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Impact of a Protocol Implementation on Identification and Referral of Women At-Risk for Hereditary Breast Cancer

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IMPACT OF A PROTOCOL IMPLEMENTATION ON

IDENTIFICATION AND REFERRAL OF WOMEN

AT-RISK FOR HEREDITARY BREAST CANCER

by

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DEDICATION

I dedicate my DNP journey to my husband, Steve Lawson, my Mom, Carol A. Davis, and my dear friend, Kelley Eshenaur, who have each played a valuable role in assisting me in the process of achieving this goal. In addition, to my Dad, John W. Davis, and to Dr. Wallace W. Sherritt, you both blessed me during your days on Earth with your unconditional love and support. I only wish you were here today to see what your gifts helped me accomplish.

ACKNOWLEDGMENTS

PREFACE

May the fundamental goal of this project be achieved, for women at-risk for hereditary breast cancer to justly and promptly gain this knowledge, in order to guide preventive health care actions that promote optimal quality and quantity of life.

"Health, the greatest of all we count as blessings." – Ariphron

"Think left and think right and think low and think high. Oh, the thinks you can think up if only you try!"

<div align="right">– Dr. Seuss</div>

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ABSTRACT

Breast cancer is the foremost new cancer diagnosis and the second highest cause of cancer death in American women (American Cancer Society, 2019). Hereditary breast cancer is most commonly caused by a mutation within the breast cancer susceptibility genes, BRCA 1 or 2, which increases women's risk for breast cancer by five to ten-fold the average population (Mayo Clinic, 2019). The U.S. Preventive Services Task Force has assigned a Grade B recommendation advising health care providers to use a risk assessment tool, such as the Breast Cancer Genetics Referral Screening Tool (B-RST™), to recognize and provide medical management recommendations for high-risk women (Nelson, Pappas, Cantor, Haney, & Holmes, 2019). Offering medical management options to this at-risk group can promote breast cancer prevention or early detection to positively affect health outcomes (ACOG, 2019; Kiely & Schwartz, 2014). The purpose of this evidence based practice (EBP) project was to determine if using the B-RST™ would aid in identifying women who are candidates for cancer genetic and/or High Risk Breast Clinic (HRBC) counseling, in comparison to the approach of reviewing cancer family history in the electronic medical record (EMR). The seven steps of the Iowa Model (Iowa Model Collaborative, 2017) guided this EBP protocol implementation. During a 12-week time period 994 women seen at a nine provider obstetrical and gynecological practice in a Midwestern state had a B-RST™ assessment performed during routine gynecological and new patient appointments. Data were collected by completing and recording the B-RST™ results in the EMR, reviewing populated reports, and performing chart audits. Additionally, chart audits established participation in scheduling and attending referral consultation appointments. Demographic information was obtained for the pre-protocol patient group ($N = 880$) along with genetics ($N = 8$) and HRBC ($N = 6$) referrals for the same 12-week time period one year prior. During this EBP project, a total of 994 participants had the B-RST™ assessment performed. Genetics referrals were provided to 32 (18.4%) of the 174 participants who qualified, with six (21.9%) of the appointments completed. From the 249 participants eligible for a HRBC

consultation, 57 (22.9%) received referrals and eight (14.0%) participants had this performed. A

Chi-square test for independence resulted in *p* values > .05 for the variables of age,

appointment type, insurance, race, and religion; thus determining the sampling was

representative of the office population. Factorial ANOVA analyses were statistically significant

for the effects of the health care providers using the B-RST™ to guide both HRBC ($F_{(6, 1860)}$,

= 9.23, *p* <.001) and genetics ($F_{(6, 1860)} = 6.46$, *p* < .001) referrals. It was determined that use

of the B-RST™ was an effective method for identifying, and subsequently providing appropriate

referrals, to women who are at-risk for hereditary breast cancer at an Ob/Gyn office setting.

Future EBP projects and research should focus on methods to: (a) educate health care

providers about hereditary breast cancer, its associated risks, and B-RST™ use to promote risk

assessment utilization, (b) increase health care provider HRBC and genetics referral rates to

provide identification and medical management for those at-risk, and (c) recognize and address

patient-reported barriers to improve referral acceptance and participation rates.

     Keywords: BRCA 1 or 2, breast cancer, Breast Cancer Genetics Referral Screening

Tool, B-RST™, genetics referral, hereditary breast cancer, High Risk Breast Clinic, protocol,

referral

CHAPTER 1

INTRODUCTION

Background

Being diagnosed with cancer is a formidable reality that many individuals face. In the

United States (U.S.), cancer is second only to cardiovascular disease for leading causes of

death (Centers for Disease Control and Prevention, 2018). In American women, breast cancer

is currently the foremost new cancer diagnosis and the second highest cause of cancer death.

In 2019, it is estimated there will be 268,600 new breast cancer cases in women in the U.S. and

that 41,760 will die from this cancer (American Cancer Society [ACS], 2019). Many factors

influence women's risk of acquiring breast cancer. An important role of a health care provider is

assessing and identifying women who have an elevated predisposition for breast cancer, in

order to offer additional medical management options which promote breast cancer prevention

or early detection (Cusack Jr & Hughes, 2012; Kiely & Schwartz, 2014).

Risk factors for breast cancer are categorized as non-modifiable and modifiable.

Female gender and advancing age, predominantly beyond 50 years old, are two primary non-

modifiable risks (ACS, 2017a; Kiely & Schwartz, 2014; Smith, Mester, & Eng, 2014). According

to the ACS (2017a), additional non-modifiable risk factors include: (a) ethnicity; (b) race; (c)

family history of breast cancer; (d) hereditary breast cancer gene mutations; (e) fetal exposure

to diethylstilbestrol; (f) early menarche; (g) late menopause; (h) dense breast tissue; (i) specific

benign breast conditions; and (j) prior chest radiation before 40 years old. Modifiable risk

factors for the development of breast cancer include: (a) lack of physical activity; (b) being

overweight or obese; (c) consuming more than two or three units of alcohol daily; (d) being

nulliparous; (e) not breastfeeding; (f) using certain forms of contraception; (g) taking combined

hormone replacement therapy after menopause (ACS, 2017b). For the purpose of this

evidence-based practice (EBP) practice project, the primary emphasis is the non-modifiable risk factor of the hereditary breast cancer gene mutations BRCA1 and 2.

Thoroughly reviewing an individual's personal and family cancer histories assists in differentiating between hereditary, familial, and sporadic breast cancers. It is estimated that 5-10% of breast cancers are hereditary, 15-20% are familial, and the remainder are considered sporadic (Meaney-Delman & Belcross, 2013). Hereditary breast cancer "red flag" characteristics include any of the following personal and family histories: (a) breast cancer prior to 50 years old, (b) breast and/or ovarian cancer in multiple family members in many generations, (c) bilateral breast occurrence and/or multiple metastases spread from the same primary site, (d) incidence of less prevalent cancers (e.g., fallopian tube, ovarian, peritoneal, male breast), (e) one or more diagnosed gene mutations, and (f) certain populations (e.g., Ashkenazi Jewish) (Meaney-Delman & Bellcross, 2013). Familial breast cancers typically occur after the age of 50 years old, are in several family members without a pattern, tend to be unilateral, and are noted to have an association between genetics and one's environment (Meaney-Delman & Bellcross, 2013; Smith et al., 2014). In contrast, the majority of breast cancer occurrence is considered sporadic with onset after 60 years old, occurs unilaterally, is unassociated with familial rates of breast or other related cancers, and is often associated with environmental and modifiable risk factors (Meaney-Delman & Bellcross, 2013).

In 2003, one of the most significant advancements in medicine occurred when sequencing of the human genome was completed (National Institutes of Health [NIH], 2017). Since then, much has been learned about the genome, or entire collection of genes, comprising the human body (NIH, 2017). Inherited changes within a gene, classified as a mutation or a pathogenic variant, can increase an individual's predisposition for cancer development depending on the specific gene and location of the modification (Buys et al., 2017; NIH, 2017). Inheriting a gene mutation from one or both parents increases the likelihood of cancer

occurrence and accounts for up to 10% of breast cancer diagnoses (ACS, 2017a; Senter & Hatfield, 2016).

The most common cause of hereditary breast cancer evolves from germline mutations of breast cancer susceptibility gene 1 (BRCA1) or breast cancer susceptibility gene 2 (BRCA2); hereafter collectively referred to as breast cancer gene (BRCA), unless noted otherwise (Bayraktar & Arun, 2017; Smith et al., 2014). All individuals have these two genes, which ordinarily serve the purpose of generating proteins that inhibit tumor production (NIH, 2018). In an individual with a BRCA mutation, cancer cells are allowed to proliferate when damaged DNA is not corrected properly (NIH, 2018). An estimated 1/300 to 1/500 individuals have a BRCA gene mutation (Nelson, Pappas, Cantor, Haney, & Holmes, 2019). Women of Ashkenazi Jewish descent have an even higher predisposition of 1/40 of inheriting this gene mutation (McReynolds, 2017). Whereas the average American woman has an estimated 12% lifetime risk of breast cancer, women with a BRCA mutation confront a significantly increased lifetime risk of up to 72% (McReynolds, 2017).

BRCA-related cancers characteristically affect individuals at younger ages with increased susceptibility to additional cancer diagnoses during their lifetime (McReynolds, 2017). Besides breast cancer, BRCA mutations are also associated with elevated risks for the following malignancies: (a) fallopian tube; (b) ovarian; (c) pancreatic; (d) peritoneal; and (e) prostate (Bayraktar & Arun, 2017; NIH, 2018). Melanoma is another malignancy associated specifically with BRCA2 (Bayraktar & Arun, 2017; Hampel, Bennett, Buchanan, Pearlman, & Wiesner, 2015; Smith et al., 2014).

Although there are additional hereditary gene mutations known to elevate breast cancer susceptibility, the most prevalent encompass the BRCA1 and BRCA2 mutations (Couch et al., 2017). These two mutations are associated with a five to ten-fold increase in lifetime risk for breast cancer and represent five to ten percent of breast cancer diagnoses annually (Meaney-Delman & Bellcross, 2013; Mayo Clinic, 2019; Nair et al., 2015). Since breast cancer is the

predominant BRCA-related malignancy risk, with medical management options available to potentially decrease or prevent disease occurrence, the focus of this EBP project is on appropriate and timely identification and referral of woman at risk for having this gene mutation.

Data from the Literature Supporting Need for the Project

A widespread consensus exists amidst many professional medical organizations and societies emphasizing the importance of obtaining and assessing an individual's personal and family medical histories for inherited hereditary breast cancer risk in order to provide additional medical management options. In August 2019, the U. S. Preventive Services Task Force (USPSTF) updated their 2005 recommendation statement for BRCA-related cancer risk assessment with an initial online publication. These guidelines inform the care for the population of women who may be at risk of having a BRCA mutation (Nelson et al., 2019). According to the USPSTF guidelines, further evaluation and management is suggested when any of the following are noted in a family's cancer history: (a) BRCA-related cancers; (b) breast cancer prior to the age of 50; (c) numerous members with breast cancer; (d) cancer affecting both breasts; (e) presence of both breast and ovarian cancer; (f) male breast cancer; and (g) Ashkenazi Jewish ethnic background (Moyer, 2014).

The 2019 USPSTF update again provided a grade B recommendation for risk assessment and encouraged use of a screening risk assessment tool for BRCA gene mutations in women with a family history of breast and/or ovarian cancer to determine appropriate candidates for genetic counseling referrals (Nelson et al., 2019). A grade B recommendation indicates that health care providers should perform this service as it is determined to provide at least a moderate benefit to an individual (USPSTF, 2017). In agreement with the prior update in 2013, this recommendation continues to support the need to "Screen women whose family history may be associated with an increased risk for potentially harmful BRCA mutations. Women with positive screening results should receive genetic counseling and, if indicated after counseling, BRCA testing" (Moyer, 2014, p. 272). Although a particular risk stratification tool

wasn't suggested for this screening assessment, of the eight tools evaluated by the USPSTF,

the Referral Screening Tool (now called B-RST™) and the Seven-question Family History

Screening are the two that received the highest quality rating of good; the ratings are

categorized as fair, fair to good, and good (Nelson et al., 2019).

  The National Comprehensive Cancer Network (NCCN) updates clinical practice

guidelines at least annually for a multitude of cancers. Version 3.2019 of Genetic/Familial High

Risk Assessment: Breast and Ovarian, contains genetic breast cancer assessment criteria that

are more specific than those delineated by the USPSTF (NCCN, 2019b). These criteria are

provided to assist with determining appropriate candidates for hereditary cancer genetic

services and are differentiated between individuals with and without a history of BRCA-related

cancers. According to the NCCN (2019b), an accurate family history assessment incorporates

all biological female and male family members, which then supports separate evaluation of

maternal and paternal lineage. NCCN guidelines are based on EBP, are frequently referenced

by professional organizations and societies, and guide medical management of individuals at

increased risk or already affected by cancer (NCCN, 2019b).

  In a Committee Opinion focusing on family history originally published in 2011 and

reaffirmed in 2018, The American College of Obstetricians and Gynecologists (ACOG) asserted,

"Family history information should be reviewed and updated regularly, especially when there are

significant changes to family history. Where appropriate, further evaluation should be

considered for positive responses, with referral to genetic testing and counseling as needed"

(2018, p.1). Those considered to be at elevated susceptibility should subsequently be referred

for genetic counseling with testing if determined necessary. Utilization of a family history

assessment tool or performance of a minimum of a three-generation pedigree is proposed. If

use of a screening tool is preferred, care should be taken to ensure that it is applicable to the

population of patients within the community where the practice is located (ACOG, 2018).

The Nurse Practitioners in Women's Health (NPWH) emphasized that hereditary breast cancer risk assessment needs to be part of routine care (NPWH, 2017). This risk evaluation ideally incorporates (a) the cancer history of the individual and her first-, second-, and third-degree maternal and paternal relatives, (b) detailing the age at diagnosis, and (c) location of the primary cancer. In addition, it is important to determine if there is Ashkenazi Jewish heritage and genetic test results available for any relatives (NPWH, 2017). This organization recommended the use of screening tools to determine appropriate candidates for genetic counseling with possible testing. In congruence with USPSTF and ACOG guidelines, specific screening tools weren't recommended, but having a strategy for approaching a hereditary breast cancer risk assessment is necessary. "A system should be established within WHNPs' [Women's Health Nurse Practitioners'] practice settings for referral, consultation, and/or collaboration to ensure that women have timely access to genetic counseling services and subspecialty follow-up" (NPWH, 2017, para. 4).

The American College of Medical Genetics and Genomics and the National Society of Genetic Counselors collaborated and released clinical guidelines for cancer assessment referrals (Hampel et al., 2015). These organizations recognized the challenging barriers health care providers confront with timely identification and management of individuals at elevated propensity for developing cancer. Similar to the NCCN guidelines, criteria for genetic referrals are based on specific risk factors that encompass personal and family history attributes (Hampel et al., 2015).

According to Cotton and Kirkpatrick (2017), merely one of the fourteen million women in the U.S. who qualify for BRCA testing have actually performed genetic testing. It is estimated that amongst individuals who have a BRCA gene mutation, only 30% of breast cancer survivors and 10% without a history of BRCA-related cancer have been identified through genetic testing (Drohan, Roche, Cusack, and Hughes, 2012). Besides the potential health consequences, not assessing risk factors and offering genetic services can result in medical malpractice lawsuits.

For breast cancer lawsuits, the highest in frequency and payouts occur with women who are younger than 50 years old, often related to an increase in cancer aggression and fatality rates (Cotton & Kirkpatrick, 2017). To apply an understanding of potential hereditary cancer risks to all aspects of a woman's health care, Snow (2014) strongly encourages hereditary cancer risk assessment performance at each office visit. Furthermore this physician asserts, "preventing life-threatening illness, such as hereditary cancer, is the most important part of our job" (Snow, 2014, p. S4).

Data from the Clinical Agency Supporting Need for the Project

Between the years of 2011 and 2015, Lake and Porter counties in Northwest Indiana had an average of 395 and 127 annual cases of breast cancer respectively, making them the 2nd and 7th leading counties of breast cancer prevalence in this state (State Cancer Profiles, 2015). In the state of Indiana, approximately 5,820 new cases of breast cancer in women are predicted to occur and nearly 870 will succumb to this condition in the year 2019 alone (ACS, 2019). From June 1, 2018 to June 1, 2019, over 21,500 patient appointments occurred at an obstetrical and gynecological (Ob/Gyn) practice with five offices locations at that time in Northwest Indiana (H. Hendricks, personal communication, June 3, 2019). Amongst these appointments, 3,415 were for routine gynecological examinations and 1,746 were new patients establishing care. This practice currently employs three physicians, three nurse practitioners (NPs), and three certified nurse midwives (CNMs). Within this practice group, collaborative agreements exist between the advanced practice registered nurses (APRNs) and the physicians, but each practitioner provides patient care with a relatively independent approach (L. Williams, personal communication, June 11, 2019). This Ob/Gyn practice does not have a protocol for the method in which patients are screened and offered referrals for genetic counseling and testing (L. Williams, personal communication, June 11, 2019). Currently, there is a lack of consistency for assessing, and/or documenting assessing, women's personal and family medical histories for hereditary breast cancer risk. Therefore, depending upon the

provider a patient is scheduled to see in this practice group, only a portion of women who are appropriate candidates for hereditary breast cancer risk assessment may be evaluated and offered a referral for genetic screening services and subsequent follow-up. Development and utilization of an EBP protocol will promote more consistent and thorough care of this at-risk population of women.

Purpose of the Evidence-Based Practice Project

The purpose of this EBP project is to answer the following compelling clinical question: In an obstetrical and gynecological practice, what is the best clinical practice for implementing a protocol for identifying women at increased risk for hereditary breast cancer, in order to refer appropriate candidates for genetic services? Additional queries consider whether the health care providers and support staff will consistently utilize the protocol; and, in order to determine strategies to improve protocol adherence, what are identified barriers and benefits to its use?

PICOT Question

Clinical inquiry promotes the continuous advancement of EBP. The PICOT format is commonly utilized to guide the process of formulating the EBP question (Adams, 2015; Fineout-Overholt & Stillwell, 2019). The "P" represents the specific population or problem of concern. "I" stands for the intervention or issue that is of importance. The "C" delineates the comparison, such as when an intervention is contrasted to a specific standard of care. "O" is for the identified and measured outcome(s). If applicable to the topic, the "T" designates a reference of time.

The PICOT question for this EBP project is: In women cared for in an obstetrical and gynecological practice (P) how does utilization of a breast cancer genetics referral screening tool (I) as compared to the current standard of care of collecting and reviewing family history in patients' electronic medical record (C) allow women at increased risk for hereditary breast cancer to be appropriately identified and referred for genetic counseling (O) within a twelve-week time frame (T)?

Significance of the EBP Project

Protocols provide structure and consistency amongst health care providers in a group practice. ACOG promotes protocol development and utilization to facilitate complying with standards while providing continuity of care, which has demonstrated improved patient safety (2019). To promote successful utilization, ACOG (2019) suggests health care providers should be ". . .engaged in the process of developing guidelines and presenting data to help foster stakeholder buy-in and create consensus, thus improving adherence to guidelines and protocols" (p. 1). The NPWH (2017) agree that, "An evidence-based protocol established according to guidelines provided by nationally recognized organizations such as NCCN must be followed to ensure that all recommended components of assessment, counseling, informed consent, appropriate testing, and follow-up are followed" (para. 3).

With the ultimate goal of decreasing hereditary breast cancer incidence, timeliness of BRCA gene mutation identification can provide additional opportunity for utilization of preventive medical management options for cancer risk modification (Drohan et al., 2012; Guo et al., 2017; Profato & Arun, 2015; Randall & Pothuri, 2016; Snow, 2014). Nair et al. (2015) reports, "The identification of BRCA mutation carriers, coupled with risk reduction strategies, has been shown to lower the incidence of both breast and ovarian cancer, as well as cancer specific and all-cause mortality" (p. 119). Meaney-Delman and Bellcross (2013) specify that guidelines from the NCCN comprise the most comprehensive, current, and widely utilized cancer risk reduction recommendations. Strategies for breast cancer risk reduction include the following: (a) breast self-awareness; (b) lifestyle factor modification (e.g., alcohol consumption, breastfeeding, exercise, combination hormone replacement therapy use); (c) once to twice yearly clinical breast examination; (d) once yearly mammography and breast magnetic resonance imaging (MRI); (e) use of a risk-reducing medication from the aromatase-inhibitor or selective estrogen-receptor modulator categories; (f) bilateral mastectomy; (g) bilateral salpingo-oophorectomy; and (h) clinical trial participation (NCCN, 2019a).

Particularly in women at-risk for hereditary breast cancer, the use of specific medical management options can lead to breast cancer reduction and improved survival rates (Meaney-Delman & Bellcross, 2013). Multiple studies have demonstrated that bilateral prophylactic mastectomy provides a 90% breast cancer risk reduction (Johns, Agarwal, Anderson, Ying, & Kohlmann, 2017). Further studies indicated a reduction of ovarian cancer by 86% when a risk-reducing bilateral salpingo-oophorectomy was performed, with an additional decrease in breast cancer risk when this surgical procedure was performed prior to menopause (Johns et al., 2017; Randall & Pothuri, 2016). Although women may initially be counseled by a geneticist, surgeon, or oncologist regarding risk-reducing recommendations, it is important that health care providers are familiar with guidelines and subsequent revisions for breast surveillance, medication, and surgical opportunities in this at-risk group.

A primary objective for this EBP project coincides with that of ACOG, "With increased awareness of the importance of family history as a screening tool and of the values of preventive measures and increased surveillance, there is hope for improved outcomes" (ACOG, 2018, p. 1). It is suggested that following the proposed EBP protocol, including the use of a breast cancer genetics referral screening tool, will provide women who are cared for at this Ob/Gyn practice with more consistent and thorough assessment of their individual risk of hereditary breast cancer regardless of the provider they are seeing. Women who are then determined to be at high risk for hereditary breast cancer can be offered further management options, to include genetic counseling with possible testing, allowing for a high level of care consistent with current organization and society guidelines.

CHAPTER 2

EBP MODEL AND REVIEW OF LITERATURE

Evidence-based Practice Model

Overview of EBP Model

Evidence-based practice encompasses the pursuit to provide the greatest quality of

health care based on the highest level of knowledge available (Doody & Doody, 2011).

Professional expertise and patient predilection are additional components of EBP (Schmidt &

Brown, 2015). EBP models facilitate the integration of this evidence into clinical practice with

the objectives of optimal or improved patient outcomes (Doody & Doody, 2011). The Iowa

Model of Evidence-Based Practice to Promote Quality Care, hereafter referred to as the Iowa

Model, was utilized for structuring this EBP project. Founded upon Martha Roger's Diffusion of

Innovations theory, the Iowa Model was originally created in 1994 by Marita G. Titler and fellow

nurses at the University of Iowa Hospitals and Clinics (Iowa Model Collaborative et al., 2017).

The Iowa Model has been revised several times, with the most recent update occurring in 2015

(Iowa Model Collaborative et al., 2017). This model is often the foundation for implementing

new guidelines into an organization to enhance the quality of care and therefore was

determined to be ideal for providing direction for this EBP project of a protocol implementation at

an Ob/Gyn practice (Iowa Model Collaborative et al., 2017; Schaffer, Sandau, & Diedrick, 2013).

With the most current revision, the Iowa Model Collaborative et al. (2017) delineates the

model's seven steps, in addition to three opportunities to determine if the process can occur

based on necessary relevance and evidence to pursue the change. The first step is to choose

the topic, which is often generated by an update in knowledge or a current obstacle in ideal

patient care provision. The focus or problem is identified during the second step. The PICOT

format is often used to provide further clarity during this task. After completion of these initial

two steps, one must pause and determine if the focus or problem is a sufficient enough of a

concern to pursue. If it is determined to be adequate at this initial checkpoint, the process continues; if it isn't, another topic should be considered.

Choosing team members is the third step. Team members will collaborate with creating and integrating the EBP change and should include key stakeholders (Doody & Doody, 2011; Iowa Model Collaborative et al., 2017). The team will then initiate the fourth step, which is obtaining and evaluating the evidence. An appraisal tool is chosen to classify the quality of the information collected. Upon reviewing the appraised evidence, the second occasion and checkpoint arises to consider if the evidence supports the change. If it does reinforce EBP, continuation to the following step can occur; if it doesn't, further research efforts are necessary.

The fifth step is the generation and trial performance of the EBP change (Iowa Model Collaborative et al., 2017). This pilot process is unique amongst the EBP models and includes evaluating data and reporting the change's effectiveness. The third opportunity occurs to decide if this change should be approved for continued use. If it is supported, the final checkpoint completion permits the last two steps to be initiated; if it isn't, it is necessary to consider different procedures in which to implement the change.

During the sixth step in the Iowa Model, the EBP change is permanently established (Iowa Model Collaborative et al., 2017). This step requires strategies to manage and reinforce these changes. Concluding with the seventh step is providing communication about the change outcome. This can range from providing education and updates at a staff meeting, to more widespread endeavors, such as a conference presentation or a journal publication (Iowa Model Collaborative et al., 2017). This final process of the Iowa Model promotes further advancement of EBP.

Application of EBP Model to DNP Project

Using the Iowa Model to guide this EBP project (see Appendix A), the first step of topic identification was initiated when it was observed that women at an Ob/Gyn practice were not consistently being assessed for their risk of hereditary breast cancer and then as appropriate,

being offered a referral for genetic services. The topic chosen became hereditary breast cancer

risk assessment. For the second step, the PICOT format was applied. In women cared for in

an obstetrical and gynecological practice (P) how does utilization of a breast cancer genetics

referral screening tool (I), as compared to the current practice of collecting and reviewing family

history in patients' electronic medical record (C), promote women at increased risk for hereditary

breast cancer to be identified and referred for genetic counseling (O) within a twelve-week time

frame (T)? This topic was then determined at this initial checkpoint to be an appreciable

concern at this Ob/Gyn practice for this process to proceed.

     Choosing team members for this EBP change was the third step. The key stakeholders

were the health care providers at this practice, consisting of CNMs, NPs, and physicians. The

managers, medical assistants (MA), and registration representatives (receptionists) are also

integral representatives of this team. Epic is the electronic medical record (EMR) system used

in this health care practice and an Epic information technologist has been recruited for

assistance with this EBP project. A literature search was performed during the fourth step to

evaluate the current EBP pertaining to this topic. Multiple databases were employed with a

variety of systematic reviews and studies obtained and reviewed. The level and quality of these

pieces of evidence was established. The reviewed literature consistently supported the urgency

of assessing women's risk for hereditary breast cancer. Upon identification of women at-risk for

hereditary breast cancer, genetic counseling promotes early detection of BRCA gene mutations

along with the ability to review medical management options. At this checkpoint, the evidence

reinforced both the focus and the need for this EBP project and supported its continuation.

     Protocol development was the catalyst for the fifth step. This was anticipated to be one

of the most time consuming portions of this process. The protocol specifically designated the

process for evaluating women's risk for hereditary breast cancer and clarified each team

member's role in this endeavor. Team members were educated on their specific responsibilities

for the protocol utilization through individual and/or group meetings. Those who are unable to

attend the meetings were contacted via email and provided protocol and specific role

information with request for feedback and questions. A web-based version of the breast cancer

genetics referral screening tool (B-RST™) was used to determine if a patient was at-risk for

hereditary breast cancer. To allow for both convenience and timeliness, the Epic charting

system contained a hyperlink within the flowsheet portion of the EMR that went directly to the B-

RST™ website. Within this fifth step was implementation of the protocol with data collection.

Prior to protocol implementation, data for the total genetics and High Risk Breast Clinic referrals

ordered by each of the providers at this Ob/Gyn office was obtained for the 12-week time period

of September 24, 2018 through December 14, 2018. To evaluate the pilot portion of this

change process, this data was compared to the number of genetic and High Risk Breast Clinic

services referrals provided by each health care provider and in total. Each week a report was

run through the EMR in order to evaluate the adherence of the protocol implementation. Data

synthesis allowed the opportunity to obtain feedback regarding each health care provider's use

of the tool. In addition, team member evaluation was requested in person and/or by email for

communication about what was working effectively and/or not as well, in order to enhance

progression of this change. Any modifications for improving the efficacy for this protocol and

augmenting the likelihood for a successful change were then communicated to each team

member through meetings and/or emails. During this last checkpoint of the process, data

analysis coupled with team member feedback aided in deciding if the process for change was

effective and could continue for the planned twelve weeks.

The sixth step incorporated continued use of the protocol with the goal of long-term

implementation. Consideration for planning efforts to maintain this change in practice occurred

simultaneously with periodic monitoring for consistency of tool use dependent upon each team

member's role. As included in the previous step, team member feedback was requested every

two weeks; this occurred more frequently if protocol compliance was noted to have decreased.

Team members continued to be updated if any portions of the process were altered.

The seventh and final step was to communicate results of the EBP project to the team members. Once again, this took place at individual or group meetings and/or through emails. Additional options for disseminating EBP project results include presenting findings at a local of national professional organization's conference and/or a journal publication. With the conclusion of this step, it will be integral that assessments occur periodically to promote sustainability of this change remaining an office-based standard of care.

Strengths and Limitations of EBP Model for DNP Project

Prior to and during its application to this EBP project, it was necessary to consider the strengths and limitations of the Iowa Model. Strengths included that the model was: (a) thorough with seven detailed steps; (b) structured, although still allowing the flexibility of an individual approach to the process of change; (c) up to date with recent modifications validated since 2015; (e) readily available to use with permission; (f) designed with three checkpoints to determine if continuation of the change is appropriate to further pursue; and (g) unique with step five's feature of a pilot process, allowing a trial period with evaluation of the results. Additional strengths consisted of the ability of anyone from beginner to expert status to use this model, its application to diverse settings, and feedback from more than 600 individuals who had previously used this model was provided for the most recent revision (Iowa Model Collaborative et al., 2017). Several weaknesses were noted, with one being multiple steps having two to nine tasks recommended to accomplish prior to advancing to the next step. Although a plausible approach both ways, steps three (build team) and four (assess evidence) seemed best approached in vice versa order, and this was the approach for this EBP project. Lastly, it would be advantageous to have further clarification with specific tips for maintaining a successful change in specific health care settings. Keeping the strengths and weaknesses in consideration, the Iowa Model best fit the procedure for this EBP project.

Literature Search

Sources Examined for Relevant Evidence

   Search engines and key words. In order to find support for the best practice in assessing breast cancer risk, a search of the current literature was conducted using six separate databases, including: Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Library, Joanna Briggs Institute EBP Database, MEDLINE via EBSCO, Nursing & Allied Health Database, and PubMed. Multiple variations of the search terms were attempted, with the following final key search terms used: (1) "breast neoplasms" OR "breast cancer;" and (2) "family history" OR genetic OR hereditary OR "high risk" OR inherited OR predisposition; and (3) apprais* OR "risk assessment" OR tool*, and (4) refer*. Related to the resource capacity of the Nursing & Allied Health Database, the search terms were limited to: (1) "breast neoplasms" OR "breast cancer;" and (2) "family history" OR genetic OR hereditary and (3) "risk assessment," and (4) refer*. Additional terms not included in the final search were: BRCA, consult*, counsel*, evaluat*, familial, gene* refer*, HBOC, model, predict*, and screen*. Depending on the database searched, these terms were eliminated based on search results either being too extensive or not contributing additional quantity of evidence obtained.

   Inclusion and exclusion criteria. Inclusion criteria consisted of: (a) female population, (b) published in the English language, (c) published between (January) 2012 through (July) 2019, (d) scholarly/peer reviewed journals, and (e) academic journals. Publications were excluded for any of the following criteria: (a) the study population was women with a current or prior diagnosis of breast cancer, (b) the study focus was on a breast cancer tumor test, gene sequencing, or a recurrence score assay, (c) the study population included those with at least one family member with a known BRCA gene mutation, (d) the breast cancer risk and/or referral tool was used at the time of mammography services only to determine if a woman qualified for a breast MRI, (e) the focus was explicitly on care provided by geneticists or other specialists providing cancer genetic services, or specific services provided at a High Risk Breast Clinic, (f)

the focus was risk for cancers other than breast, (g) the emphasis was on individual breast

cancer risk perception, or (h) the risk model was used for determining appropriateness of

chemoprevention.

Search results. Within CINAHL, the search yielded 28 pieces of evidence with 9

reviewed and 1 accepted without duplicates. Within the Cochrane Library, 104 were yielded

within the following categories: 85 Cochrane reviews and 19 Cochrane protocols; 12 were

reviewed, and 2 were accepted with 1 duplicate. Within the Joanna Briggs Institute EBP

Database, 28 were yielded with 5 reviewed and 1 accepted without duplicates. Within

MEDLINE via EBSCO, 153 were yielded, with 23 reviewed, with 3 accepted with 2 duplicates.

Within Nursing & Allied Health Database, 372 were yielded with 31 reviewed and 3 accepted

without duplicates. Within PubMed, 144 were yielded with 20 reviewed, with 7 duplicates, and

without new evidence discovered. In addition, Google Scholar and Trip Medical Database were

accessed several times with the inability to limit the final search results to less than 400

resources.

Within these six databases, a total of 829 pieces of evidence were obtained. With the

inclusion and exclusion criteria established, 100 abstracts were reviewed, and subsequently 25

pieces of evidence were then read in their entirety. Seven duplicates were discovered amongst

the different databases. Fifteen pieces of evidence were excluded due to weak support of this

EBP project, resulting in a total of 10 pieces of evidence for final review. See Table 2.1 below

for the results of the literature search.

Table 2.1

Literature Search

_____

Database	Yielded	Duplicates	Reviewed	Accepted
CINAHL	28	0	9	1
Cochrane Reviews Trials	85 19	1	12	2
JBI	28	0	5	1
MEDLINE	153	2	23	3
Nursing & Allied Health	372	0	31	3
PubMed	144	7	20	0
Total	829	10	100	10

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Note. CINAHL is the Cumulative Index of Nursing and Allied Health Literature.
JBI is the Joanna Briggs Institute.

Appraisal of Relevant Evidence

  Appraisal tool utilization. In order to support changes within health care based on

EBP, it is essential that current evidence is appraised. This appraisal consists of ranking the

level and quality of evidence with evidence hierarchies (Long, 2015). Higher levels and/or

qualities of evidence provide a solid foundation for change. The Johns Hopkins Nursing

Evidence-Based Practice Model is a model focused on the application of EBP and nursing.

Multiple tools are available for evidence evaluation along with directing the EBP process (Dang

& Dearholt, 2017). Both the level and quality ratings for this EBP evidence appraisal were

ranked utilizing the 2017 edition of the Evidence Level and Quality Guide from the Johns

Hopkins Nursing Evidence-Based Practice (see Appendix B). This tool categorizes five levels of

evidence between Level I through Level V with a hierarchy approach and are further described

as follows (Dang & Dearholt, 2017). Level I contains the highest level of evidence and is

comprised of experimental studies, such as a randomized controlled trial (RCT). Systematic

reviews of multiple RCTs and explanatory mixed methods using a level I quantitative studies are

also included in this category. Level II includes quasi-experimental studies, systematic reviews

of RCTs and/or quasi-experimental studies, or explanatory mixed methods using a level II

quantitative study. Level III consists of non-experimental studies, including systematic reviews

of multiple study types, exploratory or qualitative studies, and explanatory mixed methods using

a level III quantitative study. Level IV encompasses evidence-based guidelines from

professional medical societies or groups within these organizations, including organization-

specific best-practice recommendations. Level V incorporates evidence based on background

and experience and does not include research. This includes a combination of case reports,

professional expert opinions, integrative and literature reviews, and programs focusing on

economics or quality improvement.

It is noteworthy that this Evidence Level and Quality Guide tool is more rigorous in

ranking levels of evidence by differentiating between approaches for studies or evaluation of

studies, such as explanatory mixed and systematic reviews. Other appraisal tools group entire

categories together. For example, one particular evidence hierarchy organizes and ranks

systematic reviews and guidelines for EBP at the uppermost level of evidence without

differentiating between types of studies utilized for each of these (Long, 2015).

This appraisal tool also provides guidance for rating the quality of each level of evidence

with specifications for quantitative and qualitative studies (Dang & Dearholt, 2017). Evidence

with higher quality ratings are considered more substantial for use with proposed EBP changes.

The quality ratings for this tool are as follows: A, high quality; A/B, high/good quality; B, good

quality; and C, low quality (Dang & Dearholt, 2017). Each of these rankings has specific

qualifications depending on which level of evidence is being appraised. For quantitative studies,

high quality evidence incorporates: (a) results that are applicable to similar or other populations

along with being compatible with other studies and/or current evidence, (b) a study population

considered to be of adequate measure, (c) sufficient control, and (d) an accurate and detailed

literature search to support recommendations (Dang & Dearholt, 2017). Using Dang and

Dearholt's (2017) specific terminology, qualitative studies with a high quality or high/good quality

exhibit the following: (a) transparency, (b) diligence, (c) verification, (d) self-reflection and

scrutiny, (e) participation-driven inquiry, and (f) insightful interpretation (p. 1). Table 2.2 below

summarizes the evidence summary.

Table 2.2

Evidence Summary

Level	Included	Quality	Design
I	2	A (1) B (1)	Systematic Review of RCTs (1) Randomized Controlled Trial (1)
II	1	B (1)	Controlled Trial without Randomization (1)
III	5	A (2) A/B (1) B (2)	Pilot Exploratory Study (1) Demonstration Project (1) Qualitative Study (1) Systematic Review of Combination of Studies (1) Cross-Sectional Study (1)
IV	2	A (1) B (1)	Professional Organization Clinical Practice Guideline (1) Evidence Summary (1)
V	0		

Note. The Evidence Level and Quality Guide from the Johns Hopkins Nursing Evidence-Based Practice was used to appraise the evidence. (Dang & Dearholt, 2017)

Levels of Evidence

Using the Evidence Level and Quality Guide from the Johns Hopkins Nursing Evidence-Based Practice Model, ten pieces of evidence were appraised encompassing four of the five levels of evidence. Level I evidence included one systematic review of RCTs and one randomized controlled trial. One controlled trial without randomization met the criteria for level II. Level III encompassed the majority of the evidence and consisted of one of each of the following: (a) pilot exploratory study, (b) demonstration project, (c) qualitative study, (d) systematic review of a combination of studies, and (e) cross-sectional study. Level IV included one evidence summary and one professional organization clinical practice guideline. There were no level V pieces of evidence. For quality ratings, four pieces of evidence were graded A, one was A/B, and five received a B. See Appendix C for the Evidence Data Table.

Level I evidence. Level I evidence included one systematic review of RCTs and one randomized controlled trial. Hilgart, Coles, and Iredale (2012) performed an updated systematic review of RCTs for the Cochrane Database focusing on the impact of breast cancer risk evaluation and genetic services. Studies included women and men across the lifespan who were: (a) at-risk for breast cancer related to cancer family history, (b) without a personal history of breast cancer, and (c) without a personal known BRCA gene mutation. Five additional RCTs were appraised from the 2007 review to bring the total to eight, with $N = 1973$. Outcomes were divided into three categories: (1) Methods for performing risk evaluation; (2) approaches for providing genetic health care; and (3) differences between risk evaluation performed by a genetic specialist or a non-genetic specialist. The studies revealed that genetic services provided: (a) a decrease in cancer anxiety and enhanced emotional well-being; (b) increased personal risk perception accuracy and knowledge concerning breast cancer and genetic services, and (c) overall satisfaction with use of genetic services. The authors concluded that hereditary breast cancer risk assessment is an essential process to be performed for determining appropriateness of genetic services referrals, with the benefits of genetic services

considered to outweigh the harms. Strengths of this systematic review include an extensive

search strategy, the inclusion and exclusion criteria were precisely presented, high levels of

evidence were reviewed, the sample size was adequate, and the methods for determining

biases in the RCTs were thoroughly described and applied. Weaknesses were the omission of

summarizing strengths and weaknesses of the studies, potential bias during the literature

search since terms were not consistent from one database to another, and the inability to

perform a meta-analysis to determine an effect size due to diversification amongst the RCTs.

This systematic review was provided a quality rating of A due to the ability to generalize results,

the large sample size, and conclusions based on EBP.

The second level I item of evidence was a RCT performed by Kaplan et al. (2014). This

RCT was comprised of women ages 40 to 74 years old without a previous history of breast

cancer receiving health care at two U.S. metropolitan primary care medical offices. The

population size was sufficient with $N = 1235$, with the intervention group ($n = 580$) and control

group ($n = 655$) being randomized after baseline phone interviews using statistician-developed

sequence codes. The intervention was use of the BreastCARE web-based tool, which stratified

breast cancer risk by simultaneously using the: (a) Referral Screening Tool, (b) Gail Model, and

(c) Breast Cancer Surveillance Consortium risk model. The system for obtaining data was: (1)

Utilization of the BreastCARE appraisal tool in the intervention group; (2) a one to two week

post-visit phone survey, and (3) a six month post-visit EMR review. Outcomes were that use of

the BreastCARE tool increased: (1) Patient-provider breast cancer risk conversations with *OR*

2.07, 95% CI [1.34, 3.20], (2) patient-provider risk reduction conversations with *OR* 4.78, 95%

CI, [2.90, 7.89], (3) referrals for genetic services for those at increased risk with *OR* = 5.32, 95%

CI, [2.21, 12.8], and (4) EMR charting regarding each of these activities. Overall, this RCT

demonstrated that use of a web-based risk evaluation tool enhanced health care provider-

patient discussions about breast cancer risk and medical management options. Areas of study

weakness encompassed the potential differences between the two office settings possibly

causing a decreased ability to generalize findings; potential biases with individual-reported

information; and, the need to address health care provider challenges with performing

hereditary breast cancer risk assessment consistently due to omission of this activity in some of

the intervention patients. The sample population was sufficient and data for multiple objectives

were collected; however, since statistical findings of this RCT did not include information

regarding instrument reliability and validity and potentially lacking the ability to generalize

results, it is provided a quality rating of B.

     Level II evidence. Level II evidence consisted of a controlled trial without randomization

performed by Baer et al. (2013). The study population was new or established female and male

patients between 18 to 75 years old, without a family history of cancer documented in their

EMR, presenting for annual examinations within five urban academic primary care medical

practices. The sample sizes were adequate with the intervention group consisting of patients

from three of the practices (n = 996) and the control group from the other two practices (n =

637). The study's purpose was to determine the practicability of implementing the Your Health

Snapshot web-based hereditary breast and colon cancer risk assessment tool in the primary

care setting. The principal outcome was new documentation of cancer family history in the

EMR within one month of the patient visit. The secondary outcome was new cancer screening

test notices initiated within one month of the visit by health care providers for those with an

increased risk for breast or colon cancer. Data were obtained from the intervention group

completing the risk appraisal tool prior to their appointment with review of EMR records one

month after visits for both groups. For the first outcome, those in the intervention group had a

far greater likelihood compared to the control group of having new EMR charting regarding the

presence of cancer family history (10.6% vs. 0.8%, p = 0.0003) and an adjusted *OR* of 15.9,

95% CI, [3.5, 72.1]. For the second outcome, there was no significant statistical significance for

new cancer screening test notices for those with an increased risk for hereditary cancer

provided by health care providers between the intervention and control groups at eight vs. zero

provided respectively. Participation in the post-appointment telephone survey was suboptimal

with the intervention and control groups at 46.1% and 20.2% compliance respectively.

Additional limitations of the study were: non-randomized groups, poor overall participation with

only 10.3% of those eligible participating, differences in demographic characteristics between

the two groups, and instrument reliability and validity was not provided. Conclusions were

based solidly on results, as use of this web-based risk evaluation tool demonstrated an overall

increase in documentation of cancer family history. Due to the lack of instrument reliability and

validity, poor participant response rates, and potentially lacking the ability to generalize results

related to demographic differences, this study was provided a quality rating of B.

     Level III evidence. The majority of evidence appraised was Level III evidence, with one

each of the following: exploratory pilot study, demonstration project, qualitative study,

systematic review of a combination of studies, and cross-sectional study. Anderson et al.

(2015) implemented an exploratory pilot study with low income African American and Hispanic

women ages 25 to 69 years old, without a personal history of breast cancer, presenting for

annual examinations at two federally assisted medical institutions in the Midwest. The purpose

of this study was to evaluate the development and utilization of a breast cancer risk appraisal

policy within a practice with multiple ethnicities. In a study population of $N = 237$, prior to

examination with the health care provider, the following was collected: (a) risk factor information,

(b) baseline survey, and for those consenting, (c) a breast cancer risk evaluation using the BC

Risk Screening (BRS) web-based tool. This tool simultaneously uses the following to provide a

risk assessment: (1) Claus, (2) modified Gail, and (3) pedigree assessment tool. The majority of

the population ($n = 207$, 87.3%) chose to be informed of their breast cancer risk assessment

results with an increased likelihood with women ages 40 to 49 years old with OR 5.4 (95% CI,

[1.09, 26.67]) and from 50 to 69 years old with OR 7.99 (95% CI, [1.47 - 43.44]). Successful

use of a web-based tool in the office setting to efficiently perform the risk appraisal was

evidenced by the high rate of BRS tool use noted in this population, with consideration of health

care provider barriers of time restraints and/or lack of breast cancer risk knowledge. Limitations

were the: (1) Inability to obtain additional explanations from the women who declined receiving

their risk information; (2) potential lack of generalizability with women from other ethnic

backgrounds; and (3) potential recruitment bias as women arriving for their annual examination

presumably placed more of a priority on their health. The researchers concluded that

implementing a web-based tool, as recommended by the USPSTF 2013 recommendations,

enhanced performance of a breast cancer risk appraisal in the office setting. Furthermore, this

process occurred without disturbance of the normal workflow in a primary care practice. This

exploratory pilot study was provided a quality rating of B due to the small sample size, omission

of information regarding the reliability and validity of the BRS tool, and the potential limitation to

generalize results to women of different ethnicities.

Brannon Trexler et al. (2014) demonstrated utility of the breast cancer genetics referral

screening tool (B-RST™) through a demonstration project. The sample population was

primarily minority and low-income women ages 14 to 85 years old without a personal history of

cancer obtaining health care at one of six participating public health departments in a southern

U.S. state. The participant population was adequate with $N = 2159$. The staff was educated

through multiple methods on hereditary breast and ovarian cancer (HBOC) syndrome and how

to use the B-RST™. In order to identify and manage appropriate at-risk women, the B-RST™

was then used during medical history collection prior to the health care provider examination.

The objectives of this project were: (1) Integrating the B-RST™ within a minority population to

recognize women with increased HBOC risk; (2) assisting with the health care management of

those having positive B-RST™ results; and (3) educating staff about cancer genetic topics with

the goal of accurate utilization of the B-RST™. Validity of the B-RST™ occurred by comparing

its use to multiple models with four-generation cancer family histories. Sensitivity was

determined to be 89.4% and specificity was 90.1%. For the first objective, out of the 2159

participants: (a) 130 (6.0%) had positive B-RST™ results, (b) 110 (84.6%) from this group of

women then consented to be contacted, (c) 67 (60.9%) provided cancer family history

clarification, (d) 47 (42.7%) of these women were successfully contacted and determined to be

appropriate for testing per current medical society guidelines, and (e) 14 (12.7%) performed

cancer genetic testing, with one (7.1%) woman being diagnosed with a BRCA2 gene mutation.

She was guided through medical management strategies, which then completed the second

objective. The third objective was achieved by an increase in staff knowledge as demonstrated

by improved post-activity test results. One of the limitations was that participants were not

aware a multi-generational cancer family history was going to be requested at their

appointment, with potential inaccuracies likely causing both false negative and false positive B-

RST™ results.   Also, the reason(s) why participants declined follow up ($n = 20$) after receiving

positive B-RST™ results was not collected. The researchers concluded that their project had

favorable outcomes, especially with evaluation of breast cancer risk in a group of minority

women who likely did not have this assessed before. This study was given a quality rating of A

for the large sample population, inclusion of the tool's sensitivity and specificity, and conclusions

based on EBP.

Christianson et al. (2012) presented their qualitative study of use of a risk assessment

tool by health care providers from a variety of specialties within a community-based medical

system on the East Coast. The sample population ($N = 16$) consisted of 14 physicians and two

mid-level providers from nine medical practices within the same county. The demographics of

the sample population were primarily males ($n = 12$) and Caucasians ($n = 12$). This information

was not provided for both of the mid-level providers. The purpose of this study was to

determine health care provider perceived challenges with integration of a risk stratification tool

in order to resolve these factors and improve its future utilization. The participants attended one

of the three focus meetings in which nine questions were discussed regarding the impending

use of the MeTree web-based risk assessment tool at a local oncology center. This tool

evaluates inherited risks for breast and colon cancers, in addition to thrombophilia disorders.

Five themes were recognized: (1) Current methods utilized for evaluating risk of medical

conditions, (2) barriers associated with obtaining and using family health histories, (3)

challenges associated with applying family history to individualized health care strategies, (4)

obstacles with performance of the MeTree tool at the oncology center, and (5) medical and

educational needs. Although these themes were noted repetitively, the researchers reported

that saturation was not attained related to the small sample population. Validity and reliability

were applied by performance of the following for both of the discussions: (a) use of a topic

template guide, (b) being led by the same individual, (c) producing an audio recording, (d)

obtaining written documentation including non-verbal elements, and (e) providing a manuscript

from the audio recording. For interpretation of the data, this information was coded and

analyzed both manually and with the use of a computer software program. It is unclear if there

was a method used to verify the credibility of the data evaluation with this sample population.

Considering the small sample size and subsequent lack of saturation, the quality rating of A/B

was provided for the inclusion of distinct methods for supporting this qualitative study's purpose

and incorporating a perceptive analysis pertinent to available evidence.

Nelson et al. (2014) performed a systematic review of multiple study types as an update

to the 2005 USPSTF recommendation for hereditary breast cancer risk evaluation and genetic

services utilization. The population of interest was women across the lifespan provided health

care in locations similar to the U.S. without a personal history of a BRCA gene mutation or

BRCA-related cancer(s). For studies included in this review ($N = 27$), 16 were new for this

update and included systematic reviews, RCTs, cohort, and case-control studies. A variety of

interventions were studied: (a) five risk models/tools; (b) risk perception and cancer worry; and

(c) tests, meds, and surgeries to decrease risk of BRCA-related cancers. The outcomes of

concern evaluated potential benefits and harms in three areas: (1) BRCA risk evaluation

model/tool use, (2) genetic services results, and (3) BRCA management options for malignancy

and mortality reduction. Outcomes were based on study findings with a best practice

recommendation presented to weigh individualized benefits, harms, and risks when assessing hereditary breast cancer risk, referring for genetic services, and/or offering medical management to decrease cancer risk. Sensitivity between five referral and four risk models were compared with the Referral Screening Tool reported as having high levels of sensitivity and specificity. Although the authors were unable to perform a quantitative meta-analysis due to study heterogeneity, this systematic review was rated at an A quality due to the search strategy and findings from this systematic review being comprehensive with outcomes based on EBP.

Solomon, Whitman, and Wood (2016) performed a cross-sectional study of women with an average age of 63 years old receiving services at a mammography center in a Northeastern U.S. city. The sample population ($N = 499$) was sufficient. A questionnaire was completed at the time of mammography services. The recommendation for reviewing additional breast medical management options, such as genetics services referrals, were then based on the use of the: (1) ACS and NCCN screening guidelines for colon cancer, (2) Claus model for breast cancer risk estimation, and (3) breast cancer genetics referral screening tool (abbreviated RST by the authors). This study's aim was identification and comparison of individuals qualifying for cancer genetic services based on either a limited/first-degree cancer family history or a more comprehensive/first and second-degree family histories in order to determine appropriate candidates for genetic services referrals. Out of the 499 participants: (a) 71.9% ($N = 359$) had a family history of breast or colon cancers in a minimum of one family member; (b) 56.5% ($n = 282$) had a family history of breast cancer in a minimum of one family member; (c) 24.6% ($n = 123$) had a family history of colon cancer in a minimum of one family member; and (d) 13.2% ($n = 66$) had a family history of both breast and colon cancers. Based on cancer family history, the Claus Model and the RST were then performed to determine breast cancer risk, and ACS guidelines were applied to assess risk for colon cancer. The Claus Model recognized 3.6% ($n = 18$) as being at-risk for breast cancer; with only 28% ($n = 5$) of these 18 women classified at-risk

when the limited/first-degree cancer family history was taken into consideration. Similar results were discovered using the RST, with 1.8% ($n = 9$) of the women being considered appropriate for genetic services referrals; out of these nine women 77% ($n = 7$) were identified as being candidates for genetic services referrals with use of the limited/first-degree cancer family history. For the colon cancer risk evaluation, 12% ($n = 62$) qualified for increased risk screening procedures following ACS recommendations; whereas, 81% ($n = 50$) of the 62 women were recognized with limited/first-degree family history use. Limitations of this cross-sectional study were that selection bias was a potential due to the location of a mammography facility for questionnaire distribution, the lack of a description of the model/tool reliability and validity, and data collection occurred > one decade prior (2001 through 2002). The concluding factor drawn from this study highlighted the importance of using a risk screening tool, rather than exclusively reviewing first and second-degree cancer family history, in order to provide an accurate hereditary cancer risk evaluation. With the limitations taken in consideration, this cross-sectional study was provided a quality rating of B due to an adequate sample size and overall results applicable to practice.

   Level IV evidence. Appraisal of Level IV evidence consisted of one professional organization clinical practice guideline and one evidence summary. Based on evidence-based research findings, Berliner, Fay, Cummings, Burnett, and Tillmanns (2013) updated the 2007 National Society of Genetic Counselors (NSGC) clinical practice recommendations. Evidence was included from multiple professional organizations with the majority of the studies and articles cited focusing on hereditary breast cancer risk assessment models and BRCA genetic mutations. Six concise best practice recommendations were specified as follows: (1) Consult guidelines to determine if a woman is a candidate for cancer genetic testing and provide individualized health care risk-reducing strategies; (2) consider BRCA and other applicable gene mutations; (3) perform a cancer risk evaluation utilizing an assessment model to determine subsequent approach for health care management; (4) determine medical management options

based on cancer family history, assessed risk, medical expertise, and outcome of genetic

testing; (5) arrange referral to a genetics professional to provide resources to support

educational and emotional needs; and (6) explain current, multi-faceted consequences of

genetic testing. Each recommendation was supported by EBP. This best practice guideline is

both advantageous and easily applicable, with it being provided a quality rating of B due to the

omission of information regarding biases and evidence levels, and related to it being a six year

old guideline due to be updated.

Obeid (2017) authored a Joanna Briggs Institute Evidence Summary focused on familial

breast cancer. References used for this summary encompassed two Cochrane Database

systematic reviews, evidence from the National Institute for Clinical Excellence, and one each of

the following: meta-analysis, RCT, cross-sectional observational study, epidemiological study,

and a literature review. Regardless of practice specialty, this summary is applicable for any

health care providers involved in primary, secondary, or tertiary care of women with a family

history of breast cancer. Best practice recommendations were specified for: (1) Patient-focused

care; (2) cancer family history and provider referral; (3) screening; and, (4) genetic services.

These were subsequently graded by the author, with each receiving a grade B. Concise

instructions for these best practice recommendations were provided. Most pertinent to this EBP

project were suggestions for: (a) promoting patient-provider discussion about breast cancer risk

that respects a patient's personal decisions; (b) creating and providing handouts on pertinent

breast cancer risk topics; and, (c) producing protocols for performing genetic services referrals.

A limitation was that information was not provided in regards to the process of reducing biases.

This piece of evidence is rated as an A/high quality based on the up-to-date nature of the

summary, the high levels of evidence used, and its broad applicability.

Construction of Evidence-based Practice

Synthesis of Critically Appraised Literature

Within the evidence, several challenges were presented with enhancing care by using a cancer risk evaluation model or tool. It can be time consuming to accurately identify and reassure those at low risk for hereditary breast cancer, while informing those who are at-risk about medical management options and promoting active involvement in their health care (Anderson et al., 2015; Hilgart et al., 2012; Solomon et al., 2016). The lack of importance individuals may perceive about their cancer family history, coupled with inaccuracies of reporting this history, may impede the accuracy of risk appraisal results and consequently the management of these results (Baer et al., 2013; Brannon Trexler et al., 2014). Additional barriers of risk appraisal tool utilization consisted of: (a) time restraints; (b) health care provider knowledge and confidence limitations; (c) necessity for specific guidelines to direct care; (d) communication limitations; (e) legal responsibilities, and (f) resources restraints, including availability of health care providers to perform genetic counseling (Christianson et al., 2012). Another challenge encountered is the variance between different medical professional organization's recommendations for qualifications for genetic services (Berliner et al., 2013). Although these differences may be minimal, they can create confusion and potentially a lack of consistency in this area of health care. It is important to be knowledgeable about these factors in order to identify methods to overcome them.

Regardless of the type of model or tool utilized for the process of hereditary breast cancer risk evaluation, positive consequences for both health care providers and patients were reported. A specific recommendation that guides the focus of this EBP project is presented by Berliner et al. (2013), which highlighted that health care providers have the flexibility and responsibility of choosing which risk appraisal tool is best for their practice. A risk appraisal tool demonstrating ease of use was important for gaining health care provider support of its implementation into routine practice, while it enhanced more thorough documentation of cancer

family history, understanding of results, and conversations regarding this history (Anderson et al., 2015; Baer et al., 2013). Use of the RST improved accuracy of identifying and appropriately educating individuals at-risk for hereditary breast cancer (Obeid, 2017; Solomon et al., 2016). Using a family history tool to assess cancer risks supported communication about these risks between the provider and a patient and consequently guided management options (Berliner et al., 2013; Christianson et al., 2012; Kaplan et al., 2014). Beneficial outcomes of appropriate breast cancer risk evaluations include perceived individual benefits and enhanced satisfaction with counseling (Hilgart et al., 2012; Obeid, 2017) as well as decreased levels of worry after receiving genetic counseling (Nelson et al., 2014). The evidence appraised extensively supports incorporating a hereditary breast cancer risk evaluation tool into health care practice.

Best Practice Model Recommendation

The Best Practice Model for answering this EBP project's PICOT statement was to have women perform a B-RST™ evaluation at their routine gynecological examination and/or new patient appointments within the Ob/Gyn practice. This assessment occurred at the beginning of their appointment, prior to their health care provider seeing them. The B-RST™ was chosen due to support provided by the USPSTF related to its ease of use by both patients and health care providers, in addition to having received the highest quality rating (Bellcross, Hermstad, Tallo, & Stanislaw, 2019; Nelson et al., 2019). Furthermore, this tool was either utilized or evaluated in three of the pieces of evidence appraised with positive feedback regarding its use, in addition to high levels of sensitivity and specificity documented (Bellcross et al., 2019; Brannon Trexler et al., 2014; Nelson et al., 2014; Solomon et al., 2016). The Best Practice Model with use of the B-RST™ helped answer this EBP project's clinical question by providing a reliable and straightforward intervention for hereditary breast cancer risk assessment, data collection, and comparison to the current practice of cancer family history collection and review in the EMR.

CHAPTER 3

IMPLEMENTATION OF PRACTICE CHANGE

At the EBP project setting, the standard practice for establishing if a woman is considered at-risk for hereditary breast cancer is determined by reviewing the personal and family medical history sections in the EMR. Prior to completing charting for a patient visit, the appropriate boxes are expected to be marked in the EMR indicating that specific sections (i.e., the history sections which include both personal and family medical histories) have been reviewed. An underlying assumption in marking these areas of information as reviewed is that a woman at-risk for hereditary breast cancer is identified and counseled about associated risks and provided medical management options, with the necessary documentation indicating both these activities occurred. In addition to the EMR review, select providers within the EBP project site have their patients complete a personal and cancer family history paper questionnaire, created by a company that performs cancer genetic analysis. Although this is a method in which to identify women at increased risk for breast cancer, the intent of utilizing this form is for the health care provider to personally order genetic testing. It is neither intended for the primary purpose of identifying women who are candidates for genetic counseling, nor is it amongst the tools evaluated and recommended by the USPSTF. This lack of uniformity in screening patients in addition to the current use of tools unsupported by best practice reinforced the necessity for this EBP protocol to standardize screening women using a validated and efficient tool to effectively identify high-risk women who are candidates for genetic consultation.

Participants and Setting

The participants for this EBP project included women 18 years or older who sought care for a routine gynecological examination or a new patient appointment at an Ob/Gyn practice. The sample population included pregnant women if they were new patients but excluded those who were established patients receiving continuation of obstetrical care. Individuals with

impaired mental capacity either related to dementia or developmental conditions (e.g., mental retardation) were not offered to participate. A personal history of breast cancer was not an exclusion factor. If a woman returned to the office for repeat care during the project's time frame, the screening tool was only utilized once unless a personal or familial cancer history change occurred**.**

The EBP project setting was comprised of five office branches of an Ob/Gyn practice located in two adjoining Northwest Indiana counties. The practice is owned and operated by a hospital system, which is part of the largest health care system in this region. The organization's mission is "…to provide the highest quality care in the most cost-efficient manner, respecting the dignity of the individual, providing for the well-being of the community and serving the needs of all people, including the poor and disadvantaged" (Health Care System, nd). The values of this health care system are community, compassionate care, dignity, quality, and stewardship (Health Care System, nd). This proposed protocol embraces the mission and values of this health care system.

Three physicians, three NPs, and three CNMs are currently employed at this Ob/Gyn practice. Each health care provider sees patients in a variety of the five office locations. Approximately 400 patient appointments occur weekly. Both insured and uninsured patients are seen at this practice. The types of insurance plans utilized comprise an extensive amount of commercial plans, Medicaid, and Medicare coverage.

Pre-Intervention Group Characteristics

The geneticist employed by this health care system provides cancer genetic consultations at two nearby facilities. Between July 1, 2018 to July 1, 2019, the nine health care providers at the Ob/Gyn practice referred 30 women for genetic services (H. Hendricks, personal communication, August 20, 2019). This reported amount of referrals was likely lower than what actually occurred, as the health care provider may have initially given the geneticist's contact information to the patient as they began considering participating in this medical

management option. If this occurred and the patient then called to schedule a consultation

without updating the health care provider, a formal referral was often missing from the EMR.

Additionally, some of the providers often recommended a referral to this health care system's

High Risk Breast Clinic for additional breast cancer risk assessment to be performed first, at

which time the routine practice was for genetic services to be reviewed and offered as

appropriate (D. Faitek, personal communication, August 6, 2019). Between the dates of July 1,

2018 through July 1, 2019, a total of 38 referrals were placed to the High Risk Breast Clinic by

the nine providers at this health care practice.

Intervention

An evaluation of eight breast cancer risk appraisal tools was performed by the USPSTF,

with two receiving a quality rating of good, to include the B-RST™ (Nelson et al., 2019). The B-

RST™ was implemented in several research studies related to being straightforward and not

time consuming to incorporate into practice (Cintolo-Gonzalez et al., 2017). This web-based

tool is freely accessible for use, with the request of crediting the developer for use in this EBP

project, Dr. Cecelia Bellcross (C. Bellcross, personal communication, July 10, 2019). Dr.

Bellcross provided permission for a hyperlink to the B-RST™ to be accessible within the EBP

project site's EMR (see Appendix D). Due to being amongst the appraisal tools recommended

by the USPSTF and its reported ease of use, the B-RST™ was chosen to screen and identify

women at-risk for hereditary breast cancer.

Upon arrival at the office and being greeted by the registration representative, women

signed in for their appointment and were either provided a pen and customary paperwork or the

tablet to complete the check in process. Next, the patient was called back by the MA to

complete vital sign assessments as well as a review of history information within the EMR.

During this process, the MA accessed the B-RST™ hyperlink within the flowsheet section of the

EMR and completed this assessment with the patient. The risk evaluation result (negative-

average, negative-moderate, or positive-high) was entered in the flowsheet section by the MA

for the health care provider to review; in addition, the risk level was marked on the front of the patient results handout created by the DNP student entitled, Understanding Your Breast Cancer Genetics Referral Screening Tool (B-RST™) Results (see Appendices E and F). This one page handout was then placed in the plastic folder that contained a form listing the patient's name, date of birth, reason for appointment, and additional patient specific components requested by each health care provider. After the MA completed the rooming process, this plastic folder was either placed in a rack outside of the patient's examination room or given directly to the provider. The women were then seen by their health care provider as scheduled. The provider reviewed and discussed the B-RST™ risk results with the patient and subsequently provided the handout to the patient. These handouts were adequately supplied at each of the offices at the initiation of the project and then provided to the managers and/or personally delivered to each of the office locations as needed to ensure the supplies remained adequate. For those women with negative-moderate or positive-high risk B-RST™ results, their appointment records were reviewed approximately ten weeks afterwards to verify if a consultation appointment was made and kept at the High Risk Breast Clinic and/or with the geneticist. Appointments were verified for the final time on March 1, 2020.

The DNP student ran a weekly report through the Epic EMR to gather data on the following information: (a) participant initials and medical record number, (b) demographics, which included age, race, insurance type, and religious preference, (c) appointment type, and (d) B-RST™ results. In addition, each provider's daily schedule was evaluated in the EMR for: (a) candidates eligible for the protocol, (b) B-RST™ performance without results entered in the flowsheet, (c) B-RST™ performance without qualifying for the protocol, (d) eligibility for a referral to the High Risk Breast Clinic and/or geneticist, (e) referral provided to the High Risk Breast Clinic and/or genetic counseling, (f) referral documented but not actually ordered, and (g) documentation if a referral was declined or had been performed previously. The preceding information was recorded in an Excel EBP data spreadsheet that was organized by both the

week of the project and the provider. Printed copies of the weekly reports were kept in a locked

cabinet at the Ob/Gyn office and/or safely secured in a closet at the DNP student's place of

residence. These reports will be shred upon completion of this EBP project and the Excel files

will be permanently deleted from the DNP student's home desk top computer.

Planning. As delineated in chapter two, use of the seven steps of the Iowa Model

provided guidance for the development and implementation of this EBP project. Steps one and

two were achieved with the decision to pursue the EBP topic of hereditary breast cancer

assessment, along with the establishment of the PICOT directing the focus of evaluating risk for

identifying appropriate candidates for genetic services referrals. Nearly all staff members at this

Ob/Gyn practice were part of the EBP project team; however, during step three, key team

leaders were identified based on their strengths and heightened interest in this project. The key

team leaders were primarily MAs assigned to work with a specific provider. In accordance with

this step, the protocol process and utilization of the B-RST™ was reviewed with the staff and

their concerns, questions, and recommendations were considered and discussed.   Handouts

delineating the process and responsibilities of the health care providers and MAs were provided

and reviewed prior to the EBP protocol implementations (see Appendices G and H).

Step four of the EBP process was completed prior to protocol implementation,

encompassing a comprehensive review of the literature. A total of ten pieces of evidence were

appraised and utilized to support the EBP project and the proposed protocol. Meanwhile, the

fourth step was accomplished by choosing a tool with simple features allowing the staff to obtain

and review results promptly, with the goal of performing an accurate hereditary breast cancer

risk assessment while limiting interference with the normal daily office routine.

For step five, the EBP protocol was implemented, with the steps detailed in the

preceding section entitled "Intervention." Two weeks into EBP protocol implementation, initial

data and feedback from stakeholders was reviewed and analyzed, which guided the project

manager to make adjustments as necessary to continue this process. Health care provider

compliance was considered adequate if appropriate use of the tool occurred with at least 75% of the women who qualified for the protocol. In order to either maintain or improve participation rate, challenges specific to protocol adherence were discussed with appropriate team members. Individual compliance rates were calculated weekly by comparing the number of patients eligible for use of the B-RST™ with those who actually had the tool performed and documented. The trial portion of this fifth step was an integral part of the process towards achieving favorable EBP practice model adherence. With the exception of some providers requesting their patients to be given their results handout prior to them entering the room, it was determined during the pilot portion that the remaining ten weeks of the EBP project would be completed as initially planned.

During step six, integration of the B-RST™ in this health care setting was determined to be a proficient method for identification and referral of women at-risk for hereditary breast cancer in this health care setting. Necessary strategies for advancing beyond this step incorporated both education about this risk assessment tool and reinforcement of its use to ensure that changes remain long standing. Consequently, the DNP student will consider completing the inquiry process required for adopting this tool as a health care system-wide EMR "best practice alert," which serves as a reminder to health care providers to perform and/or review a specific task. Step seven involved informing the staff about the progress and results of the protocol implementation. Team members were incentivized for their participation throughout the project with a gift card drawing every two to three weeks. Using the Iowa Model for this EBP project guided a successful change implementation and fostered a positive learning experience.

Data measures. The B-RST™ evaluates if an individual is at increased risk for having a BRCA genetic mutation, which assists in determining which individuals are appropriate candidate for receiving a referral for genetic counseling with possible testing (Bellcross et al., 2019; Cintolo-Gonzalez et al., 2017). Developed in 2007 by Dr. Cecelia Bellcross, its original form was a paper questionnaire, named the Referral Screening Tool or RST. The current version of this tool, B-RST™ Version 3.1, is internet-accessible and available to health care

providers and the public (Bellcross et al., 2019). Emory University owns the rights to this tool

(A. Kerber, personal communication, July, 12, 2018). This tool has been recommended by the

USPSTF since 2013 and is credited for its ease of use (Bellcross et al., 2019; Cintolo-Gonzalez

et al., 2017; Nelson et al., 2019). The B-RST™ has been utilized in a variety of studies and

supported in many professional articles (Brannon Trexler et al., 2014; Paris et al., 2016; Pruthi,

Heisey, & Bevers, 2015; Solomon et al., 2016; Stewart et al., 2016; Wernke, Bellcross, Gabram,

Ali, & Stanislaw, 2019).

The B-RST™ is recognized for its straightforward use along with being highly validated

(Cintolo-Gonzalez et al., 2017). In 2010, the tool was advanced to the initial web-based B-

RST™ Version 2.0, with a sensitivity of 89.4% and a specificity of 91.5% overall with validation

against the Family History Assessment Tool, Myriad II, and a cancer family pedigree including

four generations; and when compared to the BRCAPRO and BOADICEA risk prediction models,

the sensitivity increased to 100% (Bellcross et al., 2019). Through a retrospective chart review

($N = 277$), validation of B-RST™ Version 3.0 against B-RST™ Version 2.0 was reported to have

an increased sensitivity respectively (94.0% vs. 71.1%, CI 95%, $p < 0.0001$), but a decreased

specificity respectively (29.4% vs. 53.1%, CI 95%, $p < 0.0001$); the authors reported despite the

reduction in specificity, those with positive risk results were verified to be candidates for genetic

services referrals (Bellcross et al., 2019). A two-sided McNemar's Chi-square test was used for

comparison of sensitivity and specificity of these versions (Bellcross et al., 2019).

Bellcross et al. (2019) differentiated between the following categories of B-RST™ risk

results: (1) Negative-average, (2) negative-moderate, and (3) positive. Negative-average risk

results reveal the possibility of that individual having a BRCA gene mutation is highly

improbable and the risk for breast cancer is that of the average population. Negative-moderate

risk results demonstrate the possibility of that individual having a BRCA gene mutation is low,

but risk for breast and/or ovarian cancer is elevated. Positive risk results signify the possibility

of that individual having a BRCA gene mutation is increased by at least 5-10%, with subsequent

increased risks for breast, ovarian, and other BRCA-related cancers.

B-RST™ results were reviewed by the health care provider during the appointment. The

women who had negative-average risk results who were 40 years or older had a mammogram

ordered if due for this test and per the health care provider's recommendations. Those whose

results were negative-moderate risk have an increased risk for breast cancer, but are not likely

at risk for a hereditary BRCA gene mutation. In addition to having a mammogram ordered for

those with negative-moderate risk results for those who were 40 years or older and due for this

test, they were also candidates for a referral to the health care system's High Risk Breast Clinic.

The women who had positive risk results were determined to be at an increased risk for a BRCA

gene mutation. Management recommendations included a mammogram ordered for those 40

years or older and due for this test, in conjunction with offering referrals to both the High Risk

Breast Clinic and for genetic services with the health care system's local geneticist.

Collection. Data collection for analysis included completing the B-RST™, recording

these results in the EMR flowsheet, and ordering consultation referrals. The first two steps were

completed by the MA and the last step was the responsibility of the health care provider. The

Epic information technologist initially assisted the DNP student with the process of creating

parameters and then running reports once weekly to obtain relevant data. Each provider's daily

schedule was reviewed to verify eligible patients, referrals ordered, and evaluate

documentation. Chart audits occurred at appropriate intervals to verify if a participant had

scheduled, cancelled, rescheduled, or attended a consultation at the HRBC and/or for genetic

counseling. This data was then entered in the Excel EBP project data spreadsheet.

Management and analysis. Health care provider protocol adherence and post-referral

genetics and/or High Risk Breast Clinic consultation participation rates were evaluated.

Protocol adherence was determined if there was documentation of the B-RST™ results in the

flowsheet section of the EMR and subsequent referrals provided to those with negative-

moderate or positive-high risk results. High Risk Breast Clinic and genetics consultations had to

be completed by March 1, 2020 to be included in the analysis of this EBP project.

Descriptive statistics were utilized to specify participant demographics. The Chi-square

test for independence was used to determine if the pre- and post-implementation groups were

independent of each other. Factorial ANOVA analyses were performed to determine if use of

the B-RST™ affected the health care providers ordering HRBC and/or genetics referrals in

comparison to the referral ordering practices for the pre-implementation group.

Comparison

One year prior to the protocol implementation, from September 24, 2018 through

December 14, 2018, eight women were provided referrals by the nine health care providers in

this practice to the local geneticist for counseling regarding their cancer family history. During

this same time frame, six women were referred to the High Risk Breast Clinic for management

of their increased risk for breast cancer. Use of the B-RST™ assisted in identification of

additional women at-risk for hereditary breast cancer who were then able to pursue additional

medical management options appropriate for this risk. Based on the use of this risk evaluation

tool, there was an increase in both referrals for genetic services and to the High Risk Breast

Clinic.

Outcomes

The primary outcomes of interest were the number of participants with negative-

moderate or positive-high risk results and subsequently the amount of HRBC and genetics

referrals provided to these individuals. Consistent with the appraised literature supporting this

best practice protocol, it was anticipated that compared to simply reviewing family history in the

EMR, use of the B-RST™ would increase health care provider identification and referral of

women at-risk for hereditary breast cancer. Secondary outcomes included data regarding the

participant rates for HRBC and/or genetics consultation performance. In addition, the health

care provider protocol participation in regards to referrals ordered. Although it was suspected

differences would be noted between adherence rates for the APRNs and physicians within this group, participation will be ascertained for the entire Ob/Gyn practice as an aggregate.

Time

Approximately two months prior to implementing the protocol, each of the health care providers at the Ob/Gyn office and the geneticist were recruited. Next, the DNP student trained the medical assistants individually how to use the B-RST™. Protocol details were reviewed, including who qualified for use of the tool and how to document these results. The EBP project was implemented for twelve weeks, starting September 23, 2019 and ending on December 13, 2019. Genetic and/or High Risk Breast Clinic consultation participation was verified by March 1, 2020.

Protection of Human Subjects

It is imperative during the pursuit of advancing health care knowledge that the rights of individuals are protected. Key ethical aspects prioritized during the development and implementation of this EBP project were autonomy, beneficence/nonmaleficence, and justice. An objective throughout this project was to provide consistent and comprehensive care to women in adherence with the identified best practice standards. Patients were assessed using the B-RST™ as long as the inclusion factors were met. In meeting ethical course requirements prior to the study's initiation, the NIH ethics web-based course entitled "Protecting Human Research Participants" was completed on April 5, 2018 (Certificate Number 2628916). This EBP project was found to be classified within the exempt non-research category and therefore did not require further review from the Institutional Review Board (IRB) at Valparaiso University. The EBP project was then reviewed and approved by the IRB at the health care system at which it was performed (see Appendix I).

CHAPTER 4

FINDINGS

The purpose of this EBP project was to determine if utilization of the B-RST™ risk assessment at a nine provider Ob/Gyn practice in a Midwestern state was an effective process for identifying women at-risk for hereditary breast cancer for the purpose of providing High Risk Breast Clinic (HRBC) and/or genetic counseling referrals. Pre-implementation (before protocol intervention) and post-implementation (after protocol intervention) data were compared in this project. The pre-implementation group was comprised from a chart audit and included 880 patients who were seen one year prior. Data were collected from electronic medical records by process of entering B-RST™ results in the EMR, reviewing populated EMR reports, and performing chart audits for the post-implementation group. A total of 994 women had the B-RST™ assessment completed during routine gynecological and new patient appointments during this 12-week EBP project.

Participants

Pre-implementation Demographics

Demographics information was collected through an EMR chart review between the dates of September 24, 2018 through December 14, 2018, with this range being the same 12-week time frame that the EBP project was implemented in 2019. Demographic information for this population included: age, appointment type, insurance coverage, race, and religious preference. The EMR chart audit report that populated was unable to distinguish between appointments or encounter types. Encounter types included patient-focused activities such as: clinical updates, email messages, registration for tests (labs, mammogram, etc.), or incoming/outgoing telephone calls. From the 4,181 appointments/encounters during this time frame, every third patient chart was audited to determine if the inclusion criteria were met

consisting of being ≥ 18 years old and seen for either an annual gynecological or new patient appointment, which subsequently resulted in a total of 880 patients.

The mean age of the patients in the pre-implementation group was 44.89 (*SD* = 14.361), with the ages varying from 18 to 83 years old. On average, these patients were ≥ 40 years old (*n* = 607, 61.1%) and presented for routine gynecological examinations (*n* = 659, 74.9%). In this group, the majority had commercial insurance (*n* = 669, 76.0%), were Caucasian or white (*n* = 747, 84.9%), and Christian (*n* = 458, 52.0%).

Post-implementation Demographics

Information regarding demographics was obtained by running weekly EMR reports and was determined to be consistent with those in the pre-implementation group. The ages of the post-implementation group participants ranged from 18 to 91, with a mean age of 44.87 and a *SD* = 14.337. Most participants (*n* = 748, 75.3%) were over the age of 18 and were seen for routine gynecological examinations (*n* = 748, 75.3%). Overall, they predominantly had commercial insurance (*n* = 795, 80.0%), were Caucasian or white (*n* = 861, 86.6%), and listed their religious preference as Christian (*n* = 517, 52.0%).   See Table 4.1 for additional demographic data delineation and comparisons between the pre- and post-implementation groups.

<div align="center">**Changes in Outcomes**</div>

Nearly seventy-five percent (n = 745, 74.9%) of the participants had negative-average risk B-RST™ results. The remaining quarter of the group had negative-moderate (*n* = 75, 7.5%) and positive-high (*n* = 174, 17.5%) risk results (see Figure 4.1). This data is consistent with the evidence from the literature. In a study performed by Wernke et al. (2019), 72.2% of the participants had negative-average results, 9.5% had negative-moderate, and 18.3% were positive. Per the protocol, 249 participants were eligible for a HRBC consultation and 174 for genetics. Data for pre-and post-implementation HRBC and genetics referrals are to follow.

Pre-implementation HRBC and Genetics Referrals

The nine health care providers at this EBP project site consisted of three each of CNMs, NPs, and physicians. Two of the three physicians had a NP that shares patients from their schedule. The 994 participants screened with the B-RST™ saw the providers as follows: CNM (n = 210, 21.1%), NP (n = 244, 24.5%), physician (n = 347, 34.9%), and physician/NP (n = 193, 19.4%). Pre-implementation HRBC and genetics referral totals from these providers were determined through an EMR chart audit for this same 12-week duration one year prior and included HRBC (N = 6) and genetics (N = 8). For the HRBC referrals, five (83.3%) were from the physicians/NPs and the remaining one (16.7%) was provided by a CNM. Two (25%) of the genetics referrals were from the physician/NP and the remaining six (75%) were from the NP. Two of the six HRBC consultations were performed, whereas three of the eight genetic referrals were completed. See Table 4.2 and Figure 4.2 for comparisons of pre- and post-implementation HRBC and genetics referrals provided.

Post-implementation High Risk Breast Clinic Referrals

In comparison to the pre-implementation group, the total referrals to the HRBC increased by 51. Amongst the 249 participants who qualified for a HRBC referral, n = 57 (22.9%) accepted this referral and n = 144 (57.8%) either declined or were not offered this option. Of note, the majority of participants who were eligible for genetic counseling also qualified for a consultation at the HRBC. An exception to this was individuals with a family history of ovarian cancer, but without any family members with a history of breast cancer. From the 57 HRBC referrals ordered, 30 (52.6%) were from the physicians/NPs, 19 (33.3%) from the NP, six (10.5%) from the CNMs, and two (3.5%) from the physician.

Documentation was reviewed in the EMR with the health care providers having reported that the HRBC referral was unnecessary for 31 participants (12.5%) or that the referral was ordered when in actuality this did not occur (n = 17, 6.8%). The providers documented a discussion with a HRBC eligible participant 62.7% (n = 156) of the time. If a patient declined the

referral, this was documented 58.6% of the time. It was noted that 10 patients had a prior history of completing a consultation at the HRBC. See Table 4.2 and Figure 4.2 for comparisons of pre- and post-implementation HRBC and genetics referrals.

Post-implementation Genetics Referrals

Genetics referral totals increased by 24 with the post-implementation group. A total of 174 participants qualified for a referral for genetic counseling, in which $n = 32$ (18.4%) accepted this referral and $n = 124$ (71.3%) declined or were not offered this option. The physicians/NPs ordered 16 (50%) of these referrals, with nine (28.1%) from the NP, six (18.8%) from a CNM, and one (3.1%) from the physician. Within eligible participants, the health care providers documented that the genetics referral was unnecessary for three (1.7%) participants or that the referral was ordered when in actuality this did not occur ($n = 15$, 8.6%). Documentation of a discussion with a participant eligible for a genetics consultation was present 54.6% ($n = 95$) of the time. If a participant declined the referral, this was documented 40.2% ($n = 70$) of the time. A total of 21 participants were noted to have a history of genetic counseling and/or testing performance. See Table 4.2 and Figure 4.2 for comparisons of pre- and post-implementation HRBC and genetics referrals provided.

Statistical Testing and Significance

IBM SPSS Statistics Standard Edition version 25 was utilized for variable and data entry, in addition to statistical analysis performance. Frequencies were determined for pre- and post-implementation participant demographics, B-RST™ results, referrals provided, and referrals completed (see Tables 4.1- 4.4 and Figures 4.1- 4.4). The Chi-square test for independence was used to determine if the pre- and post-implementation groups were independent of each other. A factorial ANOVA was performed to examine if there was a statistically significant difference between HRBC and/or genetics counseling referrals being provided pre- and post-implementation in comparison amongst the health care providers at the Ob/Gyn practice.

Chi-square testing. The Chi-square test is a nonparametric level of analysis that utilizes nominal or ordinal data to distinguish if groups are similar or different, for the purpose of assisting with determining whether an intervention caused a change versus differences between a variable being the reason (Peters, Schmidt, & Fearncombe, 2015). The Chi-square test for independence was used to distinguish if the demographic variables of age, appointment type, insurance coverage, race, and religious preference were statistically significant, or independent, between the pre- and post-implementation groups. Statistical significance for all analysis was established as $p < .05$.

A chi-square test for independence was conducted comparing the demographic data of the pre- and post-implementation groups. There was no statistically significant difference found between these two groups on age ($p = .946$), appointment type ($p = .855$), insurance type ($p = .054$), race ($p = .662$), and religious preference ($p = .421$). Subsequently, the patients included in this sampling were considered to be representative of the patients seeking care in this Ob/Gyn practice.

ANOVA testing. Verifying whether the means of groups vary is achieved through ANOVA (analysis of variance) testing; this can occur for multiple means and assists with type 1 error minimization (Peters, Schmidt, & Fearncombe, 2015). Between-subjects factorial ANOVA tests (hereafter referred to as ANOVA) were conducted with the independent variables of HRBC referral provided or genetics referral provided with the dependent variables of health care provider and pre- and post-implementation groups. Statistical significance for all analysis was established as $p < .05$ and confidence intervals were 95.0%. See Table 4.4 for ANOVA results.

The ANOVA test was performed to ascertain if being provided a referral for HRBC counseling varied with the health care providers at the EBP project site and the two groups (pre- and post-implementation). Statistically significant differences were found for the group means of the health care providers ($F(6, 1860) = 9.24$, $p < .001$), the pre- and post-implementation groups ($F(1, 1860), = 22.01$, $p < .001$), and lastly the interaction effect between the providers

and these two groups (F(6, 1860), = 9.23, p < .001). Therefore, the null hypothesis was

rejected as these results indicated that the differences amongst the health care providers and

between being in the pre- or post-implementation group affected the ordering of HRBC referrals.

The ANOVA test was then conducted to establish whether genetics referrals being

ordered differed between the health care providers and the two groups (pre- and post-

implementation). Statistically significant differences were found for the group means with the

health care providers (F(6, 1860) = 5.36, p < .001), the pre- and post-implementation group

(F(1, 1860) = 10.14, p < .001), and the interaction effect between the providers and the groups

(F(6, 1860) = 6.46, p < .001). Similar to the HRBC referrals, genetic referral provision

differences were noted between the health care providers and the pre- and post-implementation

groups.

Post hoc testing. Since the above ANOVA results were statistically significant, post

hoc testing was required to determine where the differences occurred within the health care

providers ordering HRBC and genetics referrals. With multiple types to choose from, Tukey

HSD was selected (Cronk, 2018). The Tukey post hoc test was not performed for the pre- and

post-implementation groups related to no additional variable being available for comparison.

The mean difference was significant at the p < .05 level.

Between the seven provider/groups previously delineated, 21 pairs of analyses

occurred. For the purpose of analyzing and interpreting the results from these pairs,

physician/NP was categorized as physician1/NP1 or physician2/NP2. CNM1, CNM2, and

CNM3 differentiated between the three CNMs. The remaining physician and NP were listed as

such.

Statistical significance was noted, indicating that the following eight pairs of providers

were statistically different from each other in regards to providing HRBC referrals: (1)

physician1/ NP1 and physician2/NP2, (2) physician1/NP1 and the physician, (4) physician1/NP1

and the NP, (5) physician1/NP1 and CNM1, (6) physician1/NP1 and CNM2, (7) physician1/NP1

and CNM3, and (8) the physician and the NP. Regarding providing genetics referrals, the

following three pairs of providers were statistically different from one another: (1) Physician

1/NP1 and the physician, (2) physician1/NP1 and the NP, and physician 1/NP1 and CNM2. The

remaining pairs for both of these Tukey post hoc tests were not found to be statistically different.

Findings

   Primary outcomes. The primary outcomes were the identification and referral of

women considered to be at increased risk for hereditary breast cancer through a B-RST™

assessment. During the 12-week EBP protocol implementation, 1253 women were eligible to

have the B-RST™ performed at their appointments and this successfully occurred for 994

participants. At the onset of this EBP project, the minimum goal was set at 75% protocol

adherence rate. At its completion, the protocol participation rate was 79.3%.

   Whereas 75% ($n = 745$) of the participants had negative-average risk results, 75 (7.5%)

had negative-moderate risk results, and the remaining 174 (17.5%) were in the positive-high risk

category. As aforementioned, the majority of participants who were eligible for genetic

counseling also qualified for a consultation at the HRBC. Fifty-seven participants were provided

a referral to the HRBC from the 249 who qualified. Amongst the 174 participants who were

eligible, 32 patients (18.4%) received referrals for genetic counseling.

   Secondary outcomes. Secondary outcomes included participant HRBC and/or

genetics consultation participation rates. Eight patients (14.0%) completed a HRBC

consultation by March 1, 2020, with an additional six patients (10.5%) having upcoming

appointments scheduled beyond this date (see Table 4.3 and Figure 4.3). Appointments were

scheduled at the HRBC and then either cancelled or not attended by nine participants (15.8%).

Nearly 60% ($n = 34$, 59.6%) of those eligible had not yet scheduled a consultation at the HRBC.

Genetic counseling appointments were completed by seven (21.9%) participants by March 1,

2020, without any further appointments scheduled (see Table 4.3 and Figure 4.4). Three

participants (9.4%) scheduled appointments and then did not attend or cancelled. A total of $n =$

22 (68.8%) had not scheduled an appointment yet.

Although the total HRBC and genetics referrals varied amongst the health care

providers, this Ob/Gyn group as a whole ordered more of both of these during the post-

implementation in comparison to the pre-implementation time period (See Table 4.2 and Figure

4.2). The total combined HRBC and genetics referrals provided in the pre-implementation

group were 14 and this increased to 89 in the post-implementation group. Four of the providers

did not provide HRBC referrals to the pre-implementation group, which decreased to one

provider during the post-implementation. Five of the providers did not provide pre-

implementation genetics referrals and two providers maintained this status post-implementation.

Table 4.1

Pre- and Post-Implementation Demographic Comparison

Totals	Pre-implementation		Post-Implementation	
	n	%	*n*	%
Group (*N*)	880		994	
Age (mean, *SD*)	45	14.361	45	14.337
Appointment Type				
Routine Annual Exam	659	74.9	748	75.3
New Patient	221	25.1	246	24.7
Insurance Coverage				
Commercial	669	76.0	795	80.0
Medicaid	112	12.7	107	10.8
Medicare	91	10.3	90	9.1
Uninsured	8	0.9	2	0.2
Race				
Caucasian or White	747	84.9	861	86.6
Other	71	8.0	63	6.3
African American or Black	62	7.0	70	7.0
Religious Preference				
Christian	458	52.0	517	52.0
No preference/none	372	42.3	431	43.4
Other	48	5.5	41	4.1
Jewish	2	0.2	5	0.5

Note. Other category for race included: Asian, Native American, and unspecified.

Table 4.2

Pre- and Post-Implementation Referral Comparison

_____

	Pre-implementation	Post-implementation
Totals	*n*	*n*

_____

Participants (*N*)	880	994
Referral Provided		
High Risk Breast Clinic	6	57
Genetics	8	32
Referral Performed		
High Risk Breast Clinic	2	8
Genetics	3	7

_____

Note. Pre-implementation participants consisted of patients seen by the nine health care providers for annual exam and new patient appointments during the same 12-week time frame one year prior.

Table 4.3

Post-Implementation Referral Eligibility, Provision, and Performance

_____

Referral Type	High Risk Breast Clinic		Genetics	
Frequency, Total	*n*	%	*n*	%

_____

Eligible for Referral	249	25.1	174	17.5
Referral Provided				
Yes	57	22.9	32	18.4
No	144	57.8	124	71.3
Documented, but not ordered	17	6.8	15	8.6
Documented as unnecessary	31	12.4	3	1.7
Referral Performed				
Yes	8	14.0	7	21.9
No	34	59.6	22	68.8
Currently scheduled	6	10.5	0	0
Scheduled, then cancelled	9	15.8	3	9.4

_____

Note. Eligibility results from the total participants ($N = 994$) who had the B-RST™ performed. Participants with positive-high risk results qualified for referrals to HRBC and genetics.

Table 4.4

Factorial ANOVA Results

_____

	df	*F* value	*p* value
	(effect, error)		

_____

	df (effect, error)	*F* value	*p* value
HRBC Referral			
Provider	6, 1860	9.24	<.001
Group	1, 1860	2.01	<.001
Provider & Group	6, 1860	9.23	<.001
Genetics Referral			
Provider	6, 1860	5.36	<.001
Group	1, 1860	10.14	<.001
Provider & Group	6, 1860	6.46	<.001

_____

Note. Statistical significance at *p* < .05

Figure 4.1

B-RST™ Results

17.5%

7.5%

75%

Legend:
- Negative-Average Risk (green)
- Negative-Moderate Risk (yellow)
- Positive-High Risk (red)

Figure 4.2

HIGH RISK BREAST CLINIC & GENETICS REFERRALS
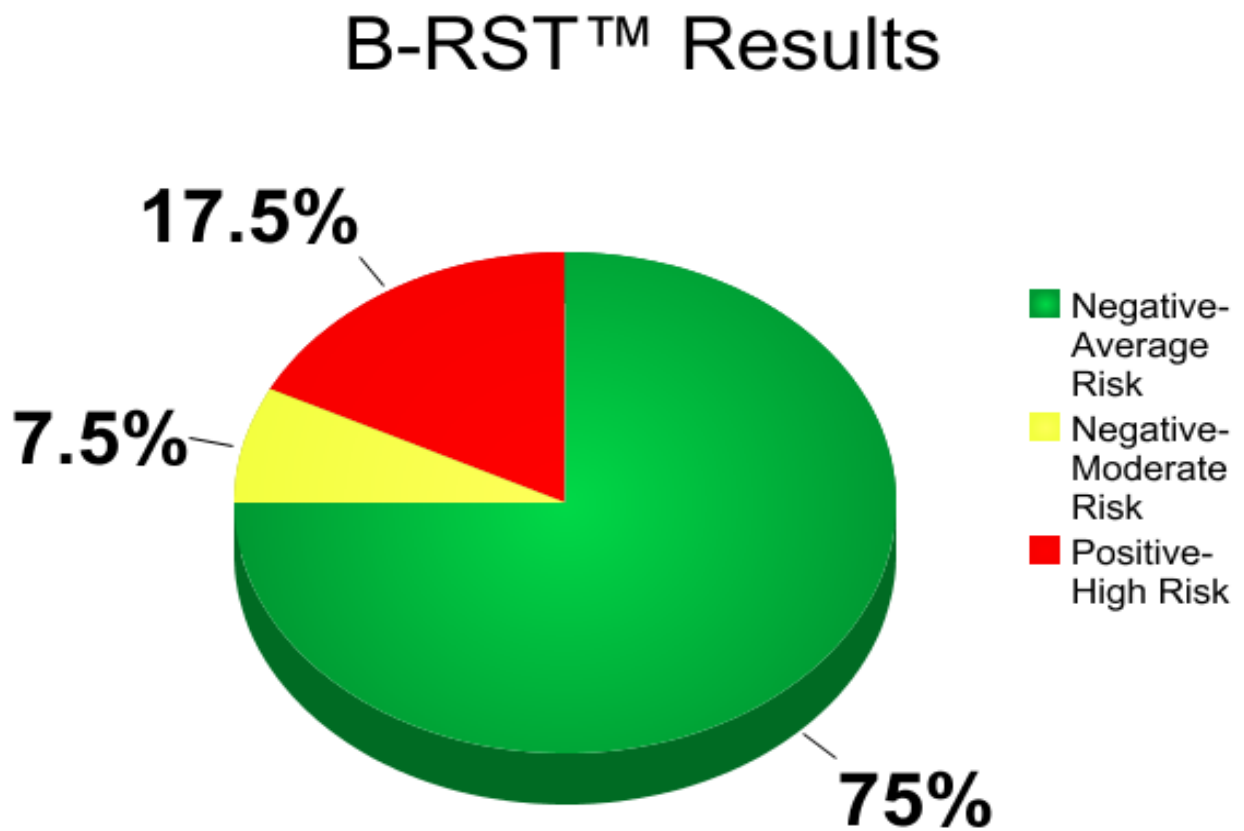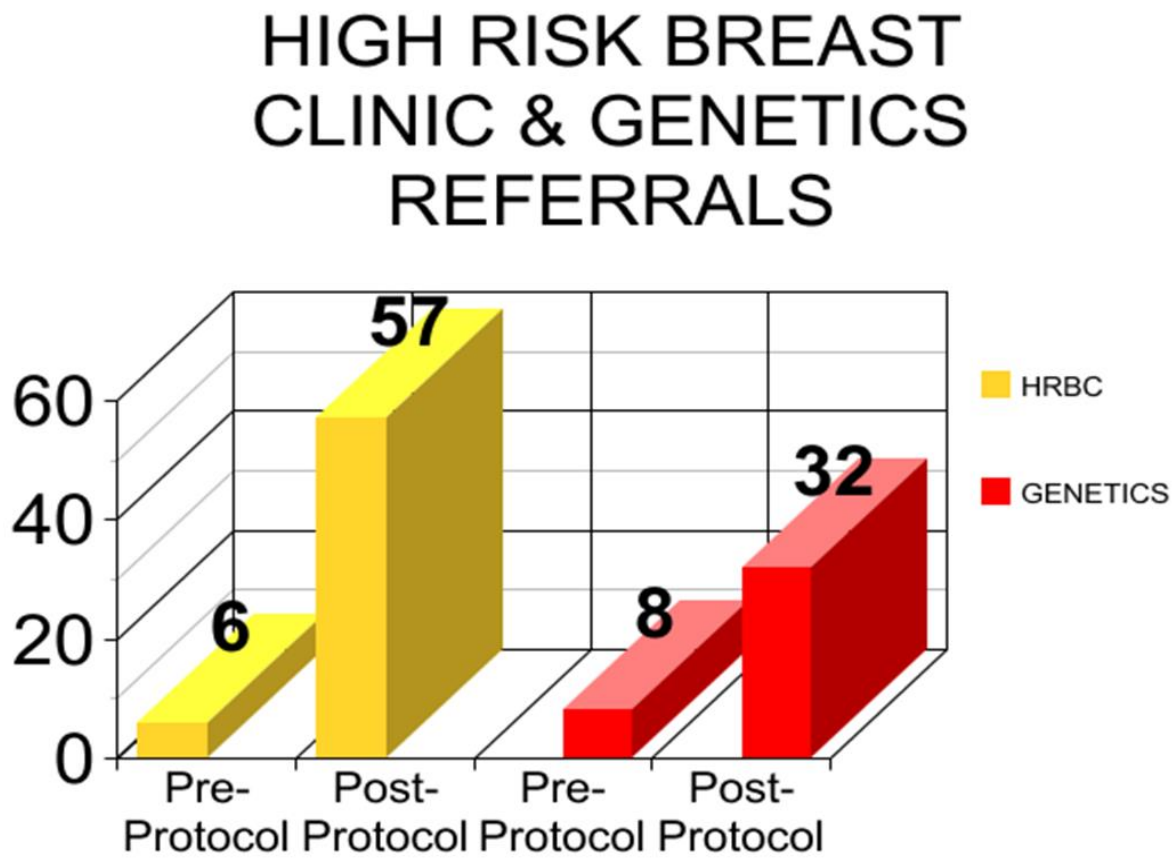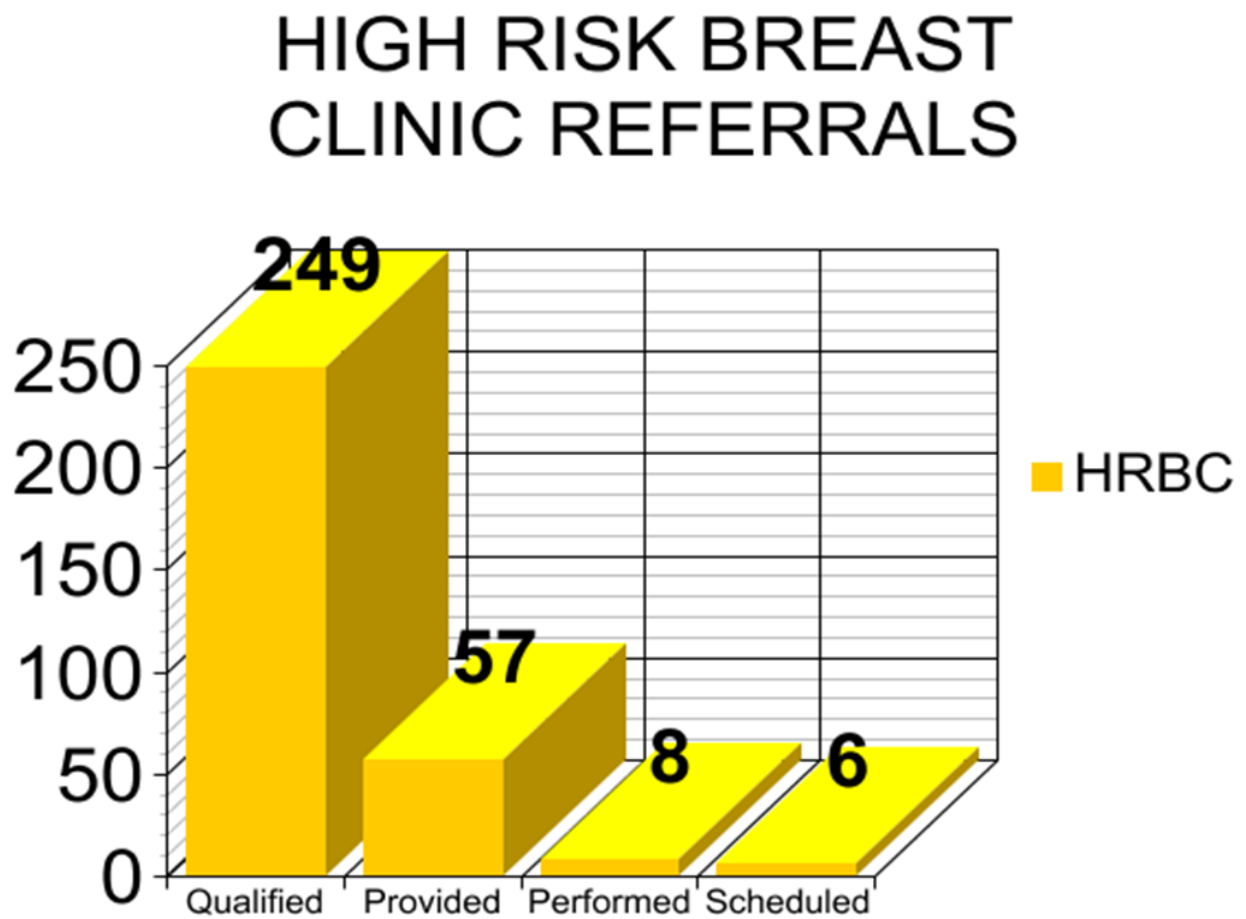
Figure 4.3

Figure 4.4
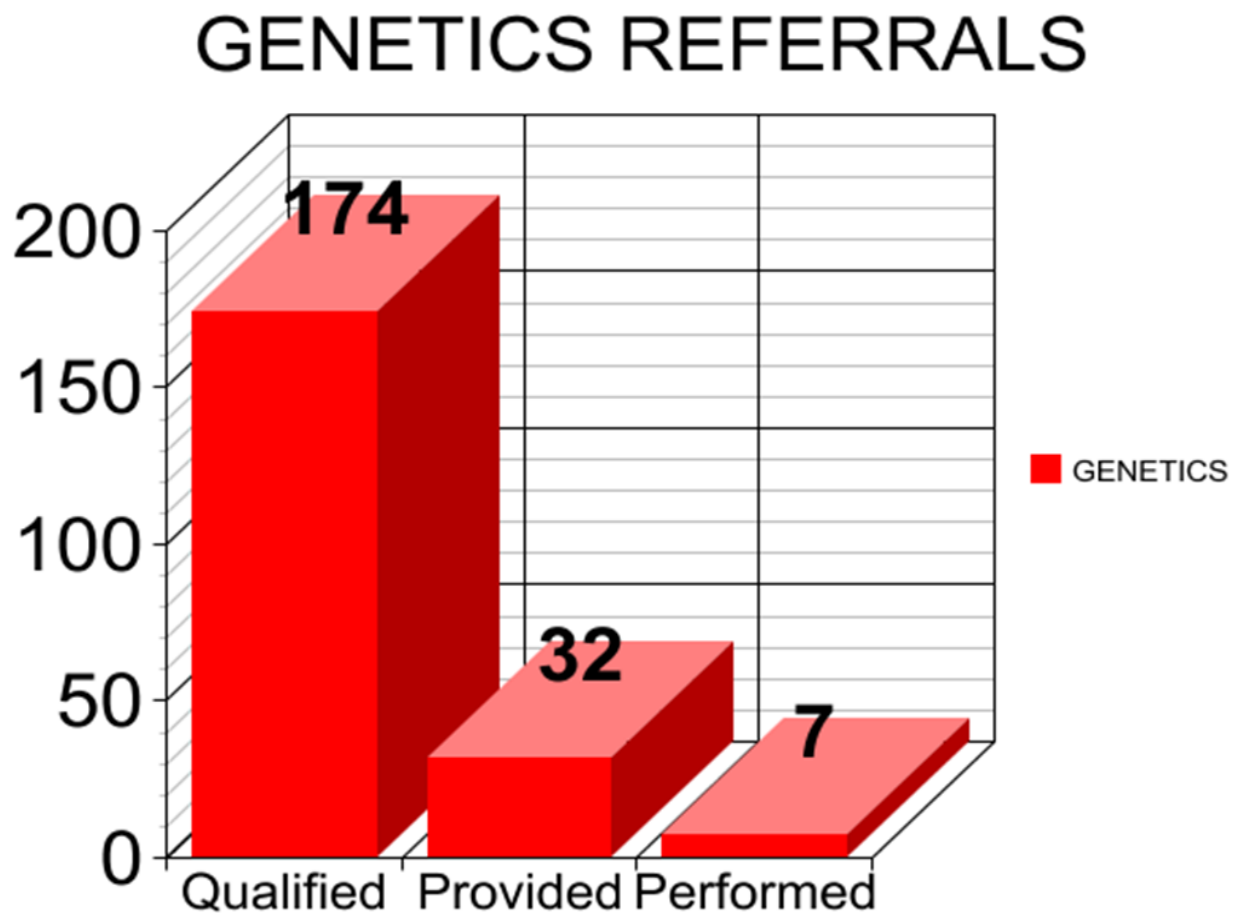
CHAPTER 5

DISCUSSION

The primary objective of this EBP project was to answer the following PICOT question: In women cared for in an obstetrical and gynecological practice, how does utilization of a breast cancer genetics referral screening tool, as compared to the current standard of care of collecting and reviewing family history in patients' electronic medical record, allow women at increased risk for hereditary breast cancer to be appropriately identified and referred for genetic counseling within a twelve-week time frame? Upon completing data analysis, statistically and clinically significant results supported the utilization of the protocol and assessment tool in this office setting. The Iowa Model was an effective approach to guiding this change. Knowledge of both the strengths and limitations with this EBP project can promote improvements and sustainability of B-RST™ use as a standard practice of care. Recommendations focus on improving adherence to utilization of the B-RST™ assessment, in addition to enhancing patient participation in referral performance, in order to facilitate medical management in women at-risk for hereditary breast cancer.

Explanation of Findings

During the 12 weeks that the EBP project occurred at the nine provider Ob/Gyn practice, 1253 patients were candidates for having the B-RST™ assessment completed at their routine gynecological or new patient appointment. The B-RST™ was successfully completed for 994 (79.3%) participants, which achieved the goal of a minimum of 75% B-RST™ performance. With 75% ($n = 745$) of the B-RST™ results being negative-average risk, the remaining 25% ($n = 249$) of participants were subsequently eligible for referrals to further assess and manage their elevated risk for breast cancer. Per the EBP protocol, participants with negative-moderate risk results were to be offered referrals to the HRBC and those with positive-high risk results to both

the HRBC and genetics. This resulted in 249 participants being candidates for consultations at

the HRBC and 174 for genetic counseling.

Participants

Pre-implementation data were obtained for the same 12-week time period one year prior

to the protocol being implemented. This group consisted of 880 patients. The post-

implementation group included 994 participants. Both of these groups were adequate in size.

The average ages were nearly identical at 44.89 (SD = 14.361) and 44.87 (SD = 14.337) for the

pre- and post-implementation groups respectively. For each of these groups, the patients were

predominantly Caucasian or white, Christian, had commercial insurance, and presented for a

routine gynecological examination. Although the results from this EBP project may be limited in

generalizability related to this population not being diverse, Chi-square test for independence

results were not statistically significant (p > .05), which indicated that the pre- and post-

implementation groups were a representative sampling of the patients seeking care at this EBP

project site. This information assisted in the further determination that the protocol

implementation likely supported the results noted, instead of differences between the

demographic variables amongst these two groups.

High Risk Breast Clinic Referral Candidates and Referrals Provided

Following the EBP protocol, participants with negative-moderate (n = 75, 7.5%) and

positive-high (n = 174, 17.5%) risk results met the qualifications for receiving referrals to the

HRBC. An exception to this was participants who had a family history of ovarian cancer, but

without an incidence of breast cancer, which would slightly decrease the total participants

eligible for the HRBC. Related to potential inaccuracies in participants' family medical history

and/or if this information was not documented by the health care provider, this exclusion was

not omitted from the total. From these 249 participants, HRBC referrals were provided to 57

(22.9%) and completed by 8 (14.0%) participants. In comparison, six referrals were ordered for

the pre-implementation group, with an improvement by nearly ten-fold ($n = 51$) during the 12

weeks the EBP protocol was implemented.

Nine HRBC appointments were scheduled and then either not attended or cancelled. In

addition, six appointments remain scheduled, but had not yet occurred by the date established

to initiate data analysis. Of importance to note, several of the health care providers documented

that referrals were provided for an additional 17 participants, but in actuality these were not

ordered. Had this been accurately performed, the HRBC referrals would have increased by

29.8% to a total of 74. Suspected reasons these referrals may not have ordered include a

miscommunication between the health care provider and the MA or if the participant changed

her decision after the appointment with the provider had concluded. Lower than anticipated

rates of referral acceptance and completion occurred, which impacted the number of women

overall who could participate in appropriate medical management for their increased risk for

breast cancer. Potential participant-related concerns regarding performing HRBC consultations

are considered further in this chapter.

Factorial ANOVA test results for providing a HRBC referral were statistically significant

for: (1) The health care providers ($F(6, 1860) = 9.24$, $p < .001$), (2) the pre- and post-

implementation groups ($F(1, 1860), = 22.01$, $p < .001$), and (3) the interaction between the

health care providers and the pre- and post-implementation groups ($F(6, 1860), = 9.23$, $p <$

$.001$). Statistical significance for analysis was established at $p < .05$. With the Chi-square

analyses indicating the two groups were dependent of each other, the ANOVA results

determined that the protocol implementation utilizing the B-RST™ assessment to guide ordering

HRBC referrals resulted in an increase in this performance. With Tukey HSD post hoc test

results, eight pairs of the health care providers were statistically different from one another in

regard to ordering HRBC referrals. Since the EBP protocol adherence and HRBC referral

provision varied per provider, this consequently affected whether an eligible participant would

receive a referral and is an additional area needing improvement.

Genetics Referral Candidates and Referrals Provided

A total of 174 (17.5%) participants had positive-high risk B-RST™ results and were appropriate for genetic consultation referrals, in which 32 (18.4%) were ordered, and seven (21.9%) were completed. This is a four-fold rise in referrals for genetic counseling in contrast to the eight provided to the pre-implementation group.

Three appointments were scheduled and then either not attended or cancelled, and have since not been re-scheduled. An additional 15 participants were candidates for genetics referrals, but these were not ordered despite being documented by the health care providers as having occurred. If these had been completed, the total referrals would have increased by 46.9% to 47. Similarly to accepting and performing HRBC referrals, those for genetics were also less than expected. Participant-related barriers for utilizing genetic services are explored further in this chapter.

Comparable to the HRBC referral outcomes, the factorial ANOVA results for providing genetic referrals were also statistically significant for: (1) The health care providers ($F(6, 1860) = 5.36$, $p < .001$), (2) the pre- and post-implementation group ($F(1, 1860) = 10.14$, $p < .001$), and (3) the interaction effect between the health care providers and the groups ($F(6, 1860) = 6.46$, $p < .001$). Utilization of the B-RST™, as demonstrated by the significant differences between the pre- and post-implementation groups, supported the increase in genetics referrals. Tukey HSD post hoc results revealed statistical difference between three pairs of the health care providers for ordering genetics referrals. Likewise, further focus on the health care providers ordering genetics referrals could potentially enhance appropriate participants being provided referrals.

Primary and Secondary Outcomes

Primary outcomes. The primary outcomes for this EBP project were the identification and referral of women considered to be at increased risk for hereditary breast cancer through a B-RST™ assessment. Chi-square test results for the pre- and post-implementation groups indicated that the demographic variables of age, appointment type, insurance coverage, race,

and religious preference were independent of each other, with $p > .05$. Factorial ANOVA results

were statistically significant ($p < .01$) for the changes in the HRBC and genetic referrals ordered

by the providers for the pre- and post-implementation groups. As evidenced by the data

analysis and supported in the literature, following the protocol and using the B-RST™ was an

effective process for recognizing and providing referrals for women at-risk for hereditary breast

cancer. In comparison to the HRBC referrals ordered for the pre-implementation group ($n = 6$),

51 additional referrals were provided to the post-implementation group ($n = 57$). Similarly,

genetics referrals increased by 24 from the pre-implementation group ($n = 8$) to the post-

implementation group ($n = 32$). Patients at this Ob/Gyn practice will benefit from continued use

of this risk assessment tool to guide the referral process.

       According to the EBP project's findings, from the 259 patients that met the protocol

criteria but did not have the B-RST™ completed it is estimated that approximately 65 (25%)

would have also been appropriate for receiving HRBC and/or genetics referrals. Although the

MAs were responsible for performing and documenting the B-RST™ results in the EMR, the

health care providers also had access to this risk assessment tool and were ultimately

accountable for its performance in patients who met the protocol qualifications. Increasing B-

RST™ utilization and referral provision are necessary areas of improvement in order to provide

optimal health care to this high-risk group.

       Secondary outcomes. Whereas the primary focus of this EBP project was to both

identify and provide referrals for women at-risk for hereditary breast cancer, it is essential that

successful performance of the HRBC and/or genetic consultations occurs for directing medical

management. HRBC and genetic consultation participation were secondary outcomes with low

appointment adherence rates noted for both of these. By March 1, 2020, a total of eight

(14.0%) HRBC consultations were performed from the 57 that were ordered and for the 32

participants who were provided genetic referrals, seven (21.9%) had been completed. It will be

advantageous for the patients at this Ob/Gyn practice to receive information about these

consultation appointments and to also have their perceived barriers addressed. Further

information regarding patient-perceived barriers and recommendations for alleviating these will

be clarified in the Implications for the Future section of this chapter.

Comparison of EBP Project Findings to Appraised Literature

In accordance with the appraised literature, utilizing the B-RST™ for this EBP project

was found to be a time efficient approach for accurately identifying and providing referrals to

women determined to be at-risk for hereditary breast cancer (Anderson et al., 2015; Hilgart et

al., 2012; Solomon et al., 2016). The MAs and health care providers reported ease of use with

performing the B-RST™ assessment, entering results, locating the results in the flowsheet, and

reviewing these results with the participants. The uncomplicated nature of using the B-RST™

promoted continued use of this risk assessment tool.

Although not directly reported by the MAs or the other health care providers, yet noted

with several of this DNP student's participants and likewise reported by Baer et al. (2013) and

Brannon Trexler et al. (2014), when patients inaccurately reported their cancer family history or

did not perceive sharing this information to be important and simply reported no history, the

accuracy of the B-RST™ risk appraisal results and consequently the management of these

results were hindered. Since one is not able to view both the participant's cancer family history

simultaneously while performing the B-RST™ in this health care system's EMR, the accuracy of

the cancer family history could not be verified during this process. However, this information

could be clarified afterwards with the B-RST™ repeated as needed to ensure accurate results

and appropriate medical management recommendations.

Although each of the health care providers in this Ob/Gyn practice agreed to participate

in the EBP project and follow the protocol implementation, the adherence rates were quite

varied. Two of the three physicians and two of the three midwives consistently did not

document whether they discussed the B-RST™ results with their patients. These same

providers also provided little to no referrals for HRBC and/or genetic counseling. According to

Christianson et al. (2012), some of the barriers for optimal risk assessment tool performance

that presumably applied to the health care providers at the EBP project site included time

restraints along with knowledge and confidence limitations. Even though it was not particularly

time consuming to review results and recommended referrals with the participants, it may not

have been integrated into the appointment routine for specific providers. This lack of

consistency may have consequently affected confidence levels. In an attempt to improve

protocol adherence and confidence levels, the providers were contacted several times, in

person and/or by email or text message, prior to and during the 12-week EBP project to provide

education regarding: Details of the protocol, the use of the B-RST™, recommended

management of the three results, and updates regarding data totals (i.e. eligible participants,

weekly participants, test results, HRBC & genetic referrals). In addition, the providers were

requested to provide feedback, which was repeatedly positive. Despite these favorable

comments, obstacles persisted for certain providers with ordering referrals.

Depending on the location of an office setting, limited resource availability could be a

barrier to referral and/or genetic testing performance (Berliner et al., 2013; Christianson et al.,

2012). However, the participants in the EBP study had access to a HRBC with locations within

the two counties that the Ob/Gyn offices were located. Although the geneticist worked in only

one of the two counties, she had two offices for the participants to choose from. The HRBC had

limited appointment availability with a maximum of three consultation appointments per week.

Both of these factors potentially affected the number of consultations completed during this EBP

project.

As evidenced by the literature and supported by the increase in the post-implementation

referrals for both the HRBC and genetics, incorporating use of a risk assessment tool, such as

the B-RST™, resulted in a more thorough review, discussion, and management of a patient's

family cancer history (Anderson et al., 2015; Baer et al., 2013; Berliner et al., 2013; Kaplan et

al., 2014). Although participant feedback was not requested at the time the B-RST™ tool was

used, beneficial outcomes were reported to the health care provider during HRBC consultations. Consistent with the literature, these benefits included satisfaction with the counseling experience related to an increase in knowledge and reassurance about available medical management options to decrease specific risk factors (Hilgart et al., 2012; Nelson et al., 2014; Obeid, 2017).

Strengths and Limitations of the DNP Project

Strengths

     Staff involved with the project. Several attributes of this EBP project promoted its successful outcomes. Each of the individuals, involved in varying roles, had essential responsibilities for building the foundation of the project. From the beginning, the health care system's Epic IT representative and the office manager volunteered their time, sharing knowledge and skills for the follow EMR tasks: Adding the B-RST™ hyperlink, creating and running reports, and performing chart audits. Aspects of these processes were tedious at times, yet the final outcomes allowed the paper version of the B-RST™ to be averted and also reduced the time required for data collection. In addition, each of the nine providers at the project site were supportive and willing to participate. Their buy-in fostered a more positive response from the MAs to participate in their roles for this project. The MAs not only appeared supportive of the EBP project, but were competitive amongst each other, as they attempted to achieve the highest B-RST™ accuracy rates and have their names chosen for one of the gift cards drawn every two to three weeks.

     Participants. Both the pre- and post-implementation groups were adequate in size, with 880 and 994 respectively, and Chi-square analyses indicated the demographics of both these groups were a representative sampling of the patients seen at this Ob/Gyn office site. The DNP student did not receive any information regarding negative feedback from the participants who had the B-RST™ performed. For the majority (75%) of the participants, the results were negative-average risk with the convenience of no further follow-up being necessary.

B-RST™ utilization and data collection. As documented in the literature, the B-RST™ was simple for the MAs to use and the health care providers to interpret results. The simplicity of performing this assessment promoted protocol adherence, with the goal of ≥ 75% compliance achieved. The hyperlink to the B-RST™ remains in the EMR with the continued accessibility allowing sustainability of utilizing the risk assessment tool and following the EBP protocol well beyond the 12-week EBP project. Creating and running reports in the EMR saved time from having to search for each participant's demographic variables.

EBP model. The seven steps of the Iowa Model were valuable in guiding the process of performing this EBP project from onset to completion. This EBP model was chosen related to it repetitively being the foundation for successfully implementing changes, such as guidelines or protocols, in a variety of health care settings (Iowa Model Collaborative et al., 2017). Choosing the EBP topic and identifying the project focus accomplished the initial two steps. A unique aspect of the Iowa Model were the three check points placed at stages in the process where it was necessary to determine if it was appropriate to proceed to the next step, or if further progress was needed to accomplish that current step. As the PICOT for this EBP project was finalized, the first checkpoint was achieved.

The third step involved choosing team members, which included the: Epic IT representative, office manager, nine health care providers, and the MAs. Key stakeholders included one primary MA for each health care provider, with these individual recruited by the DNP student based on knowledge of their clinical strengths and interest in the project's focus. The three NPs spontaneously assumed these roles and proved helpful in providing guidance to the physicians and MAs regarding B-RST™ use and referral provision. Upon completing the collection and review of the appraised evidence, the fourth step was completed. At this second checkpoint, it was determined the evidence attained not only supported the change but was also relevant to this Ob/Gyn practice.

During the fifth step, the pilot process was determined to be successful after collecting and evaluating the data for the first two weeks of the protocol implementation. Feedback from the MAs and health care providers was requested, which was positive in nature. Tips were provided for increasing accuracy of the B-RST™ utilization and ordering referrals as applicable, along with encouragement for the successful launch of this project. This was one of the most critical and gratifying steps to accomplish and upon doing so, the final checkpoint was achieved.

Establishing the EBP change as a permanent practice along with disseminating the project findings were the final two steps. The objective from the beginning of this EBP project was to develop a protocol that could prevail beyond the 12-week implementation. This has been the most difficult step and task to achieve. One of the NPs has continued to have her MA complete the B-RST™ once yearly on all patients who are 18 years of age or older. Although 12 weeks seemed adequate for developing a permanent change, several of the providers are utilizing the B-RST™ on an as-needed basis; this is primarily if they are uncertain if a patient is at-risk and eligible for referrals to the HRBC and/or for genetic counseling. One of the CNMs shared that she had not remembered to use the B-RST™ since her MA had stopped routinely performing the assessment for her patients; she added that she did know she continued to have access to the B-RST™. It was recognized that one of the physician's interest with using the B-RST™ diminished during his last few months before retiring. Results from the EBP project were shared with the health care providers and MAs after data analysis. Upon completion, the poster along with pertinent portions of the presentation material will be shared with the staff at the Ob/Gyn practice. This DNP student will continue to communicate with these providers about the benefits of using the B-RST™, in addition to addressing concerns, with the goal of consistent B-RST™ utilization and subsequent ordering of HRBC and genetic referrals.

The Iowa Model was a good fit for both the topic and office setting where it transpired. Minor changes occurred throughout the process that did not require repeating any steps or

varying from the intended course of action. The Iowa Model promoted a successful EBP project experience for all involved in this protocol implementation.

Limitations

Staff involved with the project. While challenges with performing the EBP project were certainly expected, some barriers and confounding factors encountered were not anticipated. Although each of the health care providers agreed to participate, the level of cooperation varied. It is surmised that some of the providers may have been agreeable to participate due to wanting to satisfy the request, or not wanting to disappoint, one of their colleagues. Over time, this could have consequently led to an increased probability for diminished interest and involvement in the EBP project and protocol participation. Despite multiple attempts being made, the efforts of the DNP student providing different forms of communication with the objective to motivate and support continued and/or improved adherence, may not have been adequate when faced with the busy professional schedules confronted by the individual providers. Likewise, it was a challenging role to balance not being overly assertive yet still adequately disseminating the areas of improvements necessary for correctly following the protocol.

Several staff changes occurred with the MAs at this Ob/Gyn practice during the 12 weeks that the EBP project took place. During the immediate time frame leading up to and during the EBP project there were new MAs hired and resource staffing was utilized. Although the new and resource MAs were educated about the protocol and their roles in the EBP project, the levels of commitment seemed less than that of the established staff. Accordingly, if the MA did not perform the B-RST™, it was uncommon that the provider would do so him or herself; this in turn affected the amount of patients ($n = 259$) who were eligible but did not have the B-RST™ assessment performed. Despite multiple reminders, the patients whom the MAs repetitively missed performing the B-RST™ assessment the most were new patients, and particularly those presenting to initiate OB care. In hindsight, it may have been best to have the

EBP project focus on only one group of patients, such as routine gynecological examinations, to allow less confusion regarding who was and was not eligible. In addition, participation was reduced from approximately the eight-week time period to the conclusion of the project. Factors may have included the holidays celebrated (Thanksgiving and "Black Friday") and upcoming (Christmas), MAs and health care providers taking vacation days prior to the end of the year, or diminishing interest as the project continued.

Participants. The participants from this Ob/Gyn setting were an average age of 45 years old, Caucasian or white, Christian, and had commercial insurance. These demographics may limit the generalizability of the findings to other populations of interest. Total rates for HRBC and genetics referrals provided and performed were low as many participants either declined or accepted and then did not schedule a consultation.

B-RST™ utilization and data collection. Despite the straightforward use of performing and entering the B-RST™ results in the EMR, the MAs would intermittently skip this task, which affected the protocol adherence rate. Reminders were provided in person or by email if trends were noted. A time-consuming aspect for data collection was developing the template for running the weekly chart reports. After multiple attempts to include the appointment type in the data by the Epic IT representative, this DNP student, and the office manager, it was ascertained that this information would have to be verified through a chart audit of the daily schedule. In addition, for the two NPs who saw patients from their collaborative physician's schedule, it was difficult at times to accurately ascertain which provider to assign the participant to. In many cases, both the NP and the physician documented in the participant appointment notes. Therefore, in an effort to not alter the accuracy of the data, the participants seen collectively by the NPs and physicians were grouped together for data collection and analysis.

Implications for the Future

Several recommended areas for health care priorities and/or future research were proposed in the appraised evidence. A common objective was establishing the most

advantageous methods for identifying candidates appropriate for medical management along with effective approaches for delivering genetic services (Hilgart et al., 2012; Nelson et al., 2014; Obeid, 2017). Nelson et al. (2014) also encouraged educating at-risk individuals about resources available to assist with improvements in overall knowledge and testing performance.

Some of the authors suggested performing a revision of their studies in order to expand upon their previous results. This included incorporating a hereditary breast cancer risk evaluation tool into the EMR for more convenient and comprehensive use, such as the method used for this EBP project (Kaplan et al., 2014). To assist with substantiating their prior cross-sectional study results, Solomon et al. (2016) proposed replicating their study in which the Claus model would be used in a larger and more diversified sample population. Hilgart et al. (2012) and Baer et al. (2013) emphasized additional studies should concentrate on the psychological effects and long-term consequences of testing positive for a cancer gene mutation.

Brannon Trexler et al. (2014) proposed investigating methods for collaborating with an individual's family members who were affected by cancer and therefore more appropriate for genetic consultations and testing. Anderson et al. (2015) considered the following health care provider-focused study topics for the most advantageous methods to analyze: (1) Determining best practice knowledge related to breast cancer risk appraisal; (2) improving confidence with having conversations with patients about their risk for breast cancer; and (3) enhancing overall quality of exchanging information with patients.

Conducting EBP projects or studies concentrated on any of the aforementioned recommendations could strengthen the ability for health care providers to determine the optimal methods for identifying women at-risk for hereditary breast. Consequently, these methods should also include improving the utilization of genetics services. In regards to the health care providers and participants who participated in the EBP project, the most applicable future recommendations include: (1) Maintaining current knowledge about hereditary breast cancer, associated risks, and use of screening tools (such as the B-RST™) to accurately and promptly

identify these individuals, (2) enhancing confidence with reviewing risk assessment results and risk factors, and (3) improving discussions with at-risk patients about management options, such as referrals to the HRBC and/or genetics, including expectations from these consultations. At the EBP project site, one or more of the health care providers could present up-to-date information on these topics to their colleagues. Dialogues could be shared with tips for discussing risk assessment results, medical resources, patient perceived barriers, and common questions. As more patients are determined to be at-risk and subsequent conversations occur, it is expected the providers will gain confidence in methods to best deliver this information to their patient population.

   Addressing barriers to completing genetic counseling. Low participation rates for genetic counseling were noted with this EBP project and commonly reported in the literature. In a study performed by Wernke et al. (2019), from the 35 women who had negative-moderate or positive B-RST™ results, 24 were interested in attending a complimentary genetics appointment, 20 scheduled an appointment, and only four completed genetic counseling. The genetics consultation participation rate from the EBP project (21.9%) was comparable to the results from this study (20%) (Wernke et al., 2019). Correspondingly, a 16% genetics referral completion rate was noted with a study performed by Hoskins et al. (2018). These authors reported that the leading challenges expressed by their participants regarding completing a genetic consultation included not perceiving the appointment as being a priority and the time commitment. For the study by Wernke et al. (2019), offering genetic counseling free of charge removed the potential barrier of concern regarding cost. However, studies have shown that financial concerns have been linked with underutilization of genetic services (Hayden, Mange, Duquette, Petrucelli, & Raymond, 2017; Kne et al., 2017). Additional patient reported barriers hindering genetic consultation completion consisted of: (a) lack of perceived benefits, (b) inaccurate cancer risk perception, (c) insufficient knowledge and/or confidence about the process of genetic counseling, (d) apprehension regarding privacy, (e) fear of positive genetic

results and potential impact thereof, (f) concerns regarding the opinions and potential lack of

support family members, (g) disinterest in changing medical management despite test results,

and (h) referral location too far away (Houfek, Soltis-Vaughan, Atwood, Reiser, & Schaefer,

2015; Kne et al., 2017; Wernke et al., 2019). Health care providers should inquire about

reasons that a patient may be hesitant and/or declines a referral; accordingly, this knowledge

can promote a discussion addressing reported barriers and providing information to help the

individual with this important decision-making process (Kne et al., 2017).

Since a patient's decision whether to pursue genetic services can be multi-faceted, in

addition to addressing barriers, the health care provider should also focus on the benefits of

genetic counseling. McAllister and Dearing (2015) performed a literature review and concluded

that patient empowerment was the primary benefit reported by individuals who completed

genetic counseling. Further benefits comprised: (a) the ability to reduce or eliminate specific

cancer risks, (b) a gain in knowledge regarding specific cancer genetic disorders, (c) the

potential positive effects the knowledge about test results has on family members, and (d) the

ability to establish long-term medical plans (Houfek et al., 2015). Although it is more practical

for the patient to make a decision during their appointment, providing a handout that focuses on

the benefits of genetic counseling and addresses common barriers may not only enhance the

patient's knowledge and assist with decision-making, but also allow this process to be more

efficient for the health care provider.

Practice

The findings of this EBP project supported the routine use of the B-RST™ assessment

as a best practice recommendation. At the EBP project site, it was demonstrated that utilizing

the B-RST™ was a simple process for the MA, health care provider, and the patient. With the

majority (75%) of the results being negative-average risk, it was less common that additional

time was needed to review these results and further recommendations. However, it remains a

valuable use of time educating patients about pertinent risks along with options to pursue for

decreasing these accordingly. With the B-RST™ remaining in the EMR flowsheet section of a

patient's chart, this risk assessment tool remains available to the health care providers at this

Ob/Gyn practice. In addition, it is available to the other health care providers who work in office

settings for this health care system.

Theory

In order to best guide medical management of women at-risk for hereditary breast

cancer, it is important for health care providers to be knowledgeable about patient-perceived

barriers to participating in HRBC and/or genetic counseling. Correspondingly, the Health Belief

Model is based on the awareness of an individual's perceptions towards preventive health care

activities, with communication being an important component (Jones et al., 2015). If an

individual does not identify as being at-risk for hereditary breast cancer, the likelihood that

referral acceptance will occur diminishes. In addition, referral participation is unlikely despite an

individual being aware of this risk, if personal advantages are not recognized to furthering

knowledge about approaches to eliminate or reduce risk factors. Thoroughly discussing the

process of a referral, barriers, and benefits, coupled with answering questions, can assist

individuals with more accurately understanding their risks and the positive contributions of

performing HRBC and/or genetic counseling.

Research

The findings of this EBP project were consistent with the literature indicating an

underutilization of genetic services. Future EBP projects and research should focus on

addressing and overcoming patient-reported barriers with the goal of increasing patient

participation rates. Timely follow-up is necessary for educating women at-risk for hereditary

breast cancer about medical management options that promote breast cancer prevention or

early detection (Kiely & Schwartz, 2014). It would be beneficial to determine optimal methods

for providing and reviewing information about what occurs at consultation appointments to

stimulate further discussion and promote consultation participation. This can also vary

depending on the demographics of a patient population. Determining the best approach at this

EBP project site may necessitate the health care providers specifically inquiring if patients with

negative-moderate or positive-high risk results have questions, concerns, or reservations about

having HRBC and/or genetic counseling performed. The health care providers could then share

this information with their colleagues in an attempt to more adequately meet this health care

need for their patient population.

Education

Breast cancer is the leading new cancer diagnosis and the second highest cause of

cancer death in American women (ACS, 2019). Approximately 90% of individuals who have a

breast cancer gene mutation that can cause hereditary breast cancer are not knowledgeable

about this diagnosis (Drohan et al., 2012). Consequently, it is imperative that not only health

care providers, but MAs, nurses, and students (MAs, nursing, APRNs, Physician Assistants,

and medical), are educated and remain up to date about this significant risk factor. Health care

providers can read and discuss current studies with their colleagues. In-services and genetic

testing company sponsored activities can occur to educate multiple staff members as a group.

Case studies from patients within a practice can be discussed. Key stakeholders, such as those

depicted in the Iowa Model, can assist with arranging the preceding activities. Regardless of

the scheduled reason for a patient's appointment, in the pursuit of preventive health care, the

health care provider should take the opportunity to perform a risk assessment, discuss the

results, provide additional education as needed, and order appropriate referrals.

<div align="center">

Conclusion

</div>

Findings from this EBP project supported the use of the B-RST™ as an effective method

for identifying women who are at-risk for hereditary breast cancer at an Ob/Gyn office setting.

Improved MA and health care provider adherence to performing and utilizing the B-RST

assessment is necessary; this coupled with an increase in HRBC and genetics referral provision

and performance, can effectively aid in the diagnosis and management of hereditary breast cancer gene mutations with the overall goal of promoting optimal health outcomes. Recommendations for the EBP project site include: (1) Continue B-RST™ assessment once yearly for all patients and repeat if personal or family cancer history changes, (2) increase documentation if HRBC or genetics referrals are offered, accepted, and/or declined, and (3) provide patient-reported reason(s) for a referral being declined to aid in improving genetic counseling participation rates. Considerations for the general field of health care are to: (1) Promote health care provider awareness about genetic risk assessment tool use (such as the B-RST™) and (2) enhance recognition of barriers to providing, accepting, and performing referrals to properly address these concerns with the goal of increased referral participation. The more the B-RST™ assessment is performed, the more lives that can be positively affected.

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BIOGRAPHICAL MATERIAL

Mrs. Davis Lawson graduated Summa Cum Laude from Valparaiso University with a Bachelor of Science in Nursing in 1996. She primarily worked in labor and delivery before returning to Valparaiso University to earn a Master of Science in Nursing and Maternal-Child Clinical Nurse Specialist in 2000, followed by a Post-Masters Family Nurse Practitioner degree with top class honors in 2001. She is certified through the American Academy of Nurse Practitioners (AANP). Chrysanthemum began her 15th year as a nurse practitioner specializing in women's healthcare where she currently works at an obstetrical and gynecological practice and a high risk breast clinic. She is a member of the AANP, Midwest Nursing Research Society (MNRS), Nurse Practitioners in Women's Health (NPWH), and the Zeta Epsilon chapter of Sigma Theta Tau International Honor Society of Nursing.   She presented her EBP poster at the MNRS virtual conference in April 2020. Mrs. Davis Lawson will also present her EBP poster at Valparaiso University's Graduate Academic Symposium in May 2020. Throughout her career, she has delivered presentations at conferences, health-focused community events, and schools. The topics have included breast health, breast cancer risks, infertility, teen health, and menopause. Chrysanthemum routinely volunteers for a program providing free examinations to women who are uninsured or underinsured. She has enjoyed participating as a clinical preceptor for both undergraduate nursing and nurse practitioner students attending Valparaiso University and other local universities in Northwest Indiana. Her professional interests include cancer genetics, exercise and fitness, and women's preventive healthcare. Chrysanthemum Davis Lawson will complete the Doctor of Nursing Practice degree in May 2020.

ACRONYM LIST

ACOG: The American College of Obstetricians and Gynecologists

ACS: American Cancer Society

APRN: Advanced practice registered nurse

BRCA: Breast cancer gene

BRCA1: Breast cancer susceptibility gene 1

BRCA2: Breast cancer susceptibility gene 2

B-RST™: Breast Cancer Genetics Referral Screening Tool™

CINAHL: Cumulative Index to Nursing and Allied Health Literature

CNM: Certified nurse midwife

EBP: Evidence-based practice

EMR: Electronic medical record

HBOC: Hereditary breast and ovarian cancer syndrome

IRB: Institutional Review Board

MA: Medical assistant

NCCN: National Comprehensive Cancer Network

NSGC: National Society of Genetic Counselors

NIH: National Institutes of Health

NP: Nurse practitioner

NPWH: Nurse Practitioners in Women's Health

Ob/Gyn: Obstetrical and gynecological

PICOT: Population, Intervention, Comparison, Outcome, Time

RCT: Randomized controlled trial

U.S.: United States

USPSTF: U. S. Preventive Services Task Force

Appendix A

Permission to Use Iowa Model

M Gmail   Chrys Davis <chrysruns@gmail.com>

Permission to Use The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care

1 message

Kimberly Jordan - University of Iowa Hospitals and Clinics <noreply@qualtrics-survey.com>   Wed, Jul 10, 2019 at 8:00 AM
Reply-To: Kimberly Jordan - University of Iowa Hospitals and Clinics <kimberly-jordan@uiowa.edu>
To: chrysruns@gmail.com

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Appendix B

Permission to Use Johns Hopkins Nursing

Evidence-Based Practice Level and Quality Guide

Appendix C

Evidence Data Table

Citation	Population, Setting(s)	Intervention(s), Comparison(s)	Outcomes, Effect Measures	Level of Evidence, Grade
Anderson et al. (2015) *Journal of Oncology Practice* Breast cancer risk assessment among low-income women of color in primary care: A pilot study	• Low income African American and Hispanic women ages 25 to 69 years old, without a personal history of breast cancer, presenting for annual examinations at two federally assisted medical institutions in the Midwest	• Exploratory Pilot Study • Study population: $N = 237$ • Prior to examination with health care provider, the following was collected: (a) risk factor information, (b) baseline survey, and for those consenting, (c) breast cancer risk evaluation using the BC Risk Screening (BRS) web-based tool, which simultaneously calculates the following models: (1) Claus, (2) modified Gail, and (3) pedigree assessment tool	• Outcome: Determining what factors affect women's decisions to either accept or decline breast cancer risk evaluation performance • The majority of this population ($n = 207$, 87.3%) chose to be informed of their breast cancer risk assessment results with an increased likelihood with women ages 40 to 49 years old with OR 5.4 (95% CI, 1.09 - 26.67) and 50 to 69 years old with OR 7.99 (95% CI, 1.47 - 43.44) • Women choosing not to participate in risk assessment result discussions ($n = 30$, 12.7%) shared the following characteristics: (1) younger age (< 40 years old), (2) lack of concern regarding personal risk for breast cancer, (3) prior history of mammogram, and (4) lacking private insurance coverage • High rate of BRS tool use in this population accomplished the following: (a) compliance with 2013 USPSTF breast cancer risk appraisal	Level III, B

			recommendations, and (b) in office utilization of a tool that efficiently performs the appraisal with consideration of health care provider barriers of time restraints and/or lack of breast cancer risk knowledge	
Baer et al. (2013) *Journal of General Internal Medicine* Use of a web-based risk appraisal tool for assessing family history and lifestyle factors in primary care	• New or established female and male patients between 18 to 75 years old, without a family history of cancer documented in their EMR, presenting for annual examinations within five urban academic primary care medical practices	• Controlled Trial without Randomization • Study population: intervention group from three practices ($n = 996$), control group from two practices ($n = 637$) • Intervention group: Use of the Your Health Snapshot (YHS) web-based risk assessment tool linked to the EMR prior to appointment with health care provider; family health history used to evaluate risks for cancer (breast, colon, lung, and prostate), with cancer screening test alerts created in the EMR for the health care provider • Follow-up phone call to both groups • EMR review one month after visit	• Primary outcome: New documentation of cancer family history in the EMR within 1 month of visit • Secondary outcome: New cancer screening test notices for those with an increased risk for breast or colon cancer provided by health care providers within 1 month of visit • Individuals in the intervention group were more likely to have cancer family history addressed with EMR documentation than in the control group (10.6% vs. 0.8%) with adjusted OR 15.9 (95% CI; [3.5, 72.1], $p = 0.003$) • No significant differences between the groups for receiving cancer screening test notices, with 8 provided to the intervention group and 0 to the control group, low results were believed due to an EMR accessibility issue • Use of this concise web-based risk assessment tool raised the rate of cancer family history charting in EMR	Level II, B

| Berliner et al. (2013)

Journal of Genetic Counseling

NSGC practice guideline: Risk assessment and genetic counseling for hereditary breast and ovarian cancer | • Provided by the National Society of Genetic Counselors (NSGC)

• Revised evidence-based practice guideline from 2007 recommendations for health care providers caring for women who either have or are at increased risk for breast and/or ovarian cancers | • Clinical Practice Guidelines

• Recommendations focused on three categories:
(1) Process for collecting and evaluating personal and family histories, in order to assess women's cancer risks, and provide appropriate referrals for genetic services

(2) Cancer risk appraisal model use including:
(a) BOADICEA,
(b) BRCAPRO, (c) Claus,
(d) Gail, and (e) Tyrer-Cuzick/IBIS

(3) Opportunities for medical management comprising: (a) screening tests and examination maintenance,
(b) medications, and
(c) surgical options | • Best practice recommendations:
(1) Consult guidelines to determine if a woman is a candidate for cancer genetic testing and provide individualized health care risk-reducing strategies

(2) Consider BRCA and other applicable gene mutations

(3) Perform a cancer risk evaluation utilizing models to determine subsequent approach for health care management

(4) Determine medical management options based on medical expertise, cancer family history, assessed risk, and outcome of genetic testing

(5) Arrange referral to a genetics professional to provide resources to support educational and emotional needs

(6) Explain current, multi-faceted consequences of genetic testing | Level IV, B |

| Brannon Trexler et al. (2014) *Annals of Surgical Oncology* Implementing a screening tool for identifying patients at risk for hereditary breast and ovarian cancer: A statewide initiative | • Primarily minority (73.2% African American and 8.0% Hispanic) and low-income women ages 14 to 85 years old without a personal history of cancer obtaining health care at one of six participating public health departments in a southern U.S. state | • Demonstration Project • Study population: $N = 2159$ • Use of the breast cancer genetics referral screening tool (B-RST™), while attaining the medical history prior to health care provider examination, to identify and manage appropriate at-risk women • Staff educated on hereditary breast and ovarian cancer (HBOC) syndrome and how to use the B-RST™ through the following: (a) personal stories of women with a BRCA gene mutation, (b) surgeon presentations, (c) observation and use of the B-RST™ | • Outcomes: (1) Integrating the B-RST™ within this selected minority population to recognize women with increased HBOC risk (2) Assisting with the health care management of those having positive B-RST™ results (3) Educating staff about cancer genetic topics with the goal of accurate utilization of the B-RST™ • Of the participants: (a) 130 (6.0%) had positive B-RST™ results, and (b) 110 (84.6%) then consented to be contacted, with (c) 67 (60.9%) then provided clarification of family history (d) 47 (42.7%) of these women were successfully contacted and determined to be appropriate for testing per current medical society guidelines, and (e) 14 (12.7%) performed cancer genetic testing, with (f) 1 (7.1%) woman being diagnosed with a BRCA2 gene mutation • Use of the B-RST™ promoted identification of woman at-risk for hereditary HBOC; knowledge increased in staff as demonstrated by improved post-activity test results | Level III, A |

| Christianson et al. (2012)

Journal of Genetic Counseling

The use of a family history risk assessment tool within a community healthcare system: Views of primary care providers | • Health care providers with a variety of specialties and an average of 23 years of experience from a community-based medical system on the East Coast | • Qualitative Study

• Study population: $N = 16$, with 14 physicians and 2 mid-level providers from 9 medical practices

• Three focus meetings with discussion of nine questions related to current practice and future use of the MeTree risk assessment tool at a local oncology center, with subsequent shared obligation of these results with a patient's primary care health care provider

• MeTree is a web-based tool for evaluation of inherited risks for breast and colon cancers, in addition to thrombophilia disorders | • Outcome: Determine health care provider perceived challenges with integration of a risk appraisal tool to resolve these factors and improve its future utilization

• Data coded and analyzed with themes categorized into the following:
(1) current methods for evaluating risk of medical conditions

(2) barriers associated with obtaining and using family health histories

(3) challenges associated with applying family history to individualized health care strategies

(4) obstacles with performance of the MeTree tool at the oncology center

(5) medical and educational needs

• Consideration and alleviation of anticipated health care provider and patient challenges, with the availability of necessary resources, are essential components to consider prior to implementation of a risk assessment tool | Level III, A/B |
| Hilgart et al. (2012)

Cochrane Database of | • Females and males across the lifespan (a) at risk for breast cancer due to family history, (b) without a | • Systematic Review (of RCTs)

• Performed to update 2007 systematic review | • Outcomes for those at increased risk for familial breast cancer with assessment of:
(1) Methods for performing risk evaluation | Level I, A |

Systematic Reviews
 	
Cancer genetic risk assessment for individuals at risk for familial breast cancer (Review)
	personal history of breast cancer, and (c) with or without a known BRCA gene mutation	• Total of 8 RCTs, with 5 (*N* = 1973) new to this update
		
		• Study interventions comprised:
		  • Individual vs. group genetic counseling (include # of studies focused on each topic) (2)
		  • Surgical consultation with or without hereditary risk assessment (1)
		  • Web-based risk assessment tool used in a clinic (1)
		  • Community vs. regional genetic services (1)
		  • Phone vs. in-person counseling (1)
		  • Counseling performance vs. delayed counseling (3)
		  • Provision of a letter vs. in-person consultation (1)
		  • Appraisal of psychological effects of cancer risk evaluation (8)
			(2) Approaches for providing genetic health care
			
			(3) Differences between risk evaluation performed by a genetic specialist or a non-genetic specialist
			
			• Studies revealed genetic services provide: (a) a decrease in cancer anxiety and enhanced emotional well-being; (b) increased personal risk perception accuracy and knowledge concerning breast cancer and genetic services, and (c) overall satisfaction with use of genetic services
			
			• With the benefits of genetic services considered to outweigh the harms, recommendation that a hereditary breast cancer risk assessment is performed to determine if a referral for genetic consultation is appropriate	

Kaplan et al. (2014) *Cancer Epidemiology, Biomarkers &*	• Women ages 40 to 74 years old without a previous history of breast cancer receiving health care at two U.S.	• Randomized Controlled Trial • Study population: intervention (*n* = 580) and control (*n* = 655);	• Outcomes: (1) Frequency of patient-provider breast cancer risk and risk reduction conversations (2) Genetic services referrals (3) EMR reporting of these activities	Level I, B

| *Prevention* A randomized, controlled trial to increase discussion of breast cancer in primary care | metropolitan primary care medical offices | randomized after baseline phone interviews using statistician-developed sequence codes • Intervention of breast cancer risk assessment using an office-based web-based tool, BreastCARE, to stratify breast cancer risk using the follow for risk appraisals: (a) Referral Screening Tool, (b) Gail Model, and (c) Breast Cancer Surveillance Consortium risk model • Interventions: (a) Baseline phone interviews and risk assessment, (b) BreastCARE tablet use, (c) one to two week post-visit phone survey, (d) six month post-visit EMR review | • BreastCARE use increased frequency of patient-provider discussions regarding: (a) cancer family history, *OR* 2.07, 95% CI [1.34, 3.20] (b) breast cancer risk, *OR* 4.78, 95% CI [2.90, 7.89] (c) genetic services, *OR* 5.99, 95% CI [2.69, 13.3] (d) high-risk clinic referral, *OR* 5.32, 95% CI [2.21, 12.8] • BreastCARE use increased documentation in intervention vs. control groups: (a) cancer family history (10.2% vs. 5.5%, *p* = 0.006) (b) breast cancer risk (5.3% vs. 0.2%, *p* < 0.001) (c) genetic services (3.3% vs. 0.9%, *p* = 0.005) • Especially for women at risk for hereditary breast cancer, use of a web-based risk appraisal tool increases risk and medical management options conversations | |
| Nelson et al. (2014) | • Population of interest: Women across the lifespan provided | • Systematic Review (of multiple study types) | • Outcomes of benefits and harms assessed in three areas: (1) BRCA risk evaluation tool use | Level III, A |

Annals of Internal Medicine Risk assessment, genetic counseling, and genetic testing for BRCA-related cancer in women: A systematic review to update the U.S. Preventive Services Task Force recommendation	health care in locations similar to the U.S. without a personal history of a BRCA gene mutation or BRCA-related cancer(s) • Models/tools used in the following countries: Brazil, Canada, United Kingdom, and the U.S.	• Performed to update 2005 USPSTF recommendations • Total of 27 studies, with 16 new for this update (including RCTs, systematic reviews, cohort, and case-control studies) • Variety of interventions measuring: (a) five risk models/tools; (b) risk perception and cancer worry; and (c) tests, meds, and surgeries to decrease risk of BRCA-related cancers	(2) Genetic services results (3) BRCA management options for malignancy and mortality reduction • Comparison of sensitivity between risk models/tools, with the Referral Screening Tool having a high sensitivity (>89%) • Risk perception accuracy generally increased and worry decreased after genetic counseling • Best practice recommendation: Weigh individualized benefits, harms, and risks when assessing risk, referring for genetic services, or offering medical management to decrease cancer risk; more studies recommended • Unable to perform quantitative meta-analysis due to study heterogeneity	
Obeid (2017) *The Joanna Briggs Institute EBP Database* Breast cancer (familial): Classification and care. JBI Evidence Summary	• Population of interest: Women across the lifespan at increased risk for hereditary breast cancer being provided primary, secondary, and tertiary levels of health care	• Evidence Summary • Resources included two Cochrane Database systematic reviews, evidence from the National Institute for Clinical Excellence, and one each of the following: meta-analysis, RCT, cross-sectional observational study, epidemiological study, and literature review	• Best practice recommendations for: (1) patient-focused care; (2) cancer family history and provider referral; (3) screening; and, (4) genetic services (1) Patient-focused care: Respecting patient's personal decisions, providing educational handouts, determining and discussing risk level, communicating effectively, involving family members when appropriate (grade B)	Level IV, A

			(2) Cancer family history and provider referral: Evaluating breast cancer risk by obtaining a history including first and second- degree family members, creating protocols incorporating referral process (grade B) (3) Screening: Recommending mammography, considering adding magnetic resonance imaging (MRI) as indicated, considering gene mutations specific to cancer family history (grade B) (4) Genetic services: Assessing risk and referring appropriate candidates for genetic counseling with potential testing (grade B)	
Solomon et al. (2016) *BMC Family Practice* Contribution of extended family history in assessment of risk for breast and colon cancer	• Women with an average age of 63 years old receiving services at a mammography center in a Northeastern U.S. city	• Cross-Sectional Study • Study population ($N = 499$) • Questionnaire completion at time of mammography services • Recommendation of additional breast medical management options based on the use of the: (1) ACS and NCCN screening guidelines, (2) Claus model for breast cancer risk estimation, and (3) breast cancer genetics referral screening tool	• Outcomes: Identification and comparison of individuals qualifying for cancer genetic services based on either limited/first-degree or comprehensive/first and second-degree family histories in order to determine appropriate candidates for genetic services referrals • Applying ACS guidelines, 22% of at-risk women qualifying for genetic services were missed using limited/first-degree family history • Using the Claus model, 3.6% ($n = 18$) had more than a 20% lifetime breast cancer risk, with 5 of these 18 women recognized using limited/first-degree	Level III, B

		(RST)	family history	
			• Using the RST, 1.8% ($n = 9$) qualified for breast cancer genetics referral, with 7 of these 9 women recognized using limited/first-degree family history	
			• Accurate cancer genetic risks require obtaining and evaluating comprehensive/first and second-degree family histories	

Appendix D

Permission to Use B-RST™

Bellcross, Cecelia A.   Wed, Jul 10, 2019 9:17 AM
to me

Hi Chrys –

Thank you for your interest in B-RST™. You can view the most updated version at
www.brcagenescreen.org. The attached paper describes the validation.

What needs to be done on your end depends on how you/Epic are going to use it. If you are just
going to create a hyperlink using the above URL, no specific licensing is required, and you have
my permission.

If however, EPIC wants to imbed the program within the EMR, this would require a licensing
agreement as the program/algorithm is intellectual property owned by Emory. Doing the latter
can allow for direct integration of the result report into the EMR, as well as interface
customization. The licensing agreement would need to be with EPIC, and they would pay the
associated fee. This would also allow them to market it as part of their EMR package to others.

Please let me know which of the above options you are interested in. I'm happy to discuss by
phone if it is helpful.

Best,

Cecelia

Cecelia A. Bellcross, PhD, MS, CGC
Associate Professor
Director, Genetic Counseling Training Program
Emory University School of Medicine
Department of Human Genetics

Appendix E

B-RST™ Results Patient Handout

Understanding Your Breast Cancer Genetics

Referral Screening Tool (B-RST™) Results

☐ Negative – Average Risk

- According to the information you provided today, your results indicate that you have an average risk for breast and/or ovarian cancer to occur
- Based on your personal & family cancer history, you are not likely to have inherited a BRCA gene mutation that can significantly increase your risk for breast and/or ovarian cancer
- If you are at the appropriate age, you should have **screening mammography** according to your health care provider's recommendation based on current guidelines

☐ Negative – Moderate Risk

- According to the information you provided today, your results indicate that you have a moderate, or greater than average, risk for breast and/or ovarian cancer to occur
- Based on your personal & family cancer history, you are not likely to have inherited a BRCA gene mutation that can significantly increase your risk for breast and/or ovarian cancer
- If you are at the appropriate age, you should have **screening mammography** according to your health care provider's recommendation based on current guidelines
- You should consider a **consultation at the High Risk Breast Clinic** through ████████ ████ (locations in ████████████████████████████████████) to discuss management options for this increased risk for breast cancer

☐ Positive - High Risk

- According to the information you provided today, your results indicate that you have a high, or much greater than average, risk for breast and/or ovarian cancer to occur
- Based on your personal & family cancer history, there is a possibility you have inherited a gene BRCA mutation that can significantly increase your risk for breast and/or ovarian cancer
- If you are at the appropriate age, you should have **screening mammography** according to your health care provider's recommendation based on current guidelines
- You should consider a **consultation at the High Risk Breast Clinic** through ████████ ████ (locations in ████████████████████████████████████) to discuss management options for this increased risk for breast cancer
- You should also strongly consider a **consultation with a geneticist** to discuss your personal and family cancer history in more detail, in order to determine if you are a candidate for cancer genetic testing

Note: This screening tool is not a diagnostic test. Negative-average risk results do not indicate you will not ever have breast and/or ovarian cancer occur. Likewise, negative-moderate & positive-high risk results do not indicate you will ever have breast and/or ovarian cancer occur.

Appendix F

Permission to Adapt B-RST™ Results Section for Patient Handout

Chrys Davis <chrysruns@gmail.com>
Mon 7/29/2019 9:18 PM
To: Bellcross, Cecelia A. <cecelia.a.bellcross@emory.edu>

📎 1 attachments (20 KB)
My Results Patient Handout.docx;

Dr. Bellcross,

I have printed each question and hopefully that will be sufficient for the IRB Board! I appreciate you clarifying the validation of version 3.1 (vs. 3.0). Attached is the handout I anticipate providing to the participants. I will be reviewing this with my project advisor soon. I would certainly value your input, especially if I have misconstrued any information from the B-RST™. I will be analyzing my results in the spring & will be happy to share these findings with you! Thanks again! :)

Chrys

On Mon, Jul 29, 2019 at 7:34 AM Bellcross, Cecelia A. <cecelia.a.bellcross@emory.edu> wrote:

> Chrys –
>
>
> If the IRB wants a paper version I would simply take screen shots of the questions. You are correct in that it is now very different from the original paper form.
>
>
> Yes, the 3.0 validation applies to 3.1.
>
>
> I would greatly appreciate seeing the handout you are planning to provide, and appreciate the credit.
>
>
> Lastly, I would love to learn about the outcome of your research.
>
>
> Best with your project,
>
>
> Cecelia
>
>
> Cecelia A. Bellcross, PhD, MS, CGC
>
> Associate Professor

B-RST™ Project Tip Sheet for Providers

Who qualifies: Women > 18 y/o presenting for an annual exam or new patient appointments (only performed once)

Who does not qualify: Women w/dementia or developmental delays/mental retardation

Steps:

1. Results can be reviewed in the Flowsheet tab and will be marked on the handout entitled "Understanding Your Breast Cancer Genetics Referral Screening Tool (B-RST™) Results"

2. 1 of 3 results will display upon completing use of the tool (negative-average, negative-moderate, positive-high)

3. Negative-average risk results: Order mammogram as appropriate

4. Negative-moderate risk results: Order mammogram as appropriate, offer referral to High Risk Breast Clinic

5. Positive-high risk results: Order mammogram as appropriate, offer referral for both the High Risk Breast Clinic and for genetic counseling

6. It is recommended to note in your charting that the B-RST™ results were reviewed and if referral(s) were offered & then accepted or declined

7. Please inform me of any questions you or the patients have!

8. THANK YOU for participating in my project!

Appendix H

B-RST™ Project Tip Sheet for MAs

B-RST™ Project Tip Sheet for MAs

Who qualifies: Women > 18 y/o presenting for an annual exam or
new patient appointments (only performed once)

Who does not qualify: Women w/dementia or developmental
delays/mental retardation

Steps:

1. Go to the Flowsheet tab

2. Click on B-RST™

3. Click on hyperlink

4. Answer questions with patient

5. 1 of 3 results will display upon completing use of the tool (negative-average, negative-moderate, positive-high)

6. Enter this result in the 2nd line of the B-RST flowsheet by clicking on the magnifying glass & also mark this result on the patient handout, "Understanding Your Breast Cancer Genetics Referral Screening Tool (B-RST™) Results", & place this handout back in the plastic patient folder for the provider to review with the patient

7. Patient can refer to the exam room copy of the handout that will be on the desk top in a plastic protector

8. Place referrals for High Risk Breast Clinic and/or genetic consultations as ordered by the provider (common diagnoses will be family/personal history of breast cancer, increased risk for breast cancer)

9. Please inform me of any questions you, the providers, or the patients have!

10. THANK YOU for participating in my project!

Appendix I

IRB Determination

DATE: September 5, 2019

TO: Chrysanthemum Davis Lawson

FROM: Jana L. Lacera

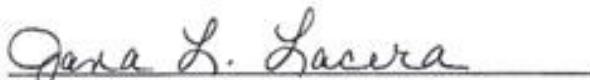CHS CIRB Determination: QA/QI Project, Not Human Subjects Research

Impact of a Protocol Implementation on Identification and Referral of Women At-Risk for
      Hereditary Breast Cancer
- Investigator: Chrysanthemum Davis Lawson, RN, MSN, FNP-C, CNS
- DnP Candidate
- Breast Cancer Genetics Referral Screening Tool (B-RST™)
- Referral Screening Tool (B-RST™) Results
- Patient Information Posters
- Valparaiso University IRB Questionnaire Response
- Determination: QA/QI Project, Not Human Subjects Research does not require further CHS CIRB oversight or approval

The CHS CIRB has determined that your submission does not fit the definition of Human Subjects Research and therefore does not require further IRB review or oversight. You are expected, however, to implement your study or project in a manner congruent with accepted professional standards and the ethical guidelines as described in the Belmont Report.

This type of project is specifically initiated with a goal of improving the performance of a practice in relation to an established standard. The purpose of QA/QI studies is to determine quality, improve (change) patient services, or improve (change) the provision of medical care. The knowledge generated is typically used for application within the institution. If the data is re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.

Note: There are no federal regulations requiring IRB review in order to publish QA/QI projects or research. However, most journals may require some type of IRB review prior to submission. You are restricted from identifying this project as "research in publications of the results. Other terms like outcomes study, efficacy study, quality project, etc., may be used instead.

Jana L. Lacera

Jana L. Lacera, RN, MSA, CDM
Human Protections Administrator, CHS CIRB
Director IRB/Bio-Ethics
Initial Review 9 5 2019