average of 66.7% of participants rated and felt as very confident in identifying patients at an increased

risk for HBOC while using the family history screening tool while 33.3% rated and felt as somewhat confident. In comparing the pre-implementation results to at-risk patient scenarios where no family history screening tool was utilized versus post-implementation results where a family history screening tool was utilized, we can see that on average, participants' average scores were better when utilizing the family history screening tool.

Question 1 assessed Providers' knowledge of inheritance patterns, in both pre- and post-surveys participants, who scored this answered correctly 100% of the time. Question 2 assessed the identification that any patient with a family history of a woman with a breast cancer diagnosis before the age of 50 should initiate a referral for genetic counseling, pre-implementation of the family history screening tool provider's average score was 60% while the implementation of the tool revealed a 66.7% rate of identifying at-risk patients. Question 3 assessed the identification that a patient with a family history of 2 or more relatives with a diagnosis of breast cancer should initiate a referral for genetic counseling, pre-implementation of the tool, providers' average score was 80% while post-implementation with the tool was 66.7%. Question 4 assessed the identification that any first-degree relative with a history of breast cancer should initiate a referral for genetic counseling. Pre-implementation of the tool, the average score was 40% while post-implementation was 100%. Question 5 assessed the identification that any relative with a diagnosis of bilateral breast cancer should initiate a referral for genetic counseling, pre-implantation of the tool result was 80% while post-implementation was 100%.

As previously mentioned, this cohort of participants is small, and it does not reflect the national average PCP knowledge, nor does this reflect the standard or average knowledge of PCPs at this institution. Though these results do reflect what has been noted in the literature. As predicted, PCPs have a variable range of knowledge of HBOC. For example, one study revealed

that among primary care providers, there were several gaps identified in BRCA1/2 knowledge (Dekanek et al., 2019). The average score to correct answers to knowledge questions for BRCA1/2 was 73%. As demonstrated previously, the average correct answer to knowledge questions amongst all providers in the pre-implementation survey was 65%. As identified, there is a variable range of knowledge when it comes to HBOC. These findings also suggest clinical knowledge is independent of experience or confidence. Providers with 3-9 years of experience who felt very confident in identifying patients at risk for HBOC scored an average of 100% on the clinical scenario knowledge questions. Whereas providers with 10+ years' experience who felt very confident in identifying patients at risk for HBOC scored an average of 50 % on the clinical scenario knowledge questions pre-implementation of the family history screening tool.

Post-implementation of the family history screening tool, participants rated the tool as very helpful in identifying patients at an increased risk for HBOC. An average of 66.7% of participants rated and felt as very confident in identifying patients at an increased risk for HBOC while using the family history screening tool while 33.3% rated and felt as somewhat confident. On average, the post-implementation clinical scenario questions while utilizing the family history screening tool showed an increase in the identification of patients at risk for HBOC.

Implications To Advanced Nursing Practice

HBOC as previously mentioned is a genetic condition that is associated with the genes BRCA 1 and BRCA2. Having a pathogenic variant in one of these genes increases an individual's lifetime risk of developing certain cancers such as breast, ovarian, pancreatic, prostate, and melanoma, greater than the average person's risk (Owens et al., 2019). As genetics is an ever-evolving field with fast-changing and continued advancements in technology, it may not be clear to primary care providers who should be evaluated by a genetics specialist. As noted

in the literature, there was a knowledge gap noted in the primary care setting of what patients are at an increased risk for HBOC. As seen in this quality improvement project, results also mirrored what is seen in the literature, a knowledge gap in the primary care setting as it relates to the identification of patients at risk for HBOC. The goal and implications to the advanced nursing practice of this quality improvement project were to identify this knowledge gap and increase the awareness and knowledge of primary care providers of the available family history screening tools and guidelines that are in place for HBOC.

Primary care providers are the gatekeepers to patients' health and the frontline to patients' health maintenance and screening. Increasing awareness, knowledge, and resources for primary care providers about HBOC can aid in increasing the identification of this patient population and these patients at risk can receive the increased screening that is recommended for them in order to reduce their risk of developing cancer.

Screening tools help to identify patients at risk and help providers to refer patients to treatment and or avoid and reduce symptoms, thus improving healthcare outcomes for patients while decreasing healthcare costs and burdens (Iragorri & Spackman, 2018). The information and data gathered from this project can lead to the incorporation of a clinical decision support tool in the electronic health record. Clinical decision support tools can be a promising approach to identifying patients who are at an increased risk for hereditary cancers (Del Fiol et al., 2020). One study conducted by authors Del Fiol et al. (2020), concluded that implementing clinical decision support tools to identify patients at an increased risk for hereditary cancers had several strengths, one of which included building on PCP workflow without creating an additional burden. The authors Del Fiol et al. (2020), also concluded that patients at risk for hereditary cancers were successfully identified using a criteria-based clinical decision platform.

On further validation of my theory that there is a knowledge gap with regard to HBOC in the primary care setting and that the use of family history screening tools can aid in the increase of identification of this patient population, this project can be expanded to include clinical decision-making tools in the electronic health record. Evidence from scholarly studies should drive clinical practice, and the way that cares is delivered to patients. Translating research evidence into clinical practice is key to efficient healthcare delivery and serving the community to provide effective and efficient care (Curtis et al., 2017).

Conclusion

Genetics is an ever-evolving field, and as a discipline, there have been advances and changes in the guidelines that are used in identifying patients at risk for HBOC. There are now recommended guidelines and tools that can be used in the primary care setting to assist primary care providers in the identification of patients at risk for HBOC. This quality improvement project aimed to identify if there was a knowledge gap in the primary care setting in regard to PCP knowledge and HBOC. While also providing PCPs with the resources and tools needed to improve their knowledge and identify patients at risk for HBOC. A paired sample T-test was performed on the data collected from the project's pre-implementation and post-implementation surveys and it revealed that there was no statistical significance. There were challenges in the project timeline in recruiting and maintaining the engagement of the participants, which led to a small sample size. Although this was a small group and non-statistically significant in the conclusions of this project, this quality improvement project reflected what is seen from PCP knowledge variability in the HBOC literature.

Descriptive statistics did reveal that using a screening tool can potentially improve the identification of patients at risk for HBOC. As average scores of participants ability to identify at

risk patient's pre-implementation and post-implementation of a family history screening tool improved. Further validation of the theory that there is a knowledge gap of HBOC in the PCP setting and that a family history screening tool can aid in the increase of identification of this patient population will need to be explored further for more statistical significance and approach.

In closing, further validation is needed but ultimately educating providers and identifying patients at risk for HBOC can increase patient opportunity for risk-reducing screening and procedures and thus potentially improve patient health care outcomes. Further expansion of this project to include clinical decision-making tools can potentially aid in further validating this theory and translating research into changing practice.

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Appendices

Appendix A

A. Project Timeline

February 1, 2022	• Description of research problem and project purpose
February 20, 2022	• Completion of literature review
March 15, 2022	• Project planning, assessment of feasibility, and SWOT analysis
April 17, 2022	• Project proposal
May 2, 2022	• Project proposal to UM IRB
June 6, 2022	• Recruitment of PCPs for quality improvement project
June 27, 2022	• Send initial survey and educational materials to participants to incorporate into practice
July-August 2022	• PCPs to incorporate family history screening tools into their practice
September 30, 2022	• Send final questionnaire to participating PCPs
October 30, 2022	• Data and survey collection
November 10, 2022	• Data compliation, statistical anylysis and finalzation of the project

Updated Plan/Project Milestones

Milestones	Description	Estimated Completion date

REDcap web platform	Begin the making of REDcap platform which includes making potential participant list and surveys for distribution	July 20, 2022 *REDcap platform cannot be made until there is IRB approval.
Potential Participants	Send out emails to potential participants to participate in QI project (Within this email it will lead potential participants to the consent and once consented they will be lead to the survey). Potential participants will be given two weeks to respond to survey. A reminder will be sent out after one week.	July 22, 2022 July 29 (Reminder)
Distribution of Family history screening tool	Once survey is complete, educational materials/family history screening tool will be distributed to participants to begin use in their practice.	August 5, 2022

Implementation of tool	Participants will be given 8 weeks to implement educational materials/ family history screening tool.	October 3, 2022
Post Implementation Survey	Send out post implementation surveys to participants. Participants will be given two week to respond to survey. A follow up reminder will be sent after one week.	October 4, 2022 October 11 (Reminder)
Data analysis	By end-October begin analyzing data and conclude findings of QI project in November.	October 31, 2022

(Moran et al., 2020)

Appendix B

B. Evidence-based Practice Guidelines Supporting Genetic Susceptibility Testing for Hereditary Breast and Ovarian Cancer Syndrome

United States Preventive Services Task Force (USPSTF) Recommendations (2019)[1]

The USPSTF recommends that "primary care clinicians assess women with a personal or family history of breast, ovarian, tubal, or peritoneal cancer or who have an ancestry associated with *BRCA1/2* gene mutations with an
appropriate brief familial risk assessment tool."

- Family history screening tools include
    - Ontario Family History Assessment Tool
    - Manchester Scoring System
    - Referral Screening Tool
    - Pedigree Assessment Tool
    - 7-Question Family History Screening Tool
    - International Breast Cancer Intervention Study instrument (Tyrer-Cuzick)
    - Brief versions of BRCAPRO

- "Women with a positive result on the risk assessment tool should receive genetic counseling and, if indicated after counseling, genetic testing."

- The USPSTF recommendation includes the following personal or family health histories as examples of increased likelihood of having a *BRCA* mutation:
    - Breast cancer diagnosed before age 50
    - Bilateral breast cancer
    - Presence of both breast and ovarian cancer in the same person
    - Breast cancer in a male
    - Multiple cases of breast cancer in the family
    - One or more family members with two primary types of *BRCA*-related cancer
    - Ashkenazi (Eastern European) Jewish ancestry
    - Family member with a known harmful genetic mutation in the *BRCA1* or *BRCA2* gene

Other recommendations

- National Comprehensive Cancer Network (NCCN) (2019) Recommendations[3]
    - Referral for *BRCA* genetic counseling is recommended for individuals with a personal history of any of the following or a first- or second-degree relative (mother, father, brother, sister, child, grandparent, aunt, uncle, niece, or nephew) with any of the following:
        - Family member with a known pathogenic or likely pathogenic *BRCA* mutation
        - Ovarian carcinoma

        - Male breast cancer
        - Pancreatic cancer
        - Metastatic prostate cancer
        - Female breast cancer and one or more of the following
            - Diagnosed ≤ age 45
            - Diagnosed age 46-50 with:
                - Another breast cancer primary at any age
                - ≥ 1 close blood relative with breast cancer or high grade (Gleason score ≥7) prostate cancer at any age
                - An unknown or limited family history
            - Diagnosed ≤ age 60 with triple negative breast cancer
            - Diagnosed at any age with
                - ≥ 1 close blood relative with
                    - breast cancer diagnosed ≤ age 50
                    - ovarian carcinoma
                    - male breast cancer
                    - metastatic prostate cancer
                    - pancreatic cancer
                - ≥ 2 close blood relatives with breast cancer at any age
                - ≥ 2 additional breast cancer primaries at any age
                - Ashkenazi or Eastern European Jewish ancestry
        - High grade prostate cancer (Gleason score ≥7) at any age and one or more of the following
            - ≥ 1 close blood relatives with
                - Ovarian carcinoma at any age
                - Pancreatic cancer at any age
                - Metastatic prostate cancer at any age
                - Breast cancer ≤50 years
            - ≥ 2 close blood relatives with
                - Breast cancer at any age
                - Prostate cancer (any grade) at any age
            - Ashkenazi (Eastern European) Jewish ancestry
        - BRCA1/2 pathogenic or likely pathogenic mutation detected by tumor profiling in the absence of germline mutation analysis

- American College of Medical Genetics (ACMG) and National Society of Genetic Counselors (NSGC) Recommendations (2014)[4]
    - Referral for genetic counseling for *BRCA* is recommended for individuals with a personal or family heath history of
        - Breast cancer diagnosed ≤ age 50
        - Triple-negative breast cancer diagnosed ≤ age 60
        - Two or more primary breast cancers
        - Ovarian, fallopian tube, or primary peritoneal cancer
        - Male breast cancer
        - Ashkenazi Jewish or Eastern European ancestry and breast or pancreatic cancer at any age

- Breast, ovarian, or pancreatic cancer and two or more cases of breast, ovarian, pancreatic, or aggressive prostate cancer in close blood relatives Aggressive prostate cancer and two or more cases of breast, ovarian, or pancreatic cancer in close blood relatives
- Aggressive prostate cancer and two or more cases of breast, ovarian, or pancreatic cancer in close blood relatives

(Centers for Disease Control and Prevention, 2021b)

Appendix C

C. Florida International University Internal Review Board Exemption Letter

FIU | FLORIDA INTERNATIONAL UNIVERSITY

Office of Research Integrity
Research Compliance, MARC 414

MEMORANDUM

To: Dr. Carmen V. Framil
CC: Joanna Gonzalez

From: Maria Melendez-Vargas, MIBA, IRB Coordinator

Date: July 12, 2022

Protocol Title: "The Effect of Implementing an Evidence-Based Family History Screening Tool in the Primary Care Setting to Increase the Identification of Patients at Risk for Hereditary Breast and Ovarian Cancer Syndrome. A Quality Improvement Project."

The Florida International University Office of Research Integrity has reviewed your research study for the use of human subjects and deemed it Exempt via the **Exempt Review** process.

IRB Protocol Exemption #: IRB-22-0329 **IRB Exemption Date:** 07/12/22
TOPAZ Reference #: 111907

As a requirement of IRB Exemption you are required to:

1) Submit an IRB Exempt Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved prior to implementation.
2) Promptly submit an IRB Exempt Event Report Form for every serious or unusual or unanticipated adverse event, problems with the rights or welfare of the human subjects, and/or deviations from the approved protocol.
3) Submit an IRB Exempt Project Completion Report Form when the study is finished or discontinued.

Special Conditions: N/A

For further information, you may visit the IRB website at http://research.fiu.edu/irb.

MMV/em

Appendix D

D. University of Miami Internal Review Board Exemption Letter

UNIVERSITY
OF MIAMI

University of Miami
Human Subject Research Office
Gables One Tower
1320 S. Dixie Highway, #650
Coral Gables, FL 33146

Ph.: 305-243-3195
Fax: 305-243-3328
www.hsro.med.miami.edu

NOT HUMAN RESEARCH

August 10, 2022

Mustafa Tekin
305-243-2381
mtekin@miami.edu

On 8/10/2022, the IRB reviewed the following submission:

Type of Review:	Initial Study
Title of Study:	The Effect of Implementing an Evidence-Based Family History Screening Tool in the Primary Care Setting to Increase the Identification of Patients at Risk for Hereditary Breast and Ovarian Cancer Syndrome. A quality improvement Project.
Investigator:	Mustafa Tekin
IRB ID:	20220315
Funding:	None
Documents Reviewed:	•Consent •IRB UM Proposal •Recruitment Email •Survey and Educational Materials

The IRB determined that the proposed activity is not research involving human subjects as defined by DHHS and FDA regulations.

IRB review and approval by this organization is not required. This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these activities are research involving human in which the organization is engaged, please submit a study modification to the IRB for a determination.

For further information please refer to the Investigator Manual (HRP-103).

Should you have any questions, please contact: Vivienne Carrasco, Manager, IRB, (phone: 305-243-6713; email: vcarrasco@med.miami.edu)