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Screening for Melanoma for At-Risk Population: A Practice Guide

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SCREENING FOR MELANOMA FOR AT-RISK POPULATION: A PRACTICE GUIDE

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ABSTRACT

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Melanoma is a lethal skin cancer that kills one American every hour (American Academy of Dermatology, 2018b). The incidence and prevalence rate of melanoma is on the rise and continues to affect people, increasing the mortality and morbidity rate and financial burden of the disease.

In 2016, the U.S. Preventive Services Task Force concluded that there was insufficient evidence to assess the balance of benefits and harms of visual skin examination by a clinician to screen for skin cancer in adults. However, this recommendation was only applicable to the patients who were asymptomatic. The routine skin cancer screening has shown promising results in patients who are at high risk for melanoma (American Cancer Society, 2018b). Primary care providers do not perform routine skin cancer screenings for melanoma or do not even perform screening to identify if the patients are at high risk for melanoma or not. Thus there is a lack of a standardized screening tools/models and workflow processes to include melanoma screening in the clinic settings.

To address this need, an evidence-based melanoma screening workflow algorithm was developed specifically to a federally qualified health center in a rural and small mountain community in Northern Colorado. The workflow algorithm included the self-assessment of melanoma risk score (SAMScore) as the risk

prediction model to screen patients at high risk for melanoma. The Doctor of Nursing Practice (DNP) scholarly project was implemented to screen patients for melanoma between ages 35 to 75 years old for annual exams, excluding well women visits, who were able to speak, read, and write in English. Depending on the screening result, an appropriate intervention was done by the providers of the clinic by performing a full-body skin exam or biopsy or referral or educating patients on primary prevention of melanoma. The project was evaluated by utilizing the Donabedian framework.

After implementation, there was a 300% increase in the number of melanoma screenings completed, increased awareness on melanoma, and melanoma screening protocols among the providers and patients. The clinic has continued to utilize the melanoma screening algorithm and SAMScore to screen patients for melanoma and continues to distribute the handout on primary prevention of melanoma by the American Association of Dermatology. Further studies are needed to assess the validity of the SAMScore in languages other than English and French and evaluate the effectiveness of the SAMScore and the melanoma screening algorithm in a larger clinic with a greater number of staff.

Keywords: melanoma screening, melanoma guideline, melanoma algorithm, skin cancer

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INTRODUCTION

Background

Melanoma is defined as "the cancerous growth of the skin cells due to unrepaired deoxyribonucleic acid damage that causes cells to multiply rapidly and form malignant tumors" (Skin Cancer Foundation, 2019, p. 1). It is highly aggressive and metastatic. Metastatic melanoma is a fatal disease with rapid systemic dissemination (Tas, 2012).

Skin is the largest organ of the body and consists of two main layers, the epidermis and the dermis (National Cancer Institute, 2019). The outer layer of the skin, the epidermis, consists of three cell types: squamous, basal, and melanocytes (National Cancer Institute, 2019). Squamous cells are the thin flat cells forming the top of the epidermis (National Cancer Institute, 2019). Basal cells are round cells located underneath the squamous cells (National Cancer Institute, 2019). Melanocytes are located under basal cells and produce a pigment called melanin that gives skin its color (National Cancer Institute, 2019). The uncontrolled proliferation of melanocytes is called melanoma. It is one of the most aggressive forms of skin cancer and can metastasize to other parts of the body via the lymphatic system and bloodstream (Dinnes et al., 2018). The most common target sites for metastasis for melanoma include the liver, bone, and brain (Tas, 2012). Approximately 4% of newly diagnosed melanoma patients will have the disease metastasized to other parts of the body at the

time of diagnosis (Tas, 2012). With any metastatic disease, including metastatic melanoma, the median survival time is about 12 months (Tas, 2012). Basal and squamous cells can proliferate in an uncontrolled manner and become basal cell carcinoma and squamous cell carcinoma. However, these malignancies are not as aggressive as melanoma and rarely metastasize to other organs or parts of the body (National Cancer Institute, 2019).

Risk Factors of Melanoma

Early diagnosis is the principal factor that can improve the prognosis of melanoma. Early diagnosis refers to catching the localized melanoma before it metastasizes to other organs or parts of the human body. The five-year survival rate for the localized melanoma is about 98% compared to regional melanoma of 64% and distant melanoma metastasis of 23% (American Cancer Society, 2019b). The etiology of melanoma is complex and heterogeneous. The risk of developing melanoma depends on both environmental and genetic factors (Craythome & Al-Niami, 2017). Prolonged exposure to ultraviolet radiation is the greatest risk factor for melanoma (Watson, Holman, & Maguire-Eisen, 2016). The ultraviolet radiation causes deoxyribonucleic acid damage through the formation of pyrimidine dimers, photoproducts, gene mutations, oxidative stress, inflammation, and immunosuppression (Potrony et al., 2015). A study was conducted on the joint effects of sun exposure during childhood and adulthood on melanoma risk (Oliveria, Geller, Heneghan, & Jorgensen, 2006). The odds ratio of having melanoma in adults with intense childhood and adulthood sun exposure was 4.5% compared to 2% of low/moderate childhood and adulthood sun exposure (Oliveria et al., 2006). Occupational exposure and intense exposure to ultraviolet radiation such as indoor

tanning are also highly associated with melanoma (Watson et al., 2016). Indoor tanning before the age of 35 years increases the risk of melanoma by 59% and the risk increases with each use (American Academy of Dermatology, 2018a). Only one indoor tanning session can increase the risk of melanoma by 20% (American Academy of Dermatology, 2018a).

Furthermore, genetic factors also strongly influence the risk of melanoma. Melanocyte produces a pigment called melanin that gives color to skin and eyes. The melanin absorbs and scatters the energy from ultraviolet light protecting the epidermal cells from damage (Watson et al., 2016). Thus the amount of melanin or the degree of pigmentation is inversely related to sun sensitivity and skin cancer risk (Watson et al., 2016). Some of the characteristics that increase the risk of melanoma include naturally fair skin tone or skin type of Fitzpatrick I; light color eyes; blonde or red hair; dysplastic nevi or common moles (more than 50 moles); and sensitive skin that burns, freckles, reddens, or becomes painful after sun exposure (Watson et al., 2016). In addition, the personal and family history of melanoma increases the risk of melanoma (Watson et al., 2016).

According to the Aim at Melanoma Foundation (2014a), at least 5% of people with a past history of melanoma will develop a new melanoma, putting them at increased risk for melanoma. The risk of melanoma multiplies by 30 to 70 times with multiple first-degree family members (Aim at Melanoma Foundation, 2014a). The Skin Cancer Foundation (2019) stated that a person with a first-degree relative diagnosed with melanoma is 50 times more likely to develop the disease compared to a person without a family history of melanoma. Immunosuppressed individuals who do not have the ability to right infections or at risk for infection are also at an

increased risk for melanoma. Melanoma high-risk genes are genes that put an individual at high risk for developing melanoma. The two genes that are associated with melanoma susceptibility are cyclin-dependent kinase inhibitor 2A and cyclin-dependent kinase 4 (Potrony et al., 2015). Also, genetic syndromes are responsible for the development of melanomas such as familial atypical mole melanoma syndrome and xeroderma pigmentosum (Watson et al., 2016).

Statistical Significance of Melanoma in the United States

Melanoma is the deadliest type of skin cancer, ranking it as the fifth and the seventh most common cancer among males and females in the United States, respectively (Jiang et al., 2017). The incidence of melanoma is rising rapidly and is expected to double by 2030 (Robinson et al., 2018). The Centers for Disease Control and Prevention (2015) stated that the incidence rate of melanoma has increased from 11.2 per 100,000 in 1982 to 22.7 per 100,000 in 2011. The incidence rate of melanoma is higher in women compared to men before the age of 50 (American Academy of Dermatology, 2018b). It is the second most common cancer in females between ages 15 to 29 years, and the incidence rate of melanoma increased up by 800% in women ages 18 to 39 years from 1970 to 2009 (American Academy of Dermatology, 2018b). The risk of melanoma increases with age among men. The rate is twice as high in men by age 65 years and three times as high in men by age 80 years (American Academy of Dermatology, 2018b). The annual incidence rate of melanoma in non-Hispanic Caucasians is 26 per 100,000 compared to 4 per 100,000 in Hispanics and 1 per 100,000 in African Americans (American Academy of Dermatology, 2018b). It has been estimated that melanoma will affect one in 27 men

and one in 40 women in their lifetime (American Academy of Dermatology, 2018b). According to the American Cancer Society (2019a), the lifetime risk of getting melanoma is 2.6% (one in 38) for Whites, 0.1% (one in 1,000) for Blacks, and 0.58% (one in 172) for Hispanics. The median age of diagnosis of melanoma is 63 years, and the median age of death related to melanoma is 69 years (U.S. Preventive Services Task Force, 2016). Johnson et al. (2017) recommended the screening age of melanoma as 35 to 75 years compared with the U.S. Preventive Services Task Force cancer recommendations for colorectal, cervical, breast, and lung cancer.

The mortality rate of melanoma is on the rise. According to the American Academy of Dermatology (2018b), melanoma kills one American every hour. In 2012, 55,488 deaths were attributed to malignant melanoma globally (Johansson, Brodersen, Gotzsche, & Jorgensen, 2016). Even though melanoma accounts for 1% of skin cancers, it is responsible for most skin cancer-related deaths in the United States (Caple & Holle, 2018). Approximately 4.9 million adults were treated for skin cancer between 2007 and 2011, with a treatment cost of $8.1 billion in the United States (American Academy of Dermatology, 2018b). The annual treatment cost for melanoma is estimated to be $3.3 billion (American Academy of Dermatology, 2018b).

Statistical Significance of Melanoma in Colorado

According to the Centers for Disease Control and Prevention (2019), the incidence rate of melanoma was 21.5 per 100,000 people in Colorado with an average of 1,274 new cases of melanoma in 2016. Out of the new cases of melanoma, there were about 746 men and 528 women. In 2016, approximately 141 deaths were due to

melanoma in Colorado (Centers for Disease Control and Prevention, 2019). The incidence rate of melanoma was highest among Whites with 23.3 per 100,000 people and lowest among Hispanics with 5.1 in 2016 (Centers for Disease Control and Prevention, 2019). The incidence rates of melanoma among White males and White females were 29.2 per 100,000 people and 18.8 per 100,000 in Colorado in 2016 (Centers for Disease Control and Prevention, 2019). The American Cancer Society (2018a) estimated there will be 26,800 new cases of melanoma in the state of Colorado in 2019 with estimated deaths of 8,120. Coloradans are at the highest risk for melanoma due to ultraviolet radiation with elevation, 300 plus days of sunshine, and love for outdoors; as a result, the Colorado Melanoma Foundation (2018) ranked Colorado as one of the highest states for skin cancer incidence and mortality rates.

Melanoma Screening Guidelines

Melanoma is a challenging disease for clinicians to treat due to potential mortality with delayed recognition and a high incidence of its benign counterpart, melanocytic nevus (Argenziano et al., 2013). Thus it is essential that melanoma is identified early so that the appropriate treatment can be identified. There are several clinical guidelines for melanoma screening; however, those guidelines are not routinely used in primary care due to inconsistencies among the recommendations for melanoma in primary care, costs, and time. The U.S. Preventive Services Task Force (2016) concluded there was insufficient evidence to assess the benefits and harms of visual skin examination by a clinician for primary- or population-level screening among asymptomatic adults. However, providers should be aware of the risk factors of melanoma and any suspicious lesions should be biopsied (U.S. Preventive Services Task Force, 2016). Other national organizations have their own screening guidelines

for melanoma such as the American Cancer Society, American Academy of Dermatology, and Skin Cancer Foundation. However, none of those guidelines provide a step-by-step approach (algorithm) to identify an at-risk population for melanoma that is evidence-based, comprehensive, and easy to implement in a primary care setting.

Risk Prediction Model for Melanoma

With any pigmentation and lesions on the skin, the diagnosis of melanoma should be considered. The targeted screening of high-risk individuals for melanoma is feasible, economical with high specificity, and decreases unnecessary procedures and patient anxiety as compared to the screening of the entire population (Williams, Shors, Barlow, Solomon, & White, 2011). To assess the risk of melanoma, there are prediction models for providers and patients. The risk prediction model can be helpful at improving the identification of people at high risk for melanoma (Usher-Smith, Emery, Kassianos, & Walter, 2014).

However, the self- assessment models of melanoma by the patients decrease the healthcare costs and person power compared to the risk assessment by healthcare providers. In addition to the self-assessment models for melanoma, other techniques can be used by healthcare providers such as asymmetry, border irregularity, color that is not uniform, diameter greater than 6 mm, and evolving size, shape, or the color (ABCDE) rule; ugly duckling sign; and the Glasgow 7-point checklist.

Self-assessment of melanoma risk score. The self-assessment of melanoma risk score (SAMScore) was created by the West Melanoma Network that consisted of a French network of dermatologists, general practitioners, and nurses (Quereux et al.,

2012). The questions on the risk score were developed using the risk factors associated with melanoma. It has a total of seven questions: phototype, number of melanocytic nevi, freckling tendency, severe blistering sunburn during childhood or teenage years, life in a country at low latitude, a history of previous personal melanoma, and a history of melanoma in a first degree relative (Quereux et al., 2012). The questions in the risk score are written in a very simple language so that people without medical knowledge will be able to comprehend and provide answers to the questions. The risk score is designed so that the high-risk individuals for melanoma can be identified (Quereux et al., 2012). Based on the answers, the patients are identified as high risk or positive SAMScore if at least one of the three criteria is verified (Quereux et al., 2012). The criteria are listed as follows:

- First criterion: Presence of at least three risk factors among the seven following risk factors i:e phototype I or II, freckling tendency, number of melanocytic nevi > 20 on both arms, severe sunburn during childhood or teenage years, life in a country at low latitude, a history of Previous melanoma, a history of melanoma in a first degree relative.
- Second criterion: A patient under 60 years of age and a number of melanocytic nevi > 20 on both arms.
- Third criterion: A patient of 60 years old or over and a freckling tendency. (Quereux et al., 2012, p. 589)

Mackie scoring system. The Mackie scoring system consists of four independent risk factors for melanoma such as freckles, moles, atypical nevi, and history of severe sunburn (Jackson, Wilkinson, Ranger, Phil, & August, 1998). There are four risk groups based on the questionnaires in the Mackie scoring system: marginally increased risk, increased risk, very increased risk, and worryingly high risk (Jackson et al., 1998).

Williams model. This model is a self- assessed clinical risk estimation model for melanoma that is used to identify people at higher risk for melanoma. The model

includes seven risk factors: sex, age, natural hair color at age 15 years, number of severe sunburns aged 2 to18 years, prior nonmelanoma skin cancer, number of raised moles on both arms, and density of freckles on arms before age 20 (Usher-Smith et al., 2016). The risk score ranges from 0 to 67 (Usher-Smith et al., 2016).

Brief cancer risk assessment tool. This assessment tool is a self-administered instrument to assess skin cancer risk. This tool includes risk factors for melanoma and other keratinocyte skin cancers: ethnicity; personal and family history of skin cancer; mole count; freckles; childhood residence; sunburn history; and sun sensitivity factors such as skin color, natural hair color, and ease of sunburn and tanning (Glanz et al., 2003).

Melanoma risk assessment tool. The melanoma risk assessment tool is an online assessment tool developed by the National Cancer Institute (n.d.a) for healthcare professionals to estimate the absolute risk of developing invasive melanoma. The tool is for non-Hispanic Whites ages 20 to 70 years (National Cancer Institute, n.d.a). Also, patients with at least one of the diagnoses of melanoma, or melanoma in situ or non-melanoma skin cancer, and/or a family history of melanoma should not use this tool to estimate their risk of developing melanoma (National Cancer Institute, n.d.a). The tool consists of demographics (race, age, location, and gender), skin characteristics (complexion and sun exposure), and physical exam (size of moles and freckling tendency) (National Cancer Institute, n.d.a).

Unsupervised self-assessment of melanoma. This tool consists of questions on melanoma risk factors: skin type, eye color, hair color, total number of nevi, presence of congenital nevi, skin damage due to solar radiation, history of sunburns, and family history of melanoma (Harbauer, Binder, Pehamberger, Wolff, & Kittler,

2003). Even though the unsupervised questionnaire is helpful in identifying individuals at high risk for melanoma, it has low accuracy, which limits the practicability of the questionnaire (Harbauer et al., 2003).

Asymmetry, border irregularity, the color that is not uniform, diameter greater than 6 mm, and evolving size, shape, or color rule. The ABCDE rule is widely used by family practice providers while looking at the simple morphologic appearance of the lesion. The detailed description of the ABCDE rule is below:

- A = Asymmetry
  Melanoma lesions or moles are not symmetrical and are irregular.
- B = Border
  Melanoma lesions or mole have irregular borders and are hard to define.
- C = Color
  Melanoma lesions or moles have more than one color such as blue, black, brown, tan.
- D = Diameter
  Melanoma lesions or moles are greater than 6 mm in diameter.
- E = Evolution
  Any changes in the color and size of the lesions or moles. (Melanoma Research Foundation, 2019, para. 3)

The purpose of the rule is to assist providers in distinguishing melanoma from benign pigmented lesions. The sensitivity (the ability of the test to correctly identify those with the disease) and specificity (the ability of the test to correctly identify those without the disease) of the ABCDE rule vary widely depending on the number of criteria for the specific lesion. Sensitivity and specificity of the ABCDE rule range from 43% and 99.6%, respectively with all five criteria present and 97.3% and 36%, respectively with only one criterion present (Herschorn, 2012). Thus people without melanoma will screen positive for melanoma when all five criteria are used, requiring unnecessary referrals and biopsies. Furthermore, the opposite is true when only one criterion is used. Using a rule of all five positive ABCDE criteria is great at

identifying a melanoma, but there is also a chance that malignant lesions can be missed if they do not meet all five criteria. Thus the rule is dependent on the provider's assessment of the lesions, the provider's confidence, and the patient's ability to explain the changes to the lesions.

Ugly duckling sign. The ugly duckling sign is another clinical approach that is increasingly popular at identifying a malignant lesion. This approach is based on the theory that most nevi on an individual's skin tend to resemble each other, and the malignant lesions appear different from their neighbors (Herschorn, 2012). This approach has sensitivity and specificity of 90% and 85%, respectively, even when used by non-dermatologists (Scope et al., 2008).

Glasgow 7-point checklist. The Glasgow 7-point checklist was developed in 1980 to help non-dermatologists identify the lesions that require further evaluation with dermatology referral (Walter et al., 2013). The checklist was revised in 1989 with three major and four minor signs of malignant melanoma. The three major signs include the change in size, shape, and color. The four minor signs include inflammation, crusting/bleeding, sensory change, and a diameter greater than 7 mm. The scoring system for this checklist was weighted with two points for major signs and one point for minor signs and any lesion scoring greater or equal to three warranted referrals to dermatologists (Walter et al., 2013). A randomized controlled trial on 1,580 lesions of 1,297 participants from 15 general practices showed that the weighted 7-point checklist with scores greater and equal to three had the sensitivity of 91.7% and the specificity of 33.1% for melanoma (Walter et al., 2013). The study also found that the single item of the irregular border had clinically significant sensitivity and specificity compared to the weighted 7-point checklist at 91.3% and

92%, respectively (Walter et al., 2013). This also suggests that the revision of a cut-off score from three to greater and equal to four can improve the specificity for the clinically significant lesions and reduce the unnecessary referrals of the benign lesions without affecting the sensitivity of melanoma (Walter et al., 2013).

Dermoscope. A dermoscope is a noninvasive optical instrument that can help providers observe and accurately identify skin lesions that are not visible to the naked eyes (Zalaudek et al., 2008). It has a hand-held light magnifier with a 10-fold magnification (Herschorn, 2012). A meta-analysis of studies compared the diagnostic accuracy of the dermoscope in a clinic setting and compared it to the naked eye examination (Vestergaard, Macaskill, Holtis, & Menzies, 2008). The analysis reviewed a total of nine studies of which two studies were randomized controlled trials and included 8,487 suspicious skin lesions (Vestergaard et al., 2008). The result showed that the diagnostic odds ratio of the dermoscope was 15.6 times higher than the naked eye examination and the sensitivity of the dermoscope was 90% as compared to 71% of naked eye examination (Vestergaard et al., 2008). Furthermore, the specificity of the dermoscope and naked eye examination did not change, suggesting that the dermoscope improved the accuracy of identifying melanoma without increasing the number of misdiagnosed melanomas (Vestergaard et al., 2008). Another study suggested that the dermoscope resulted in 42% fewer excisions compared to the naked-eye examination and had a 21% increase in specificity (Vestergaard et al., 2008).

Despite the diagnostic accuracy of the dermoscope, the use of the device is much lower in the United States among providers as compared to other countries (Morris, Alfonso, & Fernandez, 2017). A study was conducted to assess the use of the

dermoscope among United States providers, practice characteristics, and possible barriers to dermoscope use. The study recruited 1,466 providers from 49 states in the United States to complete a brief cross-sectional survey (Morris et al., 2017). The survey found that only 6% of providers were currently using the dermoscope in their clinical practice (Morris et al., 2017). Furthermore, 54% of participants had heard of the dermoscope, 26% had read about it, and only 15% had used it in the past (Morris et al., 2017). The barriers to incorporating the dermoscope in practice were the cost of the equipment, time, lack of training, and insufficient reimbursement (Morris et al., 2017).

Statement of the Problem

Melanoma is on the rise with the increase in the number of mortality and morbidity rates. The disease can be prevented with early detection and treatment. There are known environmental and genetic risk factors for melanoma. There are inconsistent guidelines and recommendations on melanoma screening from several national and international organizations. Even though the U.S. Preventive Services Task Force (2016) recommended against routine skin cancer screening, it only applies to asymptomatic adults without a history of premalignant or malignant skin lesions. There are several rationales of why skin cancer screening is important. The U.S. Preventive Services Task Force concluded that increased skin cancer screening may result in the detection and treatment of basal cell cancer and squamous cell cancer, impacting life expectancy. According to the American Cancer Society (2019a), squamous cell cancer causes about 2,000 deaths yearly in the United States. As a result, early identification of basal cell cancer and squamous cell cancer is a more valuable benefit than potential harm (Johnson et al., 2017). The U.S. Preventive

Services Task Force did not include any studies on morbidity associated with keratinocyte carcinoma and melanoma, which is a critical oversight (Johnson et al., 2017). Delay in the diagnosis of melanoma can result in thicker melanoma that requires wider excision, lymph node biopsy, lymph node dissection, and systematic therapy that can lead to increased morbidity (Johnson et al., 2017).

Furthermore, keratinocyte carcinoma treatments can result in facial disfigurement and the functional loss with decreased quality of life (Johnson et al., 2017). The U.S. Preventive Services Task Force (2016) based the recommendation on the report from Germany's screen program that screened about 360,288 adults for skin cancer with 15,983 excisions (Johnson et al., 2017). It was estimated that one per 28 excisions were needed to detect melanoma, which seemed to be an acceptable number (Johnson et al., 2017). Thus the harm of excision seems to be overestimated by the U.S. Preventive Services Task Force while formulating the draft for skin cancer screening (Johnson et al., 2017). There was also a difference in the type of biopsies in between the screening study from Germany and the United States. In Germany, the biopsies were fusiform/elliptical excisional biopsies that required deep and superficial sutures, which is time-consuming and costly with a high morbidity rate as compared to shaving, cauterization, punch, and/or excision biopsies in the United States (Johnson et al., 2017). Thus the differences in the types of biopsies were not included while making the final recommendation by the U.S. Preventive Services Task Force on melanoma screening, leading to the misinterpretation of procedural data and cosmetic outcomes (Johnson et al., 2017). One study showed a two times higher likelihood of thinner melanoma being diagnosed with a skin examination by a provider and four times higher likelihood in men over age 60 years (Swetter, Pollitt, Johnson, Brooks, &

Geller, 2012). The study was excluded due to its retrospective study design by the panel members of the U.S. Preventive Services Task Force. Furthermore, there was a reduction of 69% in the incidence of melanoma and decreased mortality of melanoma with education, intervention, and screening programs at the Lawrence Livermore National Laboratory in Northern California (Schneider, Moore, & Mendelsohn, 2008). This study was excluded by the panel members of the U.S. Preventive Services Task Force because of the lack of generalizability to primary care (Johnson et al., 2017). No dermatology expert was on the panel of the U.S. Preventive Services Task Force who developed the guideline for skin cancer screening (Johnson et al., 2017).

There are several melanoma self-assessment tools such as SAMScore, Mackie model, Williams model, brief cancer risk assessment tool, melanoma risk assessment tool, and unsupervised self-assessment tool. In addition, techniques exist for providers to assess a lesion for melanoma and they are the ABCDE rule, ugly duckling sign, Glasgow 7-point scale, and dermoscope. Each tool and technique has strengths and limitations; however, there is a lack of a standardized tool and technique for melanoma screening in the primary care settings.

Even though providers are aware of the importance of melanoma screening, it is not routinely performed in the United States. Barriers have been identified to effective melanoma screening in primary care. Some of the major reasons for the lack of skin cancer screening in primary care include lack of confidence among primary care providers, low priority for skin cancer screening, lack of reimbursement, lack of standardized guidelines, time constraints, patient embarrassment, distraction by other health problems, and the perception that most of the screenings do not result in significant findings (Jiang et al., 2017; Oliveria, Heneghan, Cushman, Ughetta, &

Halpern., 2011). It is very important that the barriers be addressed and resolved to solve the lack of inconsistency regarding melanoma screening. About two-thirds of medical students and three-fourths of primary care residents felt they did not have adequate training in a total body skin examination (Johnson et al., 2017). The National Health Interview Survey showed that only 8% of patients were screened for melanoma by their primary care providers or obstetrician/gynecologist within the last 12 months (Johnson et al., 2017). There is a very low screening rate for melanoma at 16% for men and 13% for women compared to 51% for colorectal, 54% for breast cancer, and 43% for prostate cancer (Johnson et al., 2017).

Historically, the detection of melanoma heavily relied on full-body skin exams by dermatologists. However, in spite of a notable increase in the incidence of melanoma, there has not been a rapid increase in the number of dermatologists in the United States. According to Schember (2015), only 13,847 dermatologists are in the United States, which is equivalent to a mere 1% of providers. During a four-year period from 2010 to 2014, there was only a 10% increase in the number of dermatologists in the United States (Schember, 2015). With the limited number of dermatologists, it is impossible for dermatologists to evaluate all skin conditions in a timely fashion. Primary care providers are the first providers that many patients with suspicious skin lesions will seek in a community (Fleming, Grade, & Bendavid, 2018). About 41.8% of all the annual office visits are to a family practitioner or internist in the United States (Oliveria et al., 2011). Thus primary care providers play an essential role in the early detection of melanoma by performing diagnostic biopsies of suspicious skin lesions or referring patients to dermatologists for further evaluation (Fleming et al., 2018).

Thus a standardized evidence-based and comprehensive melanoma screening tool or technique is needed that can be utilized by primary care providers to screen individuals at high-risk for melanoma. Education regarding melanoma screening is needed among primary care providers and the general population. It is very important that barriers identified by primary care providers be addressed and resolved to solve the lack of inconsistency regarding melanoma screening.

Purpose of the Project

The burden of melanoma screening relies heavily on primary care providers due to the inadequate number of dermatologists in the United States. However, primary care providers do not perform melanoma screening due to time constraints, lack of training, lack of standardized guidelines, and the complexity of a patient's medical issues. The purpose of this scholarly project was to implement an evidence-based melanoma screening algorithm using SAMScore to identify patients at high risk for melanoma in a primary care setting by primary care providers in an effort to facilitate early detection and initiate treatments to minimize the complications related to melanoma. The SAMScore was chosen over the other assessment tools and techniques because it is a validated assessment tool for healthcare providers at identifying high-risk patients for melanoma, and it requires 11.54 times fewer patients to detect a new case of melanoma as compared to a non-targeted screening (Quereux et al., 2012).

Patient Population, Intervention, Comparison/ Intervention, Outcome Question, and Time

Primary care providers play an important role in the identification of patients who are at high risk for melanoma. Even though the primary screening for melanoma

for the general population is not recommended by the U.S. Preventive Services Task Force (2016), a targeted melanoma screening has been recommended to identify high-risk patients for melanoma for early diagnosis and survival (Curiel-Lewandroski, Chen, & Swetter, 2013). Melanoma is a curable disease if diagnosed early, and the people at high-risk are not routinely screened for this disease which is a major problem. Since the SAMScore is a validated tool, this tool was utilized to screen high-risk patients for melanoma in this scholarly project. Also, an evidence-based algorithm was developed by the project lead. The patient population, intervention, comparison/intervention, outcome, and time (PICOT) question format was used to develop the clinical question in the evidence-based quality improvement project. Thus the following PICOT question was developed by the project lead to assess if the algorithm yielded an increase in the number of melanoma screening for high-risk patients by the primary care providers in a primary care setting.

Q1 In English speaking adult patients (ages 35 to 75 years), attending annual wellness visits in a primary care setting, how does the use of a melanoma screening algorithm for providers including risk-stratification questionnaire, compared with usual practice (no provider workflow, algorithm, or structured screening recommendation) affect identification of patients at high-risk of melanoma (and therefore likelihood of future evidence-based clinical interventions of skin cancer diagnosis and treatment) during a one-month intervention period as compared to one-month pre-intervention period in the same practice?

Definition of Terms

Familial atypical multiple mole melanoma syndrome. It is an autosomal dominant genodermatosis characterized by multiple melanocytic nevi (more than 50) and a family history of melanoma (Mize, Bishop, Resse, & Sluzevich, 2009). It is associated with the mutation of the CDKN2A gene.

Incidence rate. The ratio of the number of new cases to the total time the population is at risk of disease (Centers for Disease Control and Prevention, 2012).

Metastasis. The spread of the cancer cells from where they first formed to another part of the body (National Cancer Institute, n.d.b).

Odds ratio. The odds that an outcome will occur given an exposure compared to the odds of the outcome occurring in the absence of that exposure (Szumilas, 2010).

Sensitivity. The ability of a test to correctly classify an individual as diseased (Parikh, Mathai, & Thomas, 2008).

Specificity. The ability of a test to correctly classify an individual as disease-free (Parikh et al., 2008).

Xeroderma pigmentosum. An inherited condition characterized by an extreme sensitivity to ultraviolet rays from sunlight (National Institutes of Health, 2019).

Conclusion

Complications of melanoma can be prevented with early diagnosis and treatment. Primary care providers are in an optimal position to screen patients at high risk for melanoma. Consensus on the melanoma screening guidelines is lacking in the United States. An evidence-based melanoma screening model or tool or algorithm can be helpful to primary care providers so they can identify patients at high risk for melanoma. The appropriate intervention can then be initiated for patients identified as high risk.

CHAPTER II

REVIEW OF LITERATURE

Synthesis of the Literature

The literature review was conducted on melanoma, historical background on melanoma, melanoma screening guidelines from national and international agencies, melanoma screening tools and techniques, barriers to melanoma screening by providers, interventions to melanoma screening, time to perform melanoma screening with and without a dermoscope, and targeted age group for melanoma screening. The following electronic databases were utilized for the literature review: Academic Search Premier, Cochrane Central Register of Controlled Trials, Cochrane Database Systematic Review, Google Scholar, PubMed, and ScienceDirect. Keywords included in the search were melanoma screening, primary care, skin cancer screening, cancer screening, melanoma screening guideline, and melanoma screening criteria. Criteria included full-text articles published between 1998 and 2019 and written in the English language. The study types were randomized controlled trials, systematic reviews, meta-analysis studies, retrospective studies, and cohort studies.

Historical Background

The word melanoma is derived from the Greek word "melas" meaning dark and "oma" meaning tumor (Rebecca, Sondak, & Smalley, 2012). The description of melanoma first appeared in the literature in the writings of Hippocrates of Cos in the fifth century B.C. and again in the Greek physician Rufus of Eupheses (Rebecca et al.,

2012). The word melanoma was coined by Sir Robert Carswell in 1838 (Rebecca et al., 2012). The first surgical removal of melanoma was done by the Scottish surgeon John Hunter at St George's Hospital Medical School in London, and it was performed on a recurrent melanoma on the jaw of a 35-year-old man (Rebecca et al., 2012). At that time, the surgeon did not know what he was removing. Thus the tumor was preserved and was later diagnosed as melanoma in 1968 (Rebecca et al., 2012). The melanoma is housed in the Hunterian Museum at Lincolns Inn Fields in London (Rebecca et al., 2012).

The physical evidence of melanoma was first seen in the skeletons of Pre-Colombian mummies (2,400 years old) from Chancay and Chingas in Peru (Rebecca et al., 2012). In 1820, Dr. William Norris published a report on the etiology and progression of melanoma based on a study he conducted on a 59-year-old male patient with melanoma over three years until the man passed away (Rebecca et al., 2012). During the study, he found several reddish and whitish brown tints throughout the body (Rebecca et al., 2012). He also found several spots of various sizes inside the abdomen of the man upon autopsy and noted that the man's father passed away due to a similar disease (Rebecca et al., 2012). After an in-depth study of the case, he concluded that the disease was hereditary in nature (Rebecca et al., 2012). In 1857, he studied eight other cases of melanoma and proposed the relationship of melanoma with nevi and environmental factors (Rebecca et al., 2012). In 1837, Isaac Parish documented the first North American case of melanoma where he described melanoma as "a purple mark or mole about the size of a mulberry" (Rebecca et al., 2012, p. 116).

Types of Melanoma

There are four categories of melanoma: superficial spreading melanoma, lentigo melanoma, acral lentiginous melanoma, and nodular melanoma.

Superficial spreading melanoma. This is the most common type of melanoma, accounting for almost 70% of all melanomas (Skin Cancer Foundation, 2019). This type of melanoma first appears as a flat or slightly raised, discolored patch with irregular borders and travels along with the top layer of skin before extending deep into the skin (Aim at Melanoma Foundation, 2014c; Skin Cancer Foundation, 2019). These lesions commonly appear on the trunks of men, legs of women, and upper back of both sexes (Aim at Melanoma Foundation, 2014c). They are usually diagnosed in patients between the ages of 30 and 50 years. Half of this type of melanoma occurs in pre-existing moles (Aim at Melanoma Foundation, 2014c). The color varies from tan, brown, black, red, blue, or white.

Lentigo melanoma. A lentigo melanoma is a subtype of melanoma in situ, which is more commonly found in chronically sun-damaged skin and can progress to become invasive melanoma (Skin Cancer Foundation, 2019). About 5% of all melanomas are lentigo melanoma (Aim at Melanoma Foundation, 2014c). This melanoma is generally large, flat, and tan color, but can be black, blue, red, gray, or white and typically takes years to develop (Aim at Melanoma Foundation, 2014c). This melanoma is common in older adults on the face and other chronically sun-exposed areas (Aim at Melanoma Foundation, 2014c).

Acral lentiginous melanoma. Acral lentiginous melanoma is a type of melanoma that stays on the surface of the skin superficially before penetrating the deep tissue layers (Skin Cancer Foundation, 2019). The term acral comes from the

Greek word “akron,” which means extremity (Aim at Melanoma Foundation, 2014c). Thus this melanoma usually appears as a black or brown discoloration under the nails or soles of feet or palms of hands (Skin Cancer Foundation, 2019). About 2% to 3% of all melanomas are acral lentiginous melanoma (Bradford, Goldstein, McMaster, & Tucker, 2009). It is most common in African Americans and Asians and is the least common type of melanoma diagnosed among Caucasians (Skin Cancer Foundation, 2019). It is difficult to diagnose early because it appears like a bruise or injury to the palms, soles, or nail beds (Aim at Melanoma Foundation, 2014c).

Nodular melanoma. Nodular melanoma is a type of melanoma that is usually invasive and aggressive by the time it is first diagnosed (Skin Cancer Foundation, 2019). It first appears as blue-black, dome-shaped nodule on legs, arms, trunk, and scalp (Skin Cancer Foundation, 2019). It accounts for approximately 10% to 15% of cases (Skin Cancer Foundation, 2019). Thus the prognosis of the nodular melanoma is poor compared to other melanomas (Aim at Melanoma Foundation, 2014c).

Summary. Melanoma varies in its color, penetration, appearance, and exposure. There are four different types of melanoma. As a provider, it is important to have knowledge on all types of melanoma so that melanoma can be diagnosed as early as possible and appropriate intervention can be performed in a timely manner before the disease metastasizes to other parts and organs of the body.

Stages of Melanoma

It is important for primary care providers to understand the various stages of melanoma as it helps them to determine treatment options and prognosis. The American Joint Commission on Cancer has recommended a melanoma staging system that ranges from 0 through stage IV (Aim at Melanoma Foundation, 2014b). If the

staging number is lower, it means the melanoma has not spread or is localized. As the number increases, it means that the melanoma has spread or metastasized to other parts or organs of the body.

Stage 0 melanoma. This is the stage of melanoma where the tumor is only on the epidermis layer of the skin and has not grown deeper invading surrounding tissues or lymph nodes or distant sites (Aim at Melanoma Foundation, 2014b). Patients with this stage of melanoma are at lower risk for local recurrence or regional or distant metastases of the disease (Aim at Melanoma Foundation, 2014b). This melanoma is also called melanoma in situ.

Stage I melanoma. Stage I melanoma is differentiated into subclasses IA and IB. Stage IA melanoma is melanoma with no more than a 1 mm thickness and may or may not have ulceration (National Cancer Institute, 2019). Stage IB is melanoma with more than a 1 mm thickness, but no more than a 2 mm thickness and without ulceration (National Cancer Institute, 2019). There is no evidence the tumor has spread to lymph nodes or metastasize to distant sites, and patients with stage I are at a lower risk for local recurrence of regional or distant metastases (National Cancer Institute, 2019).

Stage II melanoma. Stage II melanoma is differentiated in subclasses IIA, IIB, and IIC. Stage IIA is melanoma with a 1 to 2 mm thickness with ulceration or a 2 to 4 mm thickness without ulceration (National Cancer Institute, 2019). Stage IIB is melanoma with a 2 to 4 mm thickness with ulceration of more than a 4 mm thickness without ulceration (National Cancer Institute, 2019). Stage IIC is melanoma with more than a 4 mm thickness with ulceration (National Cancer Institute, 2019).

Stage III melanoma. Stage III melanoma is differentiated into four subclasses: IIIA, IIIB, IIIC, and IIID. Stage IIIA melanoma is less than 1 mm in thickness with ulceration or between a 1 to 2 mm thicknesses without ulceration (National Cancer Institute, 2019). This melanoma is found in one to three lymph nodes by sentinel lymph node biopsy and has microsatellite tumors (tumor cells beside or below the primary melanoma that can be seen with a microscope), satellite tumors (tumor cells within 2 cm of the primary melanoma that can be seen without a microscope), and/or in-transit metastases (type of metastasis where cancer spreads through lymph vessels and grows within 2 cm from the primary melanoma) on or under the skin (National Cancer Institute, 2019). Stage IIIB has three criteria. First criteria stage IIIB is melanoma when the primary tumor cannot be visualized by the naked eye and the melanoma is found in one lymph node by a physical exam or imaging tests (National Cancer Institute, 2019). The second criterion stage IIIB is melanoma less than 1 mm thick with ulceration or between 1 to 2 mm thick without ulceration with one to three lymph nodes of involvement (National Cancer Institute, 2019). Third criteria stage IIIB is melanoma between 1 to 2 mm thick with ulceration or between 2 to 4 mm thick without ulceration and one to three lymph nodes of involvement (National Cancer Institute, 2019). Stage IIIC has four criteria. First criteria stage IIIC melanoma cannot be seen with the naked eye and is found in two or three lymph nodes or one to four or more lymph nodes with microsatellite tumors, satellite tumors, and/or in-transit metastases on or under the skin (National Cancer Institute, 2019). Second criteria stage IIIC is less than 2 mm thick with or without ulceration or more than 4 mm without ulceration and found in more than four lymph nodes or one to four lymph nodes with microsatellite tumors, satellite tumors, and/or

in-transit metastases on or under the skin (National Cancer Institute, 2019). The third criterion stage IIIC melanoma is between 2 and 4 mm thick with ulceration or more than 4 mm thick without ulceration (National Cancer Institute, 2019). This is found in one or more lymph nodes. The fourth criteria stage IIIC melanoma is more than 4 mm thick with ulceration and found in one or more lymph nodes (National Cancer Institute, 2019). Stage IIID melanoma is more than 4 mm thick with ulceration and found in more than two lymph nodes (National Cancer Institute, 2019).

Stage IV melanoma. This is the stage of melanoma where melanoma has metastasized to lymph nodes distant from the primary site and spread to internal organs such as the liver, brain, bone, and gastrointestinal tract (National Cancer Institute, 2019). The prognosis of this melanoma is poor.

Summary. The stages of melanoma are a great method to understand the progression of the disease. Understanding the stages of melanoma helps a provider formulate a treatment plan and educate the patient on their disease. It also helps in the diagnosis of melanoma and determines the prognosis of the disease.

Melanoma Genetics

Genes exist that predispose a person to melanoma and those genes are divided into low, medium, and high penetrance genes. The penetrance of a gene refers to the "likelihood of a mutation carrier developing the disease over time and reflects the overall contribution of specific gene polymorphism, or mutation to a melanoma risk" (Read, Wadt, & Hayward, 2015, p. 1). The high penetrance genes include cyclin-dependent kinase inhibitor 2A (chromosome 9p21), cyclin-dependent kinase 4 (chromosome 12 q14), BRCA1-assocaited protein-1 (tumor suppressor gene on chromosome 3p21), protection of telomeres 1 (gene that protects telomeres),

adrenocortical dysplasia protein homolog/telomeric repeat binding factor 2 interacting protein (regulates telomere length), and telomerase reverse transcriptase (catalytic subunit of telomerase) (Read et al., 2015). The medium penetrance genes include melanocortin 1 receptor gene (encodes G-protein coupled receptor that binds alpha-melanocyte stimulating hormone), microphthalmia-associated transcription factor (key regular of pigment cells including development and differentiation of melanocytes), and solute carrier family 45, member 2 variants (protective against melanoma and associated with darker skin) (Read et al., 2015). There are several low penetrance genes for melanoma; however, some of the common low penetrance genes include Agouti signaling protein, tyrosinase, tyrosinase-related protein 1, and oculocutaneous albinism type II (Read et al., 2015). Even though no single gene can guarantee melanoma development, presence of those genes places an individual at higher risk for melanoma. It is likely that people with moderate to high genetic susceptibility require fewer somatic mutations before the development of melanoma (Read et al., 2015). In addition, melanoma risk genes may directly or indirectly interact with the other genes or environmental risk factors to influence and activate melanoma growth pathways (Read et al., 2015). However, the genetic testing of melanoma remains controversial due to the low frequency of high penetrance mutations and a combination of multiple other risk factors besides genes that can increase a patients' risk for melanoma (Read et al., 2015).

Melanoma Screening Guidelines

U.S. Preventive Services Task Force melanoma screening guideline. The U.S. Preventive Services Task Force (2016) concluded that the current evidence is insufficient to assess the balance of benefit and harm of visual skin examination by a

clinician to screen for skin cancer in adults. The rating for the grade is "I" which means that the current evidence is lacking or of poor quality or conflicting to make the recommendation for the service. However, the recommendation only applies to asymptomatic adults without a history of premalignant or malignant skin lesions. Patients with suspicious skin lesions or those under surveillance due to a high risk for skin cancer, such as familial syndrome, are outside the scope of this recommendation statement (U.S. Preventive Services Task Force, 2016). Risk factors to melanoma, such as male gender, fair complexion, indoor tanning beds, personal history of sunburns or previous skin cancer, dysplastic nevus, multiple nevi, family history of melanoma, and advanced age require clinical consideration (U.S. Preventive Services Task Force, 2016). The U.S. Preventive Services Task Force recommended assessing skin lesions using the asymmetry, border irregularity, color that is not uniform, diameter greater than 6 mm, and evolving size, shape or color (ABCDE) rule. The screening interval for melanoma is unknown. The treatment of melanoma after the detection includes excision with or without lymph node management (U.S. Preventive Services Task Force, 2016).

American Academy of Dermatology. The American Academy of Dermatology (2018a) recommended that high-risk individuals perform regular self-exams to detect skin cancer early and seek an annual full-body exam. The Academy encourages the general population to perform regular self-skin exams since about half of the melanomas are self-detected (American Academy of Dermatology, 2018b). Ultraviolet radiation is the most preventable risk factor for all skin cancers; thus the Academy recommends that everyone avoid indoor tanning beds, avoid ultraviolet rays by seeking shade, wear protective clothing, and use a broad-spectrum water-resistant

sunscreen with a sun protection factor of 30 or higher (American Academy of Dermatology, 2018a).

American Cancer Society. The American Cancer Society recommends cancer screening including a skin exam every three years in patients between the ages of 20 and 40 years and yearly screening in patients older than 40 years (Zoorob, Anderson, Cefalu, & Sidani, 2001). High-risk individuals for skin cancer should have regular skin exams as determined by their healthcare provider (American Cancer Society, 2018b). The skin exam recommendation varies by the provider and the number of risk factors to skin cancer (American Cancer Society, 2018b).

American Academy of Family Physicians. The American Academy of Family Physicians published a statement in 2009 stating,

> There is insufficient evidence to assess the balance of benefits and harms of using the whole-body skin examination by a primary care provider or patient skin self-examination for the early detection of cutaneous melanoma, basal cell carcinoma or squamous cell carcinoma in the adult general population. (Johnson et al., 2017, p. 23)

Other organizations and associations. The American Medical Association recommends an annual skin examination in patients at moderate risk for skin cancer and advises patients to discuss the frequency of skin cancer screening with their providers and perform skin self-examinations monthly (Zoorob et al., 2001). The Canadian Task Force on Preventive Health Care (2018) agreed with the U.S. Preventive Services Task Force (2016) that insufficient evidence exists to recommend routine skin screening by primary care providers in low-risk patients and is a grade C recommendation. However, the Canadian Task Force on Preventive Health Care recommended that providers counsel their patients on reducing sun exposure by using sunscreen and wearing protective clothing. Thus there is an inconsistency among

several organizations regarding skin cancer screening guidelines and recommendations.

Summary. The various national and international organizations differ from each other with the recommendation for skin cancer or melanoma screening. Some guidelines have recommendations for people with low, moderate, and high risk for melanoma; however, the guidelines are not clear on what the low, moderate, and high risk for melanoma entail. While the risk factors of melanoma are listed by the U.S. Preventive Services Task Force (2016), other organizations do not list the risk factors for melanoma. There is variability among risk factors as determined by the organization. There is inconsistency in the age group and frequency of melanoma screening. Even though there are differences and inconsistencies among the recommendations for melanoma screening, the organizations agree that high-risk patients need frequent melanoma screening and interventions, such as dermatology referral and education on ways to prevent melanoma such as clothing and sunscreen. Thus the above inconsistencies clearly show there is a need for a standardized method to identify patients who are at high-risk for melanoma.

Risk Prediction Models for Melanoma

Self-assessment of melanoma risk score. The survival due to melanoma is inversely related to the thickness of the melanoma at the time of diagnosis; thus early diagnosis is a key for improving the prognosis of patients with melanoma (Quereux et al., 2012). Mass screening for melanoma is not recommended due to higher costs and lower chances of finding melanomas (Quereux et al., 2012). Instead, the targeted screening is recommended to identify patients at high risk for melanoma. A

prospective study was performed to assess the feasibility and validity of the self-assessment risk factor of melanoma, also known as the self-assessment of melanoma risk score (SAMScore) among 46 general practitioners in the city of Nantes in the Pays de Loire region located in the west of France (Quereux et al., 2012). Nantes is a big town with people of all skin types (Quereux et al., 2012). Patients older than 18 years were asked to fill out the SAMScore independently prior to being seen by the provider. Approximately 7,953 patients completed the SAMScore. Among the total sample population, 2,404 patients had at least one of the three criteria of the SAMScore verified and were identified as high-risk patients for melanoma (Quereux et al., 2012). Patients were considered high-risk for melanoma if they met one of the criteria of the SAMScore. For those who were identified as being at high risk for melanoma, providers performed a whole-body skin exam, and patients with suspicious lesions were then referred to dermatologists for further evaluation and biopsy as needed (Quereux et al., 2012). Among 2,404 high-risk patients, 10 melanomas were detected (Quereux et al., 2012). Thus the efficiency of the SAMScore was 11.54 using the logistic model with a random effect, which means that the SAMScore was 11.54 more efficient in detecting a new case of melanoma as compared to a non-targeted screening tool (Quereux et al., 2012). For the patients who did not meet the criteria for the SAMScore, they were not examined by the providers, which may have resulted in false negatives for the study (Quereux et al., 2012).

A randomized controlled trial was done on the French west coast to assess the effect of a targeted melanoma prevention intervention on patient prevention behaviors. The targeted population for the study was patients at high risk for melanoma as determined by the SAMScore with a relative risk of 11 times higher than the general

population (Rat et al., 2014). A total of 20 general providers and 470 patients participated in the study. Prior to the study, the providers reviewed an e-learning module on melanoma screening and skin exams. Half of the providers were given access to the SAMScore algorithm as the intervention group, and the other half did not have access to the SAMScore (Rat et al., 2014). All patients were given a SAMScore questionnaire to complete while they were waiting in the waiting area regardless of the type of visit (Rat et al., 2014). In the intervention group, providers utilized the SAMScore risk calculator to determine if the patient was at high risk for melanoma (Rat et al., 2014). For patients who were identified as high risk, providers performed a total skin examination, counseled the patient, and gave the information leaflet on primary and secondary prevention measures (Rat et al., 2014). However, the control providers provided the information leaflet only.

The study suggested that the multifaceted approach by the general providers of identifying patients at risk, performing skin examinations, giving advice, and handing printed information on the prevention of melanoma had a great impact on patients compared to handing printed information alone. Based on the intervention, patients in the intervention group were better able to recognize the risk factors to melanoma (71.1% versus 42.1%), more likely to perform a skin self-exam during the past 12 months (52.6% versus 36.8%), and less likely to sunbathe during the summer (24.7% versus 40.8%) (Rat et al., 2014).

Mackie scoring system. A case-control study was conducted by the Scottish Melanoma Group and Scottish Cancer Registry in 1987 to identify if clinically significant risk factors predicted the risk of invasive cutaneous melanoma (Mackie, Freudenberger, & Aitchison, 1989). The total sample population was 371 patients

who were diagnosed with invasive cutaneous melanoma. Patients were interviewed about their personal history of melanoma, history of melanoma in first degree relatives, previous residence in tropical or subtropical climates, episodes of severe sunburn, and use of artificial sources of ultraviolet radiation (Mackie et al., 1989). Patients were also examined for the number of melanocytic nevi greater than 2 mm in diameter, atypical nevi, and freckling tendency (Mackie et al., 1989). Each risk factor was calculated for the relative risk using logistic regression analysis. Based on the results, the total number of nevi was the most important risk factor (Mackie et al., 1989). Also, atypical nevi were present in 36% of men and 39% of females who had melanoma (Mackie et al., 1989). Sixteen percent of patients had three or more atypical nevi compared to 1% who did not have melanoma (Mackie et al., 1989). Furthermore, 48% of women and 52% of men with freckles had melanoma (Mackie et al., 1989). Nineteen percent of melanoma patients had a history of three or more episodes of severe sunburn (Mackie et al., 1989). Thus the relative risk was calculated for each of the risk factors and found major risk factors: total number of nevi, number of atypical nevi, freckling tendency, and number of episodes of severe sunburn (Mackie et al., 1989). The selection of variables for the personal risk chart used a forward stepwise approach based on a conditional logistic regression model, where the model tends to underestimate the true relative risk of melanoma from the presence of three or more atypical nevi and three or more episodes of severe sunburn (Mackie et al., 1989). Thus even though the relative risk of the Mackie model is an acceptable guide to the magnitude of the risk, it may underestimate the relative risk in extreme cases of melanoma (Mackie et al., 1989). Also, the model was tested among a small sample population of 371 patients with invasive cutaneous melanoma.

Williams model. A study was conducted to create a melanoma risk score based on self-assessed risk factors and determine the odds ratio for each risk factor for melanomas (Williams et al., 2011). Data were collected from a case-control study of melanoma from Washington State (Williams et al., 2011). A total of 1,113 sample population with 386 cases and 727 controls aged 35 to 74 years were interviewed via telephone (Williams et al., 2011). There were several variables for the model: sex, age, education, income, marital status, tendency to sunburn, ability to tan, number of severe sunburn from ages 2 to 18, natural hair color at age 15, density of freckles on arms before age 20, number of raised moles on both arms, prior mole removal, number of moles removed, and prior non-melanoma skin cancer (Williams et al., 2011). A multivariate model was generated to predict the risk factors for invasive melanoma (Williams et al., 2011). In the final model there were only seven risk factors: age, male sex, number of severe sunburns from ages 2 to18, natural hair color at age 15, density of freckles on the arms before age 20, number of raised moles on both arms, and prior non-melanoma skin cancer remained significant (Williams et al., 2011). The validated area under the curve for the Williams model was 0.70, which indicated that the model predicts melanoma moderately well (Williams et al., 2011).

Brief cancer risk assessment tool. A study was conducted to develop and pilot the brief cancer risk assessment tool. The tool was developed after critically reviewing the literature on the risk factors and self-assessment for melanoma and basal cell and squamous cell cancer (Glanz et al., 2003). The risk factors included personal and family history of skin cancer, total body mole count, freckles, childhood residence, sunburn history ethnicity, and sun sensitivity factors (Glanz et al., 2003). The study consisted of two pilot studies. The first pilot study included administering

the questionnaire to 173 patients between the ages of 20 and 65 and without skin cancer (Glanz et al., 2003). The same questionnaire was administered to those patients again one month later via telephone (Glanz et al., 2003). The second pilot study included sending a mailed packet to 165 patients who were considered at moderate to high risk based on the brief risk assessment tool on their sun habits and sun exposures (Glanz et al., 2003). The relative risk was calculated for each of the risk factors and ranged from 0.57 to 0.97. Thus the tool was considered an acceptable tool for skin cancer assessment, but the validation of the tool with a clinical exam would have been useful (Glanz et al., 2003). Also, the tool did not include a family history of melanoma as one of the risk factors, which was a limitation of the tool (Glanz et al., 2003). Marlene

Melanoma risk assessment tool. A melanoma risk assessment tool was developed from a case-control study with 1,663 non-Hispanic White patients in a clinic from Philadelphia, Pennsylvania, and San Francisco, California (National Cancer Institute, n.d.a). The tool calculated the absolute risk of the patients in developing invasive melanoma (National Cancer Institute, n.d.a). The tool consisted of questions on race, age, location, gender, complexion, sun exposure, moles, and freckling tendency (National Cancer Institute, n.d.a). The tool is available free of cost to the general public and providers but recommends discussing the results of the tool with a provider after it is completed (National Cancer Institute, n.d.a). This tool is only for screening and surveillance for melanoma and is not recommended to use for patients with current melanoma, melanoma in situ, non-melanoma skin cancer, and family history of melanoma (National Cancer Institute, n.d.a). Also, the tool is not validated to be used for all non-Hispanic Whites (National Cancer Institute, n.d.a).

Unsupervised self-assessment of melanoma. A case-control study was conducted to validate the unsupervised self-assessment of melanoma risk at the Department of Dermatology in Vienna (Harbauer et al., 2003). A total of 222 patients had confirmed cases of primary melanoma and 220 control patients (National Cancer Institute, n.d.a). Questions were administered to all participants with melanoma risk factors such as skin type, eye color, hair color, total number of nevi, presence of congenital nevi, skin damage from solar radiation, history of sunburns, and family history of melanoma (National Cancer Institute, n.d.a). After the questions were filled out, every patient was examined by a dermatologist. The self-assessment of risk factors and physician assessment of the risk factors were compared. The areas under the curve for self-assessment and physician assessment were 0.73 and 0.77, respectively (National Cancer Institute, n.d.a). The self-assessment was able to identify 39% of high- risk patients, and the physician assessment was able to identify 42% of high-risk patients for melanoma (National Cancer Institute, n.d.a). Even though the self-assessment tool was moderately valid at identifying the high-risk patients for melanoma, the location of the study, which was the dermatology clinic, limited the accuracy of the tool since most patients in a dermatology clinic may be at high risk for melanoma anyways (National Cancer Institute, n.d.a).

Summary. All the studies on the risk prediction model had limitations and strengths. The study on the Mackie scoring system was based on a very small sample population underestimating the relative risk of each risk factor. The study on the Williams model was administered via telephone to patients who were diagnosed with melanoma; thus the answers may not have been accurate since the questions were asked by the researchers and not done by the patients themselves. The brief

assessment tool was not validated among the non-Hispanic population since the sample size was small for the validation study. The melanoma screening tool was an online tool and may not be feasible to use for those with limited computer knowledge. The unsupervised self-assessment tool was only moderately valid, and the location of the study limited the generalizability and result of the study. Thus the SAMScore was chosen as the risk prediction model for this scholarly project since the validation study had a large sample population of 7,953, and the self-assessment questionnaire was followed by the primary care providers and dermatologists as needed. Furthermore, the SAMScore was 11.54 times more efficient in detecting a new case of melanoma.

Barriers to Melanoma Screening

A randomized survey was done to determine barriers and facilitating factors to full body skin exams among dermatologists and primary care providers. The sample for the study was randomly selected from the American Medical Association medical marketing services database that included more than 30,000 office-based practicing providers (Oliveria et al., 2011). Providers were categorized as family practitioners, internists, and dermatologists. There were two modes of data collection: a mixed-mode (electronic and postal mail survey) and an entirely postal mail survey (Oliveria et al., 2011). The survey instrument consisted of 13 questions on demographics, practice characteristics, skin cancer screening behaviors, and barriers and facilitators to performing full-body skin exam (Oliveria et al., 2011). Barriers to skin cancer screening included lack of skill or training, uncertainty about what to look for, time constraints, lack of proper equipment, patient embarrassment, not routinely doing skin assessment, lack of or inadequate reimbursement, low probability of finding cancer, lack of importance of skin examination, lack of standardized guidelines, low risk

patients for melanoma, and presence of competing comorbidities (Oliveria et al., 2011). Facilitators of performing a full-body skin exam include skill or expertise in performing an exam and diagnosing skin cancer, influence of medical training, high risk patients, patient demand, adequate reimbursement, medicolegal pressure to perform preventive procedures, completeness of patient records, and evidence supporting skin examination as a tool for skin cancer prevention (Oliveria et al., 2011). The questions were graded on a 4-point scale ranging from *not a factor* (1) to *major* (4).

Out of 2,999 providers, only 1,669 providers were included in the survey with an overall rate of 59.2% (Oliveria et al., 2011). Of all the respondents, more than two-thirds of the providers stated they perform a full-body skin exam during a complete physical examination (Oliveria et al., 2011). The full-body skin exam rates for dermatologists, family practitioners, and internists were 81.3%, 59.6%, and 56.4%, respectively (Oliveria et al., 2011). The top three barriers among all disciplines were time constraints, competing comorbidities, and patient embarrassment or reluctance (Oliveria et al., 2011). The top three facilitators included patients at high risk, patient demand for complete examination or mole checks, and the influence of medical training (Oliveria et al., 2011).

One of the most common barriers to a full body skin exam, as reported by primary care providers, was time (Oliveria et al., 2011). Zalaudek et al. (2008) formed a randomized multicenter study to determine the actual time required to perform a full-body skin exam with and without a dermoscope. There were a total of 1,359 patients from eight clinics in Austria, France, Germany, Italy, Spain, and the United States (Zalaudek et al., 2008). Out of the total number of samples, 659 received a full-body

skin exam without a dermoscope, and 669 received a full-body skin exam with a dermoscope (Zalaudek et al., 2008). Prior to the actual study, providers were asked to estimate the length of time required to perform a full-body skin exam with and without a dermoscope. They estimated it takes 6.3 minutes to perform a full-body skin exam without a dermoscope and 10.7 minutes to perform a full-body skin exam with a dermoscope (Zalaudek et al., 2008). Study results showed the actual time for a full-body skin exam with and without a dermoscope was 2.4 minutes and 1.1 minutes, respectively (Zalaudek et al., 2008). Furthermore, the length of time for a full-body skin exam without a dermoscope did not increase with the number of lesions and a minimal increase in the length of time for a full-body skin exam with a dermoscope with the number of lesions (Zalaudek et al., 2008). Overall, the total duration for an actual full-body skin exam with or without a dermoscope was less than three minutes (Zalaudek et al., 2008).

Primary care providers do not feel confident in melanoma detection and are overburdened with addressing other health concerns (Jiang et al., 2017). The study talked about systematic and personal barriers to incorporating skin examinations in daily practice. One of the most common barriers was time constraint (Jiang et al., 2017). Other barriers included undressing a patient for the full-body skin exam, uncertainty about the lesions, and workload constraints (Jiang et al., 2017). Despite personal barriers, the study showed institutional barriers to implementing evidence-based intervention of melanoma screening. The barriers were lack of participant's enthusiasm, organization's culture, high cost of implementation, intensive time demands, and interaction among these factors (Jiang et al., 2017). Thus the findings supported that a provider's confidence and skills improvement are not enough;

planning and preparation at the institutional level are imperative for the successful implementation of melanoma screening.

In **s**ummary, **s**kin cancer screening is important; however, there are barriers and facilitators to skin cancer screening in a primary care setting. Even though time constraint is one of the common barriers to skin cancer screening, a randomized study showed a full-body skin exam takes 2.4 minutes and 1.1 minutes with and without a dermoscope, respectively, which is not significant as compared to the risk associated for melanoma (Zalaudek et al., 2008). Other barriers include lack of confidence level among primary care providers. Even though the curriculum on skin cancer screening showed improvement in the confidence level of the providers in detecting melanoma, providers may not be willing to complete the curriculum in a realistic situation in a clinic setting. The Quereux et al. (2012) study with the SAMScore utilized general providers who were not trained in diagnosing melanoma early. Thus the study concluded the SAMScore was a useful tool and could be used to identify patients at high risk for melanoma, and primary care providers may need to have special training to identify those patients. But, the training and education on melanoma and its screening are always a good resource to providers. Thus this scholarly project used a melanoma early detection provider toolkit as an optional resource for the providers instead of making the toolkit mandatory for providers, which could possibly act as a barrier to the project implementation.

Melanoma Screening Interventions

Several programs have been developed to teach primary care providers melanoma risk factors, diagnosis, biopsy, and referral. Commonly used programs are

a mastery learning program on melanoma, a melanoma early detection provider toolkit, and the informed curriculum.

Mastery learning program. Robinson et al. (2018) performed a randomized controlled trial to assess the efficacy of a mastery learning program at improving primary care providers' skills in visual and dermoscope inspection. The learning program had three units: visual and dermoscopic assessment, diagnosis and management, and deliberate practice (Robinson et al., 2018). The program was developed by a team of dermatologists, primary care providers, and medical educators over 11 months (Robinson et al., 2018). Of a total of 181 eligible primary care providers, only 90 providers were randomly chosen for the study (Robinson et al., 2018). They were divided into intervention and control groups. The control group was given the posttest after three months without education on melanoma (Robinson et al., 2018). The intervention group was given a personal identification number and a link to a program to complete the educational units (Robinson et al., 2018). An analysis of covariance was conducted to determine the efficacy of the intervention (Robinson et al., 2018).

The primary care providers in the intervention group answered more questions correctly on the posttest, had no false-negative identification of melanomas, and had fewer false-positives than the control group (Robinson et al., 2018). Furthermore, the primary care providers in the intervention group referred fewer benign lesions, greater melanoma lesions than the control primary care providers (Robinson et al., 2018). As a result, it may significantly reduce healthcare costs, decrease patient anxiety, and reduce the burden of physician visits (Robinson et al., 2018). The study also emphasized that opportunistic screening among at-risk patients improves the detection

of early melanoma without unnecessary expenses or procedures and the time burden for the patients (Robinson et al., 2018).

Informed curriculum (Internet curriculum for melanoma early detection). The informed curriculum was developed as an educational course for primary care providers with a grant from the Melanoma Research Alliance (Weinstock et al., 2018). The goal of the curriculum was to improve the detection of skin cancer by increasing physician knowledge and skills on melanoma (Weinstock et al., 2018). The curriculum consists of 10 case studies on the ABCDE of melanoma, ugly duckling signs, seborrheic keratosis, nodular melanoma, melanoma subtypes, melanoma risk factors, basal cell carcinoma, and dermoscopy (Weinstock et al., 2018).

The Internet curriculum for the melanoma early detection group developed an interactive and online skill-based skin cancer curriculum for primary care providers to improve confidence and skills for skin cancer detection (Jiang et al., 2017). The sample population consisted of 54 primary care providers from the two health maintenance organizations of the nine integrated health systems (Jiang et al., 2017). The training was offered as continuing medical education credits to the primary care providers. After the training, primary care providers completed a 30-minute feedback session on the curriculum by the focus group. Four main domains were discussed during the session: overall impressions of the curriculum, recommendations for improvement, current skin examination practices, and suggestions for increasing skin screening by primary care providers (Jiang et al., 2017).

The primary care providers thought that it was beneficial to their practice. The curriculum helped to increase their confidence level at recognizing and diagnosing melanoma and making appropriate referrals (Jiang et al., 2017). Some primary care

providers suggested the curriculum should be taught by experts (dermatologists) for questions and direct feedback.

Melanoma early detection provider toolkit. The study consisted of a self-paced online educational intervention for the providers regarding the melanoma screening using melanoma early detection provider toolkit from the Oregon Health and Science University (OHSU), Department of Dermatology (2001-2019). The written permission was received from the OSHU to utilize the toolkit for the project as an optional resource for the providers (see Appendix A). The toolkit has a total of six sections and takes approximately three to four hours for participants to complete (OHSU, Department of Dermatology, 2001-2019). The toolkit is online and is free to anyone wanting to learn more about melanoma. The six sections of the toolkit include pretest, screening and biopsies, visual identification of melanoma versus benign, INFORMED case-based skin cancer education, resources for patient education, and final evaluation (OHSU, Department of Dermatology, 2001-2019). The toolkit also provides continuing medical education for the participants. During the educational intervention, participants learn about melanoma, incidence and mortality of melanoma, screening recommendations for high risk patients, rapid full-body skin exams, best practices for biopsies, practice identifying melanoma or benign lesions, and how to educate patients on early detection and self-exams (OHSU, Department of Dermatology, 2001-2019). The OHSU, Department of Dermatology partnered with Knight Cancer Institute and launched a public campaign called Our War on Melanoma on May 18, 2019. The toolkit was designed with input from primary care and specialty providers in Oregon. The vision of the toolkit was to eradicate melanoma in Oregon by increasing early detection and treatment and prevent deaths, suffering, and

high costs related to the late stage of melanoma (OHSU, Department of Dermatology, 2001-2019). The toolkit has the following four objectives.

- Identify high-risk patients.
- Apply screening recommendations.
- Diagnose melanoma and non-melanoma skin cancer with increased accuracy.
- Educate patients using provided resources. (OHSU, Department of Dermatology, 2001-2019, Learning objectives section)

Summary. Several educational trainings are available to primary care providers to improve their skin cancer screening skills and confidence levels in diagnosing melanoma early. The length of the educational training plays an important role in having primary care providers complete the module. Most of the educational trainings on melanoma are approximately two to three hours or longer, which discourages providers from completing the training. As a result, they do not perform melanoma screening among their patient population; therefore, it is important educational training to be of reasonable length and have important information on melanoma. Also, standardized training programs on melanoma are lacking for primary care providers.

Conceptual Framework

Avedis Donabedian, a professor at the University of Michigan, School of Public Health, was born to Armenian parents in 1919 in Beirut, Lebanon, and was raised in Ramallah, Palestine (Ayanian & Markel, 2016). He attended medical school and became the director of the faculty and student health service of the American University in Beirut (Ayanian & Markel, 2016). In 1953, he received a scholarship to study epidemiology and health services administration at the Harvard School of Public

Health (Ayanian & Markel, 2016). In 1961, he joined the University of Michigan (Ayanian & Markel, 2016).

In 1966, Donabedian proposed a framework using a triad of structure, process, and outcome to evaluate healthcare quality. The structure was defined as the settings, qualifications of providers, and administrative systems through which care takes place (Ayanian & Markel, 2016). In other words, the structure reflects the attributes of the service or provider such as staff to patient ratios and operating times of the service (Achieving Community Transformation Academy, n.d.). The process was defined as the components of care delivered and the outcome was defined as a recovery, restoration of function, and survival (Ayanian & Markel, 2016). The process measures reflect how the systems and processes work to deliver the desired outcome such as patients receiving certain standards of care or staffs washing their hands (Achieving Community Transformation Academy, n.d.). The outcome measures reflect the impact of the process on patients and the end result of the improved process change such as reduced mortality, reduced the length of stay, reduced hospital-acquired infections, and improved patients experience (Achieving Community Transformation Academy, n.d.). The three proposed concepts are the foundation of the quality assessment in today's world. This concept has been used by the National Quality Forum, National Committee for Quality Assurance, and Medicare to assess the quality of healthcare (Ayanian & Markel, 2016).

A study was done to assess the quality of care for patients boarding in the emergency department and to recognize the potential solutions to improve quality using the Donabedian conceptual model (Liu, Singer, & Camargo, 2011). The structure included boarding in the emergency department such as physical

environment, providers' skill set/practice/distraction, nurses' skill set/distraction, and handoffs (Liu et al., 2011). The process resulting from the structure included limited observation of those patients, compromise in comfort from being in the holding area with loud noise and without privacy, diagnosis delay/error, and therapy delay/error (Liu et al., 2011). The outcome of the study included quality of care from two perspectives: patient and hospital. The patient perspective included safety (adverse events/errors, mortality, and morbidity), timely, patient-centered, effective, equitable, and efficient (Liu et al., 2011). The hospital perspective included liability and provider satisfaction (Liu et al., 2011). The study showed how the Donabedian model illustrated the impact of certain structural problems on processes leading to poor outcomes while providing care to boarded patients in the emergency department (Liu et al., 2011). It concluded that the model was useful as a practical framework to assess the quality of care of boarded patients in an emergency department so that an evidence-based solution could be implemented (Liu et al., 2011).

Kobayashi, Takemura, and Kanda (2011) conducted a study to know if patient experiences are related to nursing services based on Donabedian's approach. The study hypothesized that classifying patient experiences related to nursing service using Donabedian's approach would be useful in improving the quality of nursing care (Kobayashi et al., 2011). Patient experiences were classified under the structure, process, and outcome (Kobayashi et al., 2011). The structure consisted of the convenience of care, comfort of surroundings, and privacy (Kobayashi et al., 2011). The process consisted of the appropriateness of care procedures, patient–nurse interactions, and patient participation in the care process (Kobayashi et al., 2011). Outcomes of the study were changes in physical status, changes in patient knowledge,

and patient satisfaction (Kobayashi et al., 2011). A total of 2,571 participants were in this study with an approximate 78.5% response rate (Kobayashi et al., 2011). The study concluded that the Donabedian model was successful at classifying patient experiences related to nursing care (Kobayashi et al., 2011). As a result, this model can be utilized by the practitioners, managers, and policymakers at identifying causes and effects of nursing practice to improve quality (Kobayashi et al., 2011).

The Donabedian model acted as a foundation for this scholarly project (see Figure 1). The three components of the model will be discussed to improve patient outcomes of melanoma screening. It was used to identify patients at high risk for melanoma in a rural underserved primary care clinic. It assisted the project lead to assess the current structure and process of the clinic to melanoma screening and implement the evidence-based melanoma screening workflow algorithm to the current practice in order to improve patient outcomes.

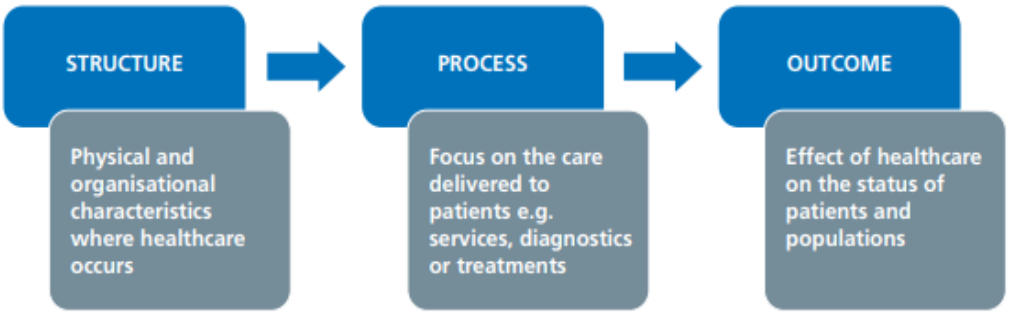

Figure 1. Donabedian model for quality of care.

Summary

To summarize, the recommendation for melanoma screening of risk populations varies across national and international organizations. Currently, there is a lack of a standardized melanoma screening recommendation, guideline, model, or tool to identify patients who are at high risk for melanoma. Due to the lack of a systematic approach and recommendation, melanoma is not identified and diagnosed early, causing a delay in the treatment and an increase in mortality and morbidity related to melanoma. Additionally, there are several identified barriers to melanoma screening leading to a lack of consistent screening in a primary care setting. Several tools and techniques are used to perform melanoma screening; however, barriers to melanoma screening must be addressed or minimized in order to incorporate melanoma screening in everyday practice in primary care settings. The Donabedian model acted as a foundation for this scholarly project in implementing a melanoma screening algorithm in a rural and underserved primary care clinic in Northern Colorado.

CHAPTER III

METHODOLOGY

Design

The Doctoral Nursing Practice (DNP) scholarly project is a quality improvement project. The project was carried out at one of the federally qualified health centers in a rural and small mountain community in northern Colorado. The health center had two full-time providers and five medical assistants who participated in the intervention to introduce the algorithm into the primary care setting. Out of the two full-time providers, one was the medical director and the other one was a physician assistant.

Setting

The project was implemented at one of the federally qualified health centers. This health center is the only such organization within a 30-mile radius that provides primary care services to publicly insured patients and to all community members, regardless of their ability to pay. The health center is in a rural mountain resort community with a population of approximately 7,000 permanent inhabitants, with only three healthcare organizations and one dermatologist serving the community. In 2018 the health center had a 1,910-patient population with 890 males and 1,020 females, among which 575 patients were Hispanics, 1,239 patients were Whites, and 96 patients were unreported.

The health center had two full-time family practice providers who participated in the project protocol. The two full-time providers and medical assistants provided verbal consent to participate in the project. The patients who participated in the scholarly project filled out a written consent (see Appendix B) prior to filling out the self-assessment of melanoma risk score (SAMScore) and participating in the project. The clinic manager and the medical director provided written permission to conduct the project at the clinic (see Appendix C), and the project lead obtained approval from the clinic Institutional Review Board and from the University of Northern Colorado Institutional Review Board (see Appendices D and E). The health center had a volunteer dermatologist who in the past use to see patients with melanoma until recently when he retired from the practice. Currently, no dermatologist was at the health center. Thus non-dermatologist providers had undertaken full responsibility for skin cancer and melanoma screening in the clinic, in addition to many other preventive and treatment interventions, as referring patients to a dermatologist for skin screening outside the system, which can be expensive and time-consuming. One dermatologist was seeing patients in the community where the clinic was located, and wait times for appointments could be three months or more.

Referrals to dermatologists outside of the community would require approximately an hour drive each way, imposing logistical and transportation barriers for patients. Since the health center served a low income and underserved population, cost is a huge barrier to seeing dermatologists for most patients. Patients cannot afford to go to or do not have access to dermatologists for melanoma screening or routine skin checking; thus primary care providers play an important role in regular melanoma

screening. It is vital that primary care providers assess patients for melanoma risk or suspicious lesions during their annual exam to catch melanoma early.

The rural mountain resort community had a population of approximately 6,352 with a median age of 58.6 in 2018 and median household income of $53,025 in 2017 (U.S. Census Bureau, n.d.). The population consisted of 98.2% Whites, 7.0% Hispanics or Latinos, and 0.8% two or more races with 6.92% of the people who spoke a different language other than English as their primary language (DataUSA, n.d.; U.S. Census Bureau, n.d.). Spanish was the second most common language spoken by the people in the community with a rate of 4.72% (DataUSA, n.d.). Approximately 12.3% of the total population in the community lived below the poverty line (U.S. Census Bureau, n.d.). In 2014, approximately 49% of males and 52% of females were in the community (U.S. Census Bureau, n.d.).

Sample

The project had two sample populations. The first sample population included the two full-time providers and five medical assistants at the health center who were presented with the evidence-based algorithm and screening tool and completed the survey questionnaires. The second sample population was the patients who qualified for evaluation for melanoma screening and whose charts were retrospectively reviewed as they met the criterion of presenting for an annual wellness visit during the specified duration of the project. The targeted sample duration for the adult patients was one month in the control group and one month in the intervention group. The primary care clinic saw approximately four to five wellness visits with new and established patients with approximately three to four patients who were English speaking in between the two providers in a day (H. Fields, personal communication,

May 13, 2019). Thus the total number of patients in the project was projected to be 60 to 80 during the intervention month.

Inclusion Criteria

The sample population for patients eligible for melanoma screening included adult patients aged 35 to 75 years presenting for their annual physical. Also, they were able to read and write in English in order to complete the SAMScore by self-report because the SAMScore had only been validated in the English and French languages. Also, the unvalidated and translated version of the tool may create difficulty with the interpretation of the results given a small and a non-homogenous sample size of the project.

Target Age Group for Skin Cancer Screening

The comparison of melanoma was done with the other cancers with the U.S. Preventive Services Task Force (2016) grading of A or B to determine the age range for melanoma to screen. The recommendations were based on the degree of certainty that the net benefit of screening was either substantial or moderately substantial even though the rationale for the screening age for other cancers was unclear (Johnson et al., 2017). Four cancers were chosen: colorectal cancer, cervical cancer, breast cancer, and lung cancer. First, the number of affected individuals with the above-mentioned cancers within the recommended age range was determined. Then, the screening age range for the cancers was associated with age-stratified incidence, mortality rates, median age at diagnosis, and total percentage of incidence rates falling within that age range (Johnson et al., 2017). Next, the number of affected individuals in each category for cancers was determined. The age range was very similar among the

grade A and B cancers, and it provided a reproducible approach to define a recommended age range for skin cancer screening (Johnson et al., 2017).

For this purpose, data from the National Cancer Institute's Surveillance, Epidemiology and End Results registry were used. The study showed that the initiation of screening occurs at an age in which the slope of the incidence and mortality curves are at or near the steepest incline, and screening ends at an age in which the incidence and mortality curves are at or near the steepest incline (Johnson et al., 2017). For melanoma, the steepest incline for the slope of the incidence and mortality curve was near age 35 years and the steepest decline was near age 77 years (Johnson et al., 2017). Furthermore, 70% of melanoma cases fell within the 35 to 74 years age range, 60% fell within the 45 to 74 years age range, and 86% fell within the 35 to 84 years age range with cases from 2008 to 2012 (Johnson et al., 2017). The U.S. Preventive Services Task Force (2016) suggested that the median age of diagnosis for melanoma to be 63 years which means that the range of possible initiation of screening should be somewhere between 35 and 51 years (Johnson et al., 2017). However, Johnson et al. (2017) suggested a slightly older termination of screening at age 77 years for melanoma with the initiation age being 35 years old. Johnson et al. stated that it seemed to be reasonable to have the screening age of 35 to 75 years for melanoma.

Exclusion Criteria

Patients were excluded who were younger than age 35 or older than 75 years old; were being seen for an acute problem and not for preventive care; and did not speak, read, and write English. Patients presenting for a Pap smear or well-woman care as a chief complaint were also excluded because, per the providers at the clinic

these visits usually do not provide enough time for non-female reproductive exams (H. Fields, personal communication, May 13, 2019). Providers usually did not perform any routine annual labs or address annual screenings such as colonoscopy during the Pap smear or well-women care visits. Patients are usually instructed to make other appointments for their annual physical, where annual screening labs can be discussed at length and can be followed up on as needed.

Project Mission, Vision, Objectives

Mission

The mission of the project was to pilot an evidence-based melanoma screening algorithm into annual visits in a primary care clinic. The project also aimed to assess and improve provider and clinical staff knowledge of and confidence in their ability to provide such screening as part of routine preventive care in this setting.

Vision

The vision of this project was to increase screening for melanoma in primary care in order to improve patient outcomes downstream. It is accepted that early detection reduces melanoma-related morbidity and mortality and primary care plays a crucial role in this process.

Specific Objectives of the Project

Melanoma screening can be incorporated into primary care, and it decreases the mortality and morbidity rate related to melanoma complications. The long-term goal of this scholarly project was to identify patients at high-risk for melanoma during adult wellness visits in a primary care setting using the evidence-based melanoma workflow algorithm (see Appendix F) to diagnose melanoma early for timely treatment in order to eventually decrease morbidity and mortality rates related to

melanoma and its complications. The specific objectives for the project were as follows:

1. Conduct a lunch and learn session to introduce the melanoma screening workflow algorithm to the providers and medical assistants at the clinic in mid-August 2019.
2. Implement a pilot of evidence-based melanoma workflow algorithm for primary care providers and medical assistants to identify patients at high risk for melanoma at the clinic during the months of August and September 2019.
3. Appraise the number of patients identified as high risk for melanoma during the intervention month of August or September and compare it to the control month of April at the end of September 2019.
4. Appraise the number of patients who were positive and negative for SAMScore and interventions for the ones with a positive SAMScore by performing retrospective chart review in September 2019.
5. Report an increase in the intention among providers and medical assistants of using the evidence-based algorithm in clinical practice compared to prior to the implementation of the algorithm.

Project Plan

An informal meeting was held with the medical director and the manager of the primary care clinic to discuss general screening needs for the population at the clinic. The providers at the clinic followed the screening recommendations and guidelines from the U.S. Preventive Services Task Force (2016) for the majority of the screening such as colorectal screening, cervical cancer screening, and breast cancer

screening. The project lead expressed interest in melanoma screening and the importance of melanoma screening in a primary care clinic by primary care providers. It was mutually agreed that melanoma screening was important and could benefit the population of the clinic. Primary care providers expressed that one of the major barriers to melanoma screening was the time and co-morbid conditions of the patients such as diabetes, hypertension, hyperlipidemia, and thyroid issues at the clinic. Primary care providers were highly qualified and knowledgeable in melanoma screening. They agreed that melanoma screening could be incorporated into the current practice to identify patients at high risk for melanoma; however, the barriers to melanoma screening such as time and medical complexity should be considered.

Melanoma Screening Algorithm Development

After the initial interview with the medical director and manager, it was determined that the first step of the project would be to develop an algorithm for the providers and staff to easily determine changes in the workflow to incorporate the more intentional, evidence-based melanoma screening in the clinic. Steps of the algorithm development included an exhaustive literature review to determine the best risk prediction models, melanoma screening tools and techniques, barriers to melanoma screening and implementation of the risk prediction models, tools and techniques, and melanoma screening interventions that could be utilized to integrate melanoma screening in a primary care setting by the primary care providers. After the review, the project lead generated a draft algorithm to be reviewed by the experts and clinic staff/providers. The draft algorithm was reviewed by the medical director of the clinic and three advanced practice nurse practitioners to determine the validity and

feasibility of the algorithm and identify any potential issues with the workflow prior to the pilot of the project. Once the validity of the algorithm was determined, the algorithm was introduced to the staff at the clinic in August 2019 and piloted during the months of August and September 2019.

Staff and Provider Education

A lunch and learn session was held at the clinic to inform the medical assistants and providers about the project, algorithm, outcomes measures, and plan of the project. The link to the melanoma early detection toolkit for the providers (Oregon Health and Science University [OHSU], Department of Dermatology, 2001-2019) was provided to the providers as an optional available resource to melanoma screening and was an open-access resource. However, providers at the clinic were fully licensed and were presumed to be proficient at melanoma screening, so evaluation of the participation in the education intervention and clinical knowledge of the providers was not evaluated in this scholarly project.

The scholarly project utilized the SAMScore for melanoma screening as an initial screening tool that was filled out by the patients while they were waiting for the providers in the exam room. Dr. Brigitte Dreno was contacted via e-mail at the skin cancer unit at Nantes University Hospital in France, and written consent was given to utilize the tool for the project (see Appendix F). The lunch and learn session was held for the providers and medical assistants approximately one week prior to the implementation of the project. The duration of the lunch and learn session was approximately 20 minutes with an additional 10 minutes for questions regarding the project. The lunch and learn session included information on melanoma, mortality and morbidity rate of melanoma, benefits of melanoma screening on high-risk

individuals, melanoma screening algorithm, and role of medical assistants on giving the SAMScore to high-risk patients with annual visits.

The following objectives were developed by the project lead for the lunch and learn session at the rural and underserved federally qualified health center:

1. Providers would be able to identify the three criteria needed for the SAMScore to be positive by the end of the lunch and learn session.
2. Providers would be able to recognize the international classification of diseases (ICD) 10 diagnosis code for melanoma screening by the end of the lunch and learn session.
3. Providers would be able to list the keywords for the plan section of the subjective, objective, assessment, and plan note for a positive SAMScore by the end of the lunch and learn session.
4. Providers would have an increase in the intention of utilizing the evidence-based algorithm by the end of the lunch and learn session.
5. Medical assistants would be able to outline the inclusion and exclusion criteria for the participants of the study by the end of the lunch and learn session.
6. Medical assistants would be able to summarize the steps on what to do with the SAMScore after the provider had reviewed it by the end of the lunch and learn session.

Pilot Algorithm Implementation

One week from the lunch and learn session the algorithm, together with the SAMScore, was implemented during the annual visits of all patients between the age

range of 35 to 75 years old and were English speakers only, as there was not a validated Spanish-language version of the SAMScore tool available.

Since the SAMScore saves time and, therefore, reduces barriers for clinic staff to identifying patients at risk for melanoma by using self-report questionnaires, patients who had a limited ability to read and write were excluded from the post-intervention group as the evidence-based algorithm requires patients to read and complete the SAMScore questionnaire independently before being treated by the provider. The two providers were given a no signature consent form (see Appendix G). The medical assistants completed the individual investigator agreement form to be covered under the Institutional Review Board (see Appendix H). The medical assistants identified annual wellness visits that met the inclusion criteria for the project. After patients were checked in by the front desk staff and were roomed by the medical assistants, patients were asked if they were willing to participate in the project by the medical assistants. Patients who agreed to participate in the project signed the consent form (see Appendix B) prior to filling out the SAMScore (see Appendix I). The medical assistants then gave the SAMScore to the consented patients to fill out while they were waiting to be seen by the providers in the exam room. The medical assistants instructed patients not to put any patient identifiers such as name, age, gender, or ethnicity in the SAMScore for privacy purposes. The SAMscore was completed by the patients while they were waiting to be seen by the providers in the exam room. Based on the decision tree algorithm, the providers then identified patients at risk for skin cancer and decided if a targeted or full-body skin exam was warranted. If the patient met the criteria for risk for melanoma skin cancer based on their SAMScore or if the patient had concerns about a lesion meeting the ugly

duckling or asymmetry, border irregularity, color that is not uniform, diameter greater than 6 mm, and evolving size, shape or color (ABCDE) criteria, providers were instructed to document a diagnosis code for screening for melanoma or encounter for screening of malignant neoplasm of skin as ICD 10 code Z 12.83 in the patient chart. Next, providers documented any intervention plan related to the skin cancer or melanoma screening diagnosis, including but not limited to the keywords annual skin cancer exam or biopsy or referral to dermatology or primary prevention. The completed SAMScore was collected by the medical assistants and copies of the SAMScore were made. The original completed SAMScore was filed separately in a secure folder behind the nurse's desk for the project lead to collect. The copied SAMScore was scanned into the patient's electronic health records. The project lead accessed the charts of the patients who met the inclusion criteria but only reviewed the charts of patients who had consented to participate in the project and had filled out the SAMScore. The connection between the patients who completed the SAMScore and their electronic health record was not made since the completed SAMScore did not get scanned into the electronic health record.

The consent forms were stored separately in a confidential folder in a secure area behind the nurse's desk. The agreement forms and consent forms were collected and transmitted to the University of Northern Colorado and will be stored at the School of Nursing in the Scholarly Project Advisor's office in a locked space for three years before they are destroyed.

The SAMScore was printed in a bright-colored yellow paper with an ordered number (no patient identification was used) written on the top of the sheet so the project lead could keep track of all the screening tools filled out by the patients. The

patients would fill out the SAMScore and have it reviewed by the providers. After the SAMScore was reviewed by the providers, the bright yellow SAMScore paper was then copied without the patient's identifiers by the medical assistants for the project lead to collect at the end of the project. The copy was scanned into the electronic health record. The original bright yellow color paper with the SAMScore was set aside by the medical assistants in a confidential folder in a secure area at the back of the nurse's desk for the project lead to collect. All the collected data on the SAMScore were confidential. No patient identifiers were included.

Retrospective Chart Review

The project lead performed a retrospective chart review of the patients for the control month of April 2019. According to the medical director and manager of the clinic (H. Fields and M. Dungan, personal communication, July 3, 2019), the electronic health system at the clinic did not have the ability to pull data on melanoma or skin cancer screening without patient identifiers. Also, the primary complaint of the visit varied depending on the subjective and objective information during the appointment, and the providers end up doing annual screening labs and preventive screenings even though the primary complaint was not an annual wellness visit (H. Fields and M. Dungan, personal communication, July 3, 2019). Thus the medical director and the manager at the clinic recommended that the project lead review each patient chart between ages 35 to 75 years seen by the two providers during the month of April 2019 irrespective of the type of the visit to obtain accurate data on the number of melanoma screening. The project lead utilized a binomial method (yes/no) while reviewing the charts of the patients for melanoma or skin cancer screening (see Appendix J). During the implementation of the project, it was identified that further

data were necessary to make the project stronger and robust; thus an addendum to the Institutional Review Board of the University of Northern Colorado was submitted and approved on September 12, 2019 (see Appendix K). After the approval from the Institutional Review Board, the total number of annual wellness and established care visits were collected for the control month of April 2019.

Intervention Chart Review

The chart review was done for the patients who consented (see Appendix B) to the project during the intervention month by the project lead. The scanned SAMScore in the chart of the patients was reviewed and matched with the original SAMScore as identified by the numbers on the top of the scanned SAMScore. Then, the chart was reviewed for diagnosis in the assessment section and keywords in the plan section of the subjective, objective, assessment, and plan note. The project lead identified the number of patients with a positive and negative SAMScore. The project lead also compared the number of melanoma screenings to identify at-risk patients during the intervention month (August/September 2019) to the control month (April 2019). The intervention chart review (see Appendix L) collected data on age, gender, number of patients positive for SAMScore, number of patients negative for SAMScore, number of patients with a melanoma screening ICD 10 code, number of patients with keywords in the plan note section, and number of patients who received intervention or education. The addendum to the Institutional Review Board of the University of Northern Colorado was submitted and approved on September 12, 2019. As a result, the total number of annual wellness visits, establish care visits, and the number of the patients eligible and not eligible to participate in the study were also collected for the intervention months of August/September 2019.

The data collected from the retrospective and intervention chart review were stored in an encrypted file with a password, and the project lead was the only holder of the password. Those data were destroyed at the end of the implementation of the project.

Education Evaluation

The survey questionnaires were administered to the providers and medical assistants before and after the lunch and learn session. The two providers and the five medical assistants were given a no signature consent form. The providers and medical assistants were asked to provide survey identification that included a numerical format of their birthday month and date. The pre-survey questionnaire for the providers (see Appendix M) assessed the providers' intention of screening patients for melanoma or utilizing toolkits to help them in assessing and diagnosing melanoma and if they had heard or learned about SAMScore. The post-survey questionnaire for the providers (see Appendix N) assessed their intention to use the algorithm and toolkit, understanding of the SAMScore, risk factors to be considered at high risk for melanoma, ICD 10 code, and keywords for the plan section of the subjective, objective, assessment, and plan note. It also had a space to give comments and feedback on barriers to screening, the algorithm, and/or their experiences with skin cancer screening during preventive primary care. The post-post-survey questionnaire for providers (see Appendix O) was used at the end of the implementation of the project to assess if the staff at the clinic intended to utilize the algorithm for melanoma screening for the annual wellness visits in the following months. The post-post-survey questions for the providers assessed their intention of utilizing the algorithm to screen for melanoma in the future and open-ended questions on their feedback to the project. The pre-survey questionnaire for the medical assistants (see Appendix P) assessed if

they had learned or heard about the SAMScore and specific questions about the SAMScore. The post-survey questionnaire for the medical assistants (see Appendix Q) assessed their knowledge of the inclusion and the exclusion criteria for the participants of the project and their role with the completed SAMScore. It also had a space to provide written comments to the open-ended questions. The survey questionnaire was confidential and anonymous. The survey questionnaire was stored in a confidential folder inside the office of the medical director of the clinic and was destroyed at the end of the project implementation. The medical director of the clinic and the project lead were the only two people with access to those survey questionnaires.

It was expected that the staff and providers would be able to choose the correct answers in the post-survey questionnaire after the lunch and learn session. Feedback was used to evaluate the lunch and learn session and make changes to the implementation plan or algorithm as needed prior to the implementation of the algorithm in August/September 2019. The feedback obtained in the post-post-survey question was utilized to provide the direction to improve melanoma screening in the future. Table 1 shows a summary of this project using the Donabedian framework.

Table 1

Summary of Project

Time	Structure	Process	Outcomes (patient focused)
Current	2 family practice providers & 5 medical assistants FQHC Rural and underserved patient population No formal training or education on melanoma screening Historically, there was a dermatologist who volunteered, but now he has retired, and PCP are responsible for all screening. There are 1-2 dermatologists in the community with wait list at least 2-3 months.	No protocol to screen patients with melanoma Melanoma screening at provider's discretion depending on subjective and objective information.	Currently, average number of patients screened for melanoma is approximately 3 per month between two full time providers (H. Fields, personal communication, May 21, 2019)
Proposed changes	Lunch and learn session regarding melanoma screening workflow algorithm for 2 full time providers and 5 medical assistants. Make changes to the implementation plan and algorithm from the feedbacks prior to implementation of the scholarly project in August/ September 2019	Development of melanoma screening protocol from exhaustive literature and expert review. Medical assistants will identify patients to give the bright yellow sheet of paper with SAMScore who meet above mentioned inclusion and exclusion criteria. Medical assistants will ask patients and have patients sign the consent form prior to having them fill the SAMScore Medical assistants will instruct patients to complete the SAMScore while waiting to be seen by the providers and not to write any patient identifiers such as name, age, gender, and ethnicity on the sheet. Providers will review the sheet and determine if the patients are at risk for melanoma based on positive SAMScore and/or meeting at least one of the 3 criteria After patients fill out the SAMScore, sheet will be copied and put aside in an envelope for the project lead; copied sheet will then be scanned into patient's medical record. For positive SAMScore, providers will document a relevant ICD 10 diagnosis Z12.83 as screening for melanoma or encounter for screening of malignant neoplasm of skin and keywords in the plan section of the SOAP note: annual skin cancer exam or biopsy or referral to dermatology or primary prevention. For negative SAMScore, providers will counsel patients on sunscreen and exposure and provide handout from the American Academy of Dermatology.	Increase in the number of melanoma screening at high risk patients age 35-75 years old compared to control month through retrospective chart review. Increase in the number of referrals to dermatology or biopsy or education on ongoing care. Increase in the intention and attitude of providers and medical assistants to utilize algorithm at the clinic in the future.

Table 1 (continued)

Time	Structure	Process	Outcomes (patient focused)
Proposed outcomes (evaluation of changes)	The survey questionnaires for providers and medical assistants will demonstrate an increase in knowledge regarding the use of the evidence-based melanoma algorithm and its implementation after the "lunch and learn" session.	Melanoma screening algorithm will be incorporated into the care of patients during their well visits as determined by chart review of consented patients. Providers will provide diagnosis code and plan in the SOAP note for those patients who have positive SAMScore and will be screened for melanoma as evidenced in the chart review of consented patients.	90% of consented patients who meet the inclusion and exclusion criteria will complete SAMScore. 75% of consented patients who score positive on the SAMScore will have ICD 10 code and keywords listed in the plan section of the electronic health records. 75% of consented patients who score negative on the SAMScore will have evidence of patient education provided in their electronic health record.

Note. FQHC = federally qualified health center; ICD = international classification of diseases; PCP = primary care physician; SAMScore = self-assessment of melanoma risk score; SOAP = subjective, objective, assessment, plan.

Instrumentation

The project used two instruments: the SAMScore and survey questionnaires.

Self-Assessment of Melanoma Risk Score

The SAMScore has seven question based on the risk factors for melanoma: skin type, freckles, history of severe blistering sunburn as a child or adolescent, living in a country with intense sun exposure, personal history of melanoma, and first degree relative with melanoma (Quereux et al., 2012). The patient is considered positive for a SAMScore if any one of three criteria is met. The first criteria is presence of at least three risk factors out of the seven risk factors, the second criteria is patients younger than 60 years old with more than 20 melanocytic nevi on both arms, and the third criteria is patients older than 60 years old with freckling tendency (Quereux et al.,

2012). The SAMScore is the tool that was filled out by patients who met the inclusion criteria. It was printed on bright yellow paper with ordered numbers written on the top of the paper to avoid misplacement of the completed SAMScore (no patient identification was used). The tool had instructions for the patients not to put any patient identifiers on the sheet such as name, date of birth, or gender. After the SAMScore was completed by the patient, the provider reviewed the tool and evaluated if the patient had any one of the three criteria. If the patient had any one of the three criteria, it alerted the provider that the patient was at high risk for melanoma, and thus a skin exam was warranted. If the patient did not have any one of the three criteria, then the providers educated the patients on the primary interventions for melanoma and gave them the handout from the American Association of Dermatology (see Appendices R and S). The completed SAMScore was then copied. The copied SAMScore was scanned into the electronic health record, and the original SAMScore was set aside in a confidential folder behind the nurse's desk for the project lead to collect.

Survey Questionnaire

The survey questionnaires (see Appendices M, N, O, P, and Q) were developed by the project lead to assess the current practice for melanoma screening at the rural and underserved primary care clinic and staff knowledge on the melanoma screening workflow algorithm for providers and medical assistants (see Appendices T and U). The questionnaires were given to the providers and medical assistants before and after the lunch and learn session. The questionnaires were de-identified with a numerical format of their birthday month and date. The pre-survey questionnaire for the providers (see Appendix M) had a total of nine questions with one open-ended

question. Out of nine questions, five questions were scored as binomial with four yes/no questions, one true/false question, and three questions were multiple-choice with two open-ended questions. For the pre-survey, question 5 was scored as correct if they answered three as the number of risk factors. Question 6 was scored as correct if they answered three choices "at least 3 of the 7 risk factors, younger than 60 with more than 20 nevi on both arms and older than 60 with freckling tendency." For question 7, the question was scored as correct if they answered "yes" and incorrect if they answered "no." The post-survey questionnaire for the providers (see Appendix N) had a total of five questions with two yes/no questions, one true/false question, two multiple-choice questions, and one open-ended question. For the post-survey, question 2 was scored as correct if they answered three as the number of risk factors. Question 3 was scored as correct if they answered three choices "at least 3 of the 7 risk factors, younger than 60 with more than 20 nevi on both arms and older than 60 with freckling tendency." Question 4 was scored as correct if they answered "yes" and incorrect if they answered "no." The post-post-survey questionnaire for the providers (see Appendix O) had a total of two yes/no questions and one open-ended question. The pre-survey questionnaire for the medical assistants (see Appendix P) had a total of six questions with two yes/no question, two multiple-choice questions, and two open-ended questions. The post-survey questionnaire for the medical assistants (see Appendix Q) had a total of four questions with one true/false, two multiple-choice questions, and one open-ended question. For the true/false question, the question was scored as correct if they answered "yes" and incorrect if they answered "no." For the multiple-choice questions, the inclusion criteria for the patients to have a SAMScore was scored as correct if they answered three choices "patients aged 35-75 presenting

for their annual physical, able to read, write and speak English, English and Spanish speakers." The exclusion criteria for the patients to not have a SAMscore were scored as correct if they answered two choices, "patients younger than 35 and older 75 for acute visits and well women visits."

Analysis

For the retrospective chart review, descriptive statistics, including frequency and percentage, were used to describe the total number of annual visits and total number of melanoma screenings over the control month. For the intervention chart review, descriptive statistics, including frequencies and percentages, were used to describe the total number of annual wellness visits, total number of establish care visits, total number of consented patients, total number of completed SAMScores by the consented patients, total number of patients positive and negative SAMScores, total number of patients with melanoma screening as evidenced by the ICD 10 code and keywords in the plan section, and total number of patients receiving interventions after melanoma screening.

Analysis of the pre-, post-, and post-post-survey questionnaire was completed using the descriptive statistics with percentages and frequencies.

Duration of the Project

An extensive literature review was performed during the months of February and March to develop a draft evidence-based algorithm for melanoma screening with an annual physical by primary care providers in a primary care setting. The algorithm was validated to use for the ease of use, clarity, and accuracy by one medical doctor and three advanced nurse practitioners prior to the implementation of the scholarly project. Then implementation of this project began with the lunch and learn session

with survey questionnaires to the providers and medical assistants during the month of August 2019. The clinic team was asked to utilize the algorithm and SAMScore questionnaires starting August 7 until September 6, 2019, for a period of one month. The project lead retrospectively reviewed the charts of patient visits meeting inclusion criteria that occurred during the control or comparison month (April) and the intervention month (August 7 until September 6) and anticipated the completion of the chart review by September 2019. The number of melanoma screenings over the month of August 7 and September 6 were compared to the number of melanoma screenings over the month of April.

Ethical Considerations

The scholarly project is a quality improvement project. The goal of the scholarly project was to increase the number of patients identified as high-risk for melanoma in the population of the primary care clinic using the project lead's evidence-based melanoma screening workflow algorithm. Even though the project involved the SAMScore tool that was completed by the patients, it was de-identified for privacy purposes for the project lead to collect. The pre-, post-, and post-post-survey questionnaire from the providers and staff at the clinic were confidential and de-identified as well. The risks for the participants of the project were minimal. Risks included potential patient embarrassment to undress or lift clothing for providers to assess the skin for melanoma or skin cancer. The project would benefit the clinic and the patient population as this project specifically evaluated an intervention that would improve access to evidence-based skin cancer screening in the setting in which the project was being performed. This project was submitted for review and approval

through the institutional review boards of the primary care clinic and the University of Northern Colorado to evaluate any risks to the participants.

Project Limitations

One of the biggest limitations of the scholarly project was language. The SAMScore is a self-reported tool and only available in the English and French languages, not available in the Spanish language, and was not validated in the Spanish language; thus the tool could only be administered to those able to read, write, and speak English. Also, the clinic was a very small rural clinic with only two full time providers and five medical assistants. Thus the number of staff and providers was another limitation of the scholarly project. Further study is needed to see if the SAMScore can be translated and validated in different languages and implemented in a bigger clinic with a greater number of providers

CHAPTER IV

DATA ANALYSIS AND RESULTS

The overarching aim of the Doctor of Nursing Practice (DNP) scholarly project was to identify patients at high-risk for melanoma during the adult wellness visits in primary care by primary care providers using the evidence based self-assessment of melanoma risk score (SAMScore) and melanoma workflow algorithm in order to decrease mortality and morbidity rate related to melanoma and its complications. The DNP scholarly project was submitted and approved by the institutional review boards of the University of Northern Colorado and the project clinic site on the first week of August 2019. The project implementation was started on August 7, 2019, and ended on September 6, 2019.

Survey Questionnaires

The lunch and learn session was held in the conference room at the clinic. The two sessions were held separately for the five medical assistants and the two providers. The pre-survey questionnaires were given to the five medical assistants and the two providers prior to the presentation. The medical assistants and providers were instructed to write the numerical format of their birth month and day on the pre-survey questionnaires and post-survey questionnaires. All the medical assistants and providers found the presentation informative and stated that they were excited to start the project and see the result of the project. It was mutually agreed between the two providers and the five medical assistants that the project would be implemented on the

same day after the lunch and learn session. After the completion of the lunch and learn session, two separate folders were made for the completed consent forms and SAMScore and stored in a secure area behind the nurse's desk. Any questions regarding the inclusion and exclusion criteria of the project were answered.

Pre-Survey Questionnaires
For Medical Assistants.

Out of the five medical assistants, only one medical assistant had heard about SAMScore because he/she had worked with a dermatologist in the past at the same clinic who had recently retired. There were two other medical assistants who stated that they had heard or learned about the SAMScore, but they wrote in parenthesis as "during the presentation" (see Table 2). Four medical assistants correctly answered the inclusion criteria for the patients to receive the SAMScore, which were patients between 35 to 75 years old presenting for their annual physical and able to read, write, and speak English. Three medical assistants did not answer the exclusion criteria of the scholarly project incorrectly. One medical assistant did not answer the exclusion criteria. All five medical assistants correctly answered their role with the completed SAMScore filled by the patients (see Table 3). None of them had any feedback or suggestions for melanoma screening in primary care in the pre-survey questionnaires.

Table 2

Pre-Survey Questionnaires for Medical Assistants (Yes/No)

Item	Yes no.	Yes %	No no.	No %
Heard or learned about self-assessment of melanoma risk score (SAMScore) for melanoma screening	3	60	2	40

Table 3

Pre-Survey Questionnaires for Medical Assistants (Correct/Incorrect)

Item	Correct no.	Correct %	Incorrect no.	Incorrect %
Inclusion criteria for the patients to have the self-assessment of melanoma risk score (SAMScore)	4	80	1	20
Exclusion criteria for the patients to have the SAMScore	1	20	3	60
Identified the role of medical assistants with the completed SAMSore by the patients and placing the copied SAMcore to be scanned into the electronic health record and original SAMScore in a secure folder to the project lead to collect	5	100	0	

Post-Survey Questionnaires
For Medical Assistants

After the lunch and learn sessions, all five medical assistants were able to correctly answer the inclusion criteria for the patients to have the SAMScore and their

role in making a copy of the completed SAMScore so that the copied SAMScore can be scanned into the medical records and original SAMScore can be set aside for the project lead to collect. Only three medical assistants correctly answered the exclusion criteria for the patients not to have the SAMScore (see Table 4). Those medical assistants who did not answer the exclusion criteria correctly were re-educated on the inclusion and exclusion criteria prior to the implementation of the project. Also, a note with the inclusion and exclusion criteria was taped at the nurse's desk. None of the medical assistants had any feedback or suggestions for melanoma screening in primary care.

Table 4

Post-Survey Questionnaires for Medical Assistants (Correct/Incorrect)

Item	Correct no.	Correct %	Incorrect no.	Incorrect %
Inclusion criteria for the patients to have the self-assessment of melanoma risk score (SAMScore)	5	100	0	
Exclusion criteria for the patients to have the SAMScore	3	60	2	40
Identified the role of medical assistants with the completed SAMSore by the patients and placing the copied SAMcore to be scanned into the electronic health record and original SAMScore in a secure folder to the project lead to collect	5	100	0	

Pre-Survey Questionnaires for Providers.

Both providers answered that they did not routinely screen patients for melanoma and did not have a systematic method to screen patients for melanoma regardless of the visit types.

On average, the percentage of the people screened for melanoma at the clinic was about 25% according to both providers. Both providers had not heard or learned about melanoma prior to the presentation. One provider did not answer the question specific to the SAMScore for the number of risk factors to make a positive SAMScore. The other provider answered both questions incorrectly. Both providers were aware that the international classification of diseases (ICD) 10 code and keywords would be used by the project lead to evaluate the objectives of the scholarly project. One provider had heard about the melanoma screening toolkit for providers and another provider had not heard or learned about any toolkit for melanoma screening (see Table 5). Both providers intended to use the melanoma early detection toolkit as a resource for melanoma screening that was provided by the project lead.

Table 5

Pre-Survey Questionnaires for Providers (Yes/No)

Item	Yes no.	Yes %	No no.	No %
Do you currently screen patients for melanoma during their annual wellness visits?	0		2	100
Heard or learned about self-assessment of melanoma risk score (SAMScore) for melanoma screening?	0		2	100
Heard or Learned about melanoma early detection provider toolkit through Oregon Health and Science University (OSHU) or any toolkit for melanoma screening?	1	50	1	50
Intend to use melanoma early detection provider toolkit as a resource for melanoma screening?	2	100	0	

Both providers provided comments to the open-ended question in the pre-survey questionnaire. One provider commented that time was the biggest barrier in performing melanoma screening and a 20-minute appointment time was not adequate; thus a second visit was needed for melanoma screening. Another provider commented that time, multiple competing health conditions, and lack of a standardized practice recommendation on melanoma screening are some of the barriers to melanoma screening (see Tables 6 and 7).

Table 6

Pre-Survey Questionnaires for Providers (Percentage)

Item	100%	75%	50%	25%		0%
				no.	%	
Percentage that approximates the number of patients currently screened from melanoma	0	0	0	2	100	0

Table 7

Pre-Survey Questionnaires for Providers (Correct/Incorrect)

Item	Correct		Incorrect	
	no.	%	no.	%
Number of risk factors on the self-assessment of melanoma risk score (SAMScore) to the patients to be considered at risk for melanoma	1	50	1	50
Criteria for positive SAMScore	1	50	1	50
International classification of diseases ICD10 code and keywords will be used to evaluate the objectives	2	100	0	

Post-Survey Questionnaires for Providers

Both providers intended to utilize the SAMScore and evidence-based algorithm in their practice to increase the number of melanoma screening among annual wellness visits after the lunch and learn session. Out of the two providers, one

provider was able to correctly identify the number of the risk factor for positive SAMScore. The same provider was able to recognize the ICD 10 code and keywords to evaluate the objectives of the scholarly project. Also, both providers were willing to utilize the melanoma early detection provider toolkit as a resource for melanoma screening. Both providers provided comments to the open-ended question in the post-survey questionnaire. One provider commented that time constraints of the appointment as a barrier to melanoma screening in primary care. The other provider stated, "This seems like it will be helpful—look forward to piloting this" (see Tables 8 and 9).

Table 8

Post-Survey Questionnaires for Providers (Yes/No)

Item	Yes		No
	no.	%	
Intend to change your current practice for melanoma or skin cancer screening by incorporating self-assessment of melanoma risk score (SAMScore) or evidence-based melanoma algorithm?	2	100	0
Intend to use melanoma early detection provider toolkit as a resource for melanoma screening?	2	100	0

Table 9

Post-Survey Questionnaires for Providers (Correct/Incorrect)

Item	Correct no.	Correct %	Incorrect no.	Incorrect %
Number of risk factors on the self-assessment of melanoma risk score (SAMScore) to the patients to be considered at risk for melanoma	1	50	1	50
Criteria for positive SAMScore	1	50	1	50
International classification of diseases (ICD) 10 code and keywords will be used to evaluate the objectives	2	100	0	

Post-Post-Survey Questionnaires for Providers

The post-post-survey was given a week after the last day of implementation. Both providers replied that they intend to continue to screen patients for melanoma during the annual wellness visits and use the melanoma screening algorithm or melanoma early detection provider toolkit as a resource for melanoma screening in the future (see Table 10).

Table 10

Post-Post-Survey Questionnaires for Providers

Item	Yes no.	%	No
Intend to continue to screen patients for melanoma or skin cancer during the annual wellness visits	2	100	0
Intend to use the melanoma screening algorithm or melanoma early detection provider toolkit as a resource for melanoma screening	2	100	0

One of the providers said that the questionnaires in the SAMScore expedited the history taking to identify patients at risk for melanoma reducing the time to ask those questions, which was identified as one of the barriers to the melanoma screening at the clinic in the past. The provider added that "the SAMScore was a great conversation starter even for non-melanoma skin cancer." Furthermore, patients who consented to the study and filled out the SAMScore really liked the format, the SAMScore, and the primary prevention handout from the American Academy of Dermatology. The provider stated that the SAMScore was a great tool, and it would be great to have it validated in the Spanish language in the future. The provider reported, "I would like to continue the study for a longer time and would love to repeat the study in an electronic medical record with data analytics capability [EPIC] for the ease of the study."

The other provider felt that the duration of the study was short, and the exclusion criteria of the study were too restrictive since the clinic had several non-

English speaking patients. The provider commented that the project lead did a great job involving the staff of the clinic. The provider added that the study was well designed and increased awareness among the patients and providers on skin cancers. As a result, the provider screened and performed two biopsies during the intervention month among the patients who did not meet the criteria for the study but needed the screenings.

Implementation of the Project

Implementation of the quality improvement project started on the day of the lunch and learn session upon agreement between the project lead, the two providers, and the five medical assistants. Two separate folders were made by the project lead to collect completed consent forms and SAMScore. The folders were placed in a secure place behind the nurse's desk. A week after the implementation of the project, an e-mail was sent to the two providers with a link to the melanoma early detection provider toolkit as a resource for melanoma screening. It was decided that additional data on the number of annual visits and establish care visits for the control month of April 2019 would make the scholarly project robust. Also, additional data on the number of annual visits, establish care visits, and the percentage of patients who participated in the study and did not participate in the study for the intervention month of August/September 2019 would be important. Thus an addendum to the data collection process was submitted and approved by the Institutional Review Board of the University of Northern Colorado on September 12, 2019.

Throughout the implementation of the project, the medical director and the project lead were in contact via telephone updating the project lead on the implementation process and the number of screened patients. The medical director

and the staff of the clinic continued to give feedback on the project. There were a total of 10 patients who met the inclusion criteria for the project and only nine completed a SAMScore. Out of nine completed a SAMScore, one was completed outside the implementation month; thus it was not included in the result of the project. Also, one patient did not consent to participate in the study but completed the SAMScore.

Retrospective Chart Review

The retrospective chart review for the control month of April 2019 was performed after the implementation of the project (see Table 11). There were a total of 279 patients who were seen at the clinic during the month of April 2019 between the two providers. Among the total number of patients, there were nine annual well visits and 18 establish care visits during the control month of April 2019 between the two providers. Among the nine annual wellness visits, there was one well-woman visit and two well-child checkups. Among the 18 establish care visits, there was one well-woman visit, one well-child checkup, and four acute problem visits. There were only two patients who were screened for melanoma or skin cancer during the visit because both had skin concerns and had a skin check as their chief complaint of the visit. Three patients had a history of melanoma, but it was not the primary diagnosis or chief complaint during the visit of April 2019.

Table 11

Retrospective Chart Review of April 2019

Total patients no.	Annual visits no.	Establish care visits no.	Melanoma screenings no.
279	9	18	2

Intervention Chart Review

The intervention chart review was started during the middle of the implementation month September 2019. There were a total of 404 patients who were seen at the clinic in between the two providers (see Table 12). Among those patients, there were 40 annual wellness visits and 29 establish care visits. Among the 40 annual wellness visits, there were 18 sports physicals, nine well-child checkups, and two well-women visits. Among the 29 establish care visits, there were four visits that turned into acute problem visits, one well-child checkup, and one well-woman visit. There were 10 patients who were at the clinic for annual or establish care visits, between ages 35 to 75 years, and able to read, write, and speak in English, making them eligible to participate in the scholarly project. Out of 10 patients, only eight patients consented to participate in the study and completed the SAMScore. There was one extra consent form from a patient to participate in the study; however, it was done on September 11, 2019, which was outside the intervention period. The SAMScore was negative for melanoma risk for that patient. That consent form and the SAMScore were not included in the result. Also, there was one extra SAMScore

without a consent form, which showed that the patient who filled out the SAMScore was negative for melanoma risk. Among the total of annual and establish care visits, there were about 59 patients who were not eligible to participate in the study. Some of the reasons included younger than 35 years and older than 75 years, well-women visits, complex medical conditions, acute visits, and not able to speak, read, and write in English.

Table 12

Intervention Chart Review of August/September 2019

Total no. of patients	No. of annual visits	No. of establish care visits	No. of patients meeting inclusion criteria	Number of patients not meeting criteria
404	40	29	10	59

There were a total of eight patients who consented to participate in the study and completed the SAMScore. The age range for the completed SAMScores included patients 38 years to 70 years out of which there were five females and three males. Three patients were positive for SAMScores, and five patients were negative for SAMScores. Among the positive SAMScores, there were two females and one male. All the patients who were positive for SAMScores had ICD 10 diagnosis code as Z12.83, keywords (annual skin cancer exam or biopsy or referral to dermatology or primary prevention) and interventions (counseling and providing handout from the

American Academy of Dermatology) in the chart. However, none of the patients who were positive for SAMScore had any suspicious lesions or skin issues during the total skin exam that needed skin biopsies. For five patients who were negative for SAMScores, two patients had ICD 10 diagnosis code as Z12.83, keywords, and interventions charted; two patients did not have ICD 10 diagnosis code, keywords, and interventions charted; and one patient had ICD 10 diagnosis code, but no keywords and interventions charted.

Conclusion

The DNP scholarly project was implemented to increase melanoma screening and identify patients at high risk for melanoma in a small rural clinic in northern Colorado. The project utilized the SAMScore and melanoma screening algorithm. Prior to the implementation of the project, the clinic did not have a protocol to screen patients for melanoma, and it was up to a provider's discretion to screen patients for melanoma depending on subjective and objective information. With the implementation of the project, the melanoma screening increased from two patients during the control month to eight patients during the intervention month, with a 300% increase in melanoma screening. Furthermore, it increased patients' and providers' awareness of melanoma and the importance of diagnosing melanoma early to prevent long term complications of the disease.

CHAPTER V

DISCUSSION

Melanoma is a fatal skin cancer and is on the rise. There is a lack of a standardized tool and inconsistent guidelines and recommendations on melanoma screening for primary care providers. Furthermore, there are an inadequate number of dermatologists in the United States to screen and treat people with suspected or diagnosed lesions or skin issues. The majority of doctor visits are in a primary care setting; thus primary care providers are at an ultimate position to screen and treat patients with suspicious lesions, to identify if they are at high-risk for melanoma, and to educate patients on prevention of melanoma or nonmelanoma skin cancers. This led the project lead to develop an evidence-based algorithm using the self-assessment of melanoma risk score (SAMScore) to increase melanoma screening at a federally qualified health center. The SAMScore served as a primary risk prediction model for the algorithm which was already validated in the English and French languages to identify patients at risk for melanoma. The primary stakeholders of the project included five medical assistants, two providers, and consented patients.

Project Objectives

The overall aim of this project was to improve melanoma screening at a federally qualified health center. The data from the retrospective and intervention chart review demonstrated the meeting of this objective. A review of all patient records during the control month of April 2019 resulted in a total of two melanoma

screenings. With the implementation of this Doctor of Nursing Practice (DNP) scholarly project, there was an increase in the number of melanoma screenings from two to eight, a 300% increase in the number of melanoma screenings at this clinic. The following discussion outlines the results from each of the project objectives.

Conducting the Lunch and Learn Session

The first objective of this scholarly project was to develop a lunch and learn session, which was done during the first week of August after the approval from the institutional review boards of the clinic and the University of Northern Colorado. Two separate sessions were held for medical assistants and providers regarding melanoma and the implementation of the DNP scholarly project. The pre- and post-survey questionnaires were given to the medical assistants and the providers, and questions regarding melanoma and DNP scholarly project were answered. The staff at the clinic was generous of their time by participating and providing their feedback. The staff participated in the lunch and learn session with an open and growth mindset to learn more about melanoma and improve patient care.

The lunch and learn session was an effective method to have all the team members of the clinic together. The project lead was able to obtain the baseline assessment of the understanding and knowledge of the staff on melanoma and melanoma screening at the clinic via pre-survey questionnaires. Also, the staff was able to learn about the doctoral project including melanoma, workflow algorithm, and SAMScore prior to the implementation of the project. The feedback from the staff during the lunch and learn session was appreciated and considered by the project lead, such as having a separate sheet of paper with the inclusion and exclusion criteria

behind the nurse's desk for easy access. The lunch and learn session helped in clarifying questions that medical assistants and providers had regarding the project implementation and assisted in the smooth implementation of the project. It is highly recommended that a similar session to the lunch and learn session be performed prior to a quality improvement project in a healthcare setting.

There was an increase in the number of correct answers for the inclusion criteria, exclusion criteria, and role of the medical assistants with the completed SAMScores while comparing the pre-survey and post-survey questionnaires for the medical assistants. Previously, studies have focused on educating providers on melanoma and its screening, but not other staff within a clinic setting. One study by Robinson et al. (2018) looked at the knowledge and skills of 89 primary care providers by analyzing a pretest and posttest assessment before and after completing the mastery learning course. The study showed that the primary care providers in the intervention group were able to correctly identify melanomas in the posttest, had fewer false positives, and referred fewer benign lesions than the control group (Robinson et al., 2018). Furthermore, the mastery learning course improved the detection of early melanoma and patient care, decreasing unnecessary procedures, financial burdens, and time burdens (Robinson et al., 2018). Similarly in this project, the providers improved their understanding of risk factors for melanoma and criteria for a positive SAMScore after the education session. Additionally, in this project, the providers demonstrated an increase in the intention to continue to utilize the algorithm, SAMScore, and melanoma early detection provider toolkit to increase melanoma screening at the clinic. No other studies were found that evaluated the intention of the providers on melanoma screening interventions.

Key facilitators. One of the biggest facilitators for the success of the lunch and learn session was a positive attitude and open-mindedness of the medical assistants and providers to learn about melanoma and improve patient care. In addition, the medical assistants and providers found the PowerPoint on melanoma, workflow algorithm, and SAMScore to be very helpful. Also, any questions on the project were answered immediately during the session.

Key barriers. One of the key barriers was difficulty in finding time to have medical assistants and providers meet for the lunch and learn session at the same time. It was a challenge to have medical assistants and providers to meet the project lead at the same time. Thus two separate sessions were held for medical assistants and providers. Both providers had their computers with them and were charting during the lunch and learn session which could have affected their attention to the lunch and learn session.

Implement a Pilot of Evidence-based Melanoma Workflow Algorithm

After the successful lunch and learn session, the algorithm was implemented on the same day. Questions from the medical assistants and providers were answered. The inclusion and exclusion criteria of the project were written on a paper and taped to the nurse's station with a secure folder for consents and completed SAMScores per the request of the staff of the clinic. The staff was informed that the project lead would be at the clinic twice a week during the implementation period or as needed. The cell phone number of the project lead was shared with the medical director of the clinic to call the project lead with any questions regarding the project.

Throughout the implementation of the project, the medical director and the project lead were in contact via telephone updating the project lead on the implementation process and the number of screened patients. The medical director and the staff of the clinic continued to give feedback on the project. There were a total of 10 patients who met the inclusion criteria for the project and only nine completed the SAMScore. Out of nine completed SAMScores, one was completed outside the implementation month; thus it was not included in the result of the project. Also, one patient did not consent to participate in the study but completed the SAMScore. Thus only eight completed SAMScores and eight completed consent forms were included in the project.

Only eight completed SAMScores and eight completed consent forms were included in the DNP scholarly project. Out of eight completed SAMScores, there were three patients who were positive for a SAMScore. The providers also stated that the project increased their awareness of skin lesions and melanomas. As a result, one provider performed two biopsies in the clinic during the intervention month. However, the biopsies came back negative for melanomas. Also, no biopsies were performed on patients who were positive for a SAMScore since they did not have any suspicious lesions during the full-body skin exam. A similar study was done using the SAMScore to identify the patients at high-risk or not for melanoma in France. For those patients who were identified as high-risk for melanoma, they received an invitation via mail to consult with their primary care providers for annual skin examination (Rat et al., 2015). Based on the provider's discretion, primary care providers either performed total skin examination or referred patients to dermatologists as needed (Rat et al., 2015). Out of 3,745 patients who received a mail

invitation, 61% consulted with their primary care providers and 16% consulted with a dermatologist (Rat et al., 2015). There were a total of 83 patients who had suspicious lesions and had excisions (Rat et al., 2015). Furthermore, there were six melanomas, five squamous cell carcinomas, and 15 basal cell carcinomas diagnosed (Rat et al., 2015).

Key facilitators. One of the key facilitators of the implementation of the project was the readiness of the staff and the design of the project. The five medical assistants, two providers, and patients who participated in this project were eager to learn about melanoma, identify patients at high risk for melanoma in the community, improve the melanoma screening using the evidence-based melanoma workflow algorithm, and educate patients on the prevention of melanoma and non-melanoma skin cancers. The staff at the clinic was ready to start the project and said that the design of the project was well planned and easy to follow. The patients who met the inclusion criteria of the project were excited about the project and appreciated the staff for implementing such an important topic in a primary care setting. The implementation of the project would not have been successful if the staff and patients were not devoted to the project.

Key barriers. One of the biggest barriers to the implementation of the DNP scholarly project was the lack of validation of the SAMScore in languages except for English and French. Due to this limitation, the inclusion and exclusion criteria of the project were narrow and not able to include a larger number of the patient population, even though there were patients who might have been at higher risk for melanoma or non-melanoma skin conditions. Another barrier was the size of the clinic with the limited number of staff. One of the providers reported that one of the barriers to the

project was that it was a DNP project, and medical assistants were not as familiar with the rigor and details of a DNP project as compared to any clinic-based quality improvement project. The provider added if it was just a quality improvement project rather than being a DNP project without strict rules on inclusion and exclusion criteria, it would have resulted into a higher number of melanoma screenings. Attempts were made throughout the implementation month to educate the medical assistants regarding the inclusion and exclusion criteria of the project and the overall DNP project.

Appraise the Number of Patients Identified as High Risk for Melanoma

The chart review was performed by the project lead for the control and the intervention month. There were only two melanoma screenings that were performed during the control month of April 2019 between the two providers. The melanoma screening increased to eight screenings during the intervention period after the implementation of the melanoma algorithm and the SAMScore at the clinic. The patients were identified as high risk for melanoma or not based on their responses in the SAMScore and if they met any one of the criteria of the SAMScore. Two other studies (Quereux et al., 2012; Rat et al., 2015) utilized the SAMScore to identify patients who were at high risk for melanoma. The studies by Rat et al. (2015) and Quereux et al. (2012) identified 3,897 patients and 2,404 patients as high risk for melanoma, respectively, using the SAMScore. Once they were identified as high risk for melanoma, they were then advised to consult with either their primary care providers or dermatologists (Quereux et al., 2012; Rat et al., 2015).

Key facilitators. During the implementation month, the two providers and the five medical assistants identified the patients who met the inclusion criteria of the study every morning by looking at the schedule for the day. This helped to ensure that all the patients meeting the inclusion criteria received the consent forms and SAMScore prior to being seen by the providers. Having the SAMScore and consent forms in two separate colors helped to make sure that each patient received both during their appointment time and that those documents did not get lost during the process. Again, the SAMScore was very easy to read and follow and assisted providers to decide if the patient was at high risk for melanoma or not.

Key barriers. One of the barriers was the strict inclusion and criteria of the study for the patients to participate. According to the staff of the clinic, there were patients who were interested in the study, but they did not meet the inclusion and exclusion criteria for the study due to language, age, and type of visit. Another barrier to this DNP scholarly project was the validation of the SAMScore. Since the SAMScore was only validated in the English and French languages, the model could not be used for people who were not able to speak, read, or write in either the English or French language. Spanish was the second most common language at the clinic where the project was implemented, making it hard to screen the Hispanic population who were not able to speak, read, and write English.

Another important barrier was the time that providers had for one patient. The providers only had 20 minutes for one patient at either acute care visits or annual wellness visits. Even if the patient had an annual wellness visit as their chief complaint, most of the patients had several comorbid conditions or the visit ended up being an acute care visit, and the providers felt like they did not have time to talk

about melanoma screening or perform a full-body skin exam even if the patients were at high risk.

Appraise the Number of Patients Positive and Negative for Self-Assessment of Melanoma Risk Score and Interventions for the Ones with Positive Self-Assessment of Melanoma Risk Score

The chart review of the intervention month showed that there was a total of three positive SAMScores among the consented patients. All three patients had keywords, international classification of diseases (ICD) 10 code and interventions charted in their electronic health record. For the patients who had positive SAMScores and did not have any suspicious lesions or skin issues that led providers to perform biopsy or refer them to the dermatologists, the providers noted in the plan section of the electronic health record that those patients were positive for the SAMScore or at high risk for melanoma needing annual skin exam. As a result, those patients would be followed up and would be screened for melanoma every year during their annual wellness visits. If any suspicious lesion was found by the providers during the full-body skin examination, appropriate intervention such as biopsy or referral would be immediately done by the providers. There were five patients with a negative SAMScore, which means that they were not at high risk for melanoma at the time of the visit. Having a negative SAMScore does not mean that those patients would or would not have melanoma in the future. But it is important to continue to screen those patients to assess their most current risk for developing melanoma using the SAMSocre. All the patients who were positive and negative for the SAMScore

received the primary prevention handout from the American Association of Dermatology. The combination of the SAMScore and primary care providers' examination and counseling is an efficient way to promote patient behaviors that may reduce melanoma risk (Rat et al., 2014). Furthermore, identification of the patients who are at high risk for melanoma allows the primary care providers to focus their attention, energy, and time on educating those patients (Rat et al., 2014).

Key facilitators. The design of the project made it easier to collect the data for the patients who were positive and negative for SAMScore and related interventions. The providers were educated during the lunch and learn session to chart in the electronic medical record if the patients who filled out the SAMScore were positive or negative for the SAMScore and related interventions such as biopsy, referral, or annual skin exam.

Key barriers. As mentioned above, one of the key barriers to the appraisal of the number of patients positive and negative for a SAMScore was the lack of validation of the SAMScore in the Spanish language. If the SAMScore would be validated in the Spanish language, it would broaden the inclusion criteria of the project, making it possible to include the Hispanic population. This would have resulted in a greater number of patients screened for melanoma. As a result, it would increase the number of patients who were positive and negative for a SAMScore. Another barrier included the short timeframe. The implementation period of the DNP scholarly project was only one month, which was insufficient to assess the effectiveness of the project. It would be interesting to see the result if the project would be implemented for a longer period of time such as six months to one year. If

the project was implemented for a longer period of time, it would have been possible to catch melanoma during that timeframe.

Report an Increase in the Intention Among Providers and Medical Assistants

With the pre-, post-, and post-post-survey questionnaires, providers reported that they intend to increase the melanoma screening using the melanoma workflow algorithm and SAMScore. Both providers stated that they intended to use the melanoma early detection provider toolkit as a resource. One of the providers asked the project lead if the clinic could continue to use the printed SAMScore even after the intervention month to improve melanoma screening rate of the clinic. All five medical assistants reported that the design of the DNP Scholarly project was well planned and the SAMScore was simple and easy for the patients to use with minimal to no input from the staff members in completing the SAMScore. There are no studies with SAMScore that evaluated the intention of the staff to continue to use the SAMScore. This is the first project that asked specific questions on the intention of the providers to continue to use SAMScore and melanoma early detection provider toolkit.

Key facilitators. The design of the project made it easier to collect the data on the intention of the providers to continue to use the SAMScore, workflow algorithm, and melanoma early detection provider toolkit since there were yes/no questions in the pre-, post-, and post-post-survey.

Key barriers. Even though the providers stated that they intended to use the melanoma early detection provider toolkit in their pre-, post-, and post-post-survey, none of the providers had signed up or completed the toolkit by the end of the implementation month. The key barrier to the lack of participation in the toolkit was

the time and length of the toolkit to complete all modules. However, the providers reported that they would keep the toolkit in mind and would keep it as a resource for future reference.

Limitations

The DNP scholarly project was developed and implemented with an intention to increase melanoma screening in a primary care setting by the primary care providers and improve the staff's knowledge and confidence level at screening patients for melanoma. However, one of the limitations was the duration and timing of the quality improvement project. There were a lower number of patients who met the inclusion and exclusion criteria of the project than expected prior to the implementation of the project. The duration of one month for the implementation and chart review was not adequate; as a result, the completed SAMScore was not scanned into the electronic health records for the project lead to compare with the original SAMScore. The whole team was extremely supportive and appreciative of implementing the DNP scholarly project at the clinic.

Recommendations

Further study is needed to validate the SAMScore in languages other than English and French. Also, the same project could be done for a longer period of time to evaluate the effectiveness of the SAMScore in the same clinic and compare it to the results of the current project. Further study can be done if there is another risk prediction model that is comparable or simple, easy, and applicable in a primary care setting to identify patients at high risk for melanoma or skin cancers. In addition, the project could easily be replicated in a clinic with a higher number of providers and patients.

The clinic celebrates the month of May as skin cancer awareness month, where the clinic conducts free skin cancer screening. Once the SAMScore is translated and validated in other languages, especially Spanish, it can be used to identify patients at risk for melanoma and can be distributed to the majority of the patients seen at the clinic over the month of May. Furthermore, the primary prevention handout from the American Academy of Dermatology can also be used to educate patients on melanoma.

In the future, it would be important to collaborate with the information technology department of the clinic to integrate the SAMScore into the electronic medical records of the patients. The SAMScore can be laminated and used by the patients during their appointment, which then can be translated into the electronic medical record by the medical assistants. This saves the amount of paper used for the SAMScore and saves time for the medical records department to scan the SAMScore into the charts; paper can be easily misplaced or not labeled with the correct patient's identifiers. Another recommendation would be to utilize an electronic system such as an Ipad with a built-in SAMScore that can still be filled out by the patient while waiting for providers. This also makes it easy for the providers to access all the medical records of the patients rather than in the scanned document of the electronic medical records.

The Donabedian model was used as a foundation for the scholarly DNP project. The three frameworks of the Donabedian model, structure, process, and outcome, helped the project lead to assess the current structure of the clinic and melanoma screening process at the clinic, identify the barriers to the melanoma screening, develop a melanoma screening workflow algorithm for the clinic, and

evaluate the outcome of the implementation of the algorithm at the clinic. It is recommended that this model be used as a guide for future studies or projects related to improving melanoma screening at any facility.

There was a minimal budget planned for this scholarly DNP project. The cost included the time of the clinic staff for the educational training sessions, time of the DNP student, and lunch provided at the lunch and learn session. There were gifts, or monetary compensation, to the clinic staff. The providers did not review or login into the melanoma early provider toolkit from the Oregon Health and Science University (OHSU), Department of Dermatology, since the toolkit was time-consuming. Moving forward, offering an incentive to the providers to complete the education on melanoma might have resulted in an increased number of participations in completing the toolkit since the toolkit had great information on melanoma.

Attainment of Personal Goals

This DNP scholarly project offered a great learning experience to the project lead and the staff at the clinic regarding melanoma, the importance of screening for melanoma, detecting melanoma early, and the important role of primary care providers at identifying high-risk patients for melanoma. The project lead grew from being a novice student on melanoma to an expert on melanoma and its screening. The limitations, barriers, and facilitators of the DNP scholarly project provided insight into having a standardized and evidence model to screen high-risk patients for melanoma. The whole process of choosing a DNP project topic to perform a literature review to writing all five chapters was challenging and exhausting. Despite those limitations, barriers, and facilitators, the DNP scholarly project taught the project lead about resilience and to have a growth mindset.

Essentials of Doctoral Education for Advanced Nursing Practice

The American Association of Colleges of Nursing proposed that a DNP final project must meet the outcomes of the American Association of Colleges of Nursing Essentials of Doctoral Education in Advanced Nursing Practice using the five criteria (Waldrop, Caruso, Fuchs, & Hypes, 2014). The five criteria are enhances, culmination, partnerships, implements, and evaluation. The essentials were integrated into this scholarly DNP project, and the five criteria were used to demonstrate how the project aligned with the American Association of Colleges of Nursing Essentials of Doctoral Education.

The first criterion is enhancing health outcomes, practice outcomes, or healthcare policy (Waldrop et al., 2014). This scholarly DNP project identified the need for melanoma screening in primary care to identify the patients at risk for melanoma and reduce the morbidity and mortality rate associated with it so that appropriate treatment could be started as soon as possible. A literature review on melanoma screening was performed and the barriers to melanoma screening at the clinic were identified. This led to the identification of the best risk prediction model for melanoma and developing a melanoma screening workflow algorithm for the clinic to enhance or improve patient outcomes.

The second criterion is reflecting a culmination of practice inquiry (Waldrop et al., 2014). The project lead also identified a gap between the literature and knowledge that a change in melanoma screening in primary care was necessary, and it was the right time to bring that change. An exhaustive literature review on melanoma screening was completed. The barriers of the clinic and the providers on melanoma

screening were identified and, a melanoma screening workflow algorithm was developed that was practical and easy to implement. The electronic medical record was used to perform the chart reviews of the patients for the control and intervention month.

The third criterion is requiring engagement in partnerships (Waldrop et al., 2014). Partnership and collaboration with the manager, providers, medical assistants, and patients of the clinic made the DNP scholarly project a success. There was open communication between all the team members regarding the project and any questions were timely answered. The project was also approved by the institutional review boards of the clinic and the University of Northern Colorado. The constructive feedbacks were provided by the team from the start to the completion of the scholarly DNP project.

The fourth criterion is implementing or applying or translating evidence into practice (Waldrop et al., 2014). The SAMScore was found to be the best, effective, efficient, and validated risk prediction model to identify high-risk patients for melanoma. The model was used to screen patients for melanoma at the clinic. Based on the literature and constructive feedback from the staff of the clinic, inclusion and exclusion criteria were determined. As a result, the evidence-based melanoma screening workflow algorithm was developed and successfully translated into practice.

The last and fifth criterion is the evaluation of healthcare, practice, or policy outcomes (Waldrop et al., 2014). The evaluation of the project was done after exhaustive literature review and implementation of the scholarly DNP project. It was determined that the SAMScore was simple, easy to implement, and was an effective model in assessing patients' risk for melanoma. The project can be easily reproduced

and is sustainable as the clinic continues to use the SAMScore and the American Academy of Dermatology handout on primary prevention of melanoma even after the implementation month.

Conclusion

The incidence and prevalence rate of melanoma is increasing worldwide, and it is a significant public health concern (Alendar, Drljevic, Drljevic, & Alendar, 2009). Melanoma is a challenging disease for a provider to detect, and it is not possible to perform full-body skin examination on every patient seen in a primary care clinic. Also, not every patient sees a dermatologist regularly to have their skin checked. In addition, there is a lack of standardized guidelines on the melanoma screening that can be utilized in a primary care setting.

Early detection of melanoma is important to decrease the mortality as the disease is highly curable at an early stage (Fleming et al., 2018). Also, primary care providers can improve early the detection of melanoma directly by performing biopsies of suspicious lesions and referring patients to a dermatologist (Fleming et al., 2018). To improve early detection of melanoma, it is important that patients are screened for melanoma and are identified if they are at high risk for melanoma or not.

As a result, the DNP scholarly project utilized the SAMScore and melanoma screening workflow algorithm at a small rural clinic in Northern Colorado with a goal to improve melanoma screening and identify patients at high risk for melanoma. The implementation of the project showed that there was a 300% increase in the number of patients who were screened for melanoma during the intervention months of August/September 2019 compared to the control month of April 2019. Furthermore, the SAMScore and melanoma screening workflow algorithm was found to be effective

at identifying patients at high for melanoma. Both interventions were simple and easy to use with minimal to no input from the staff. The project also improved and increased awareness of the staff and patients on melanoma. Further studies are needed to validate the SAMScore in different languages, continue the same project for a longer duration, and replicate the same project in a larger clinic.

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APPENDIX A

PERMISSION LETTER FROM ELIZABETH STOOS TO USE MELANOMA EARLY DETECTION PROVIDER TRAINING TOOLKIT

Elizabeth Stoos May 16, 2019, 9:37 PM (5 days ago)

to me

Hi Sapana,

So sorry about the delay!

Can you use this link? https://www.ohsu.edu/war-on-melanoma/melanoma-early-detection-provider-training

You have permission to use the online toolkit – it is now approved for CME through ACCME but I don't know if those transfer out of state?

Thanks!
Liz

From: Sapana Shakya <shakyas10@gmail.com>
Sent: Friday, May 10, 2019 11:55 PM
To: Elizabeth Stoos <stoos@ohsu.edu>
Subject: Re: Melanoma early detection Toolkit

Hello Liz,

•••

I am utilizing the early melanoma detection toolkit for my project as an optional resource. I am needing an email saying that you gave me permission to use the toolkit for my project. I would really appreciate if I can have that. Thank you.

Hello Sapana,

Thank you it is great to meet you! I am so glad to hear you are working on this…

Talk soon,
Liz

Elizabeth Stoos, M.Ed.
Instructional Designer | Outreach Manager
OHSU Department of Dermatology
3303 SW Bond Ave CH16D | Portland, OR 97239
☎ 503.494.6024| ✉ stoos@ohsu.edu

APPENDIX B

CONSENT FORM FOR HUMAN PARTICIPATION IN PROJECT

UNIVERSITY OF
NORTHERN COLORADO

CONSENT FORM FOR HUMAN PARTICIPATIONS IN PROJECT

Project Title: *Screening for melanoma for at-risk population: A Practice Guide*

Researcher: Sapana Shakya, RN-BSN, Doctor of Nursing Practice Student
Email: shak5662@bears.unco.edu
Committee Chair: Melissa Henry, PhD, RN, FNP-C
University of Northern Colorado, School of Nursing, Gunter Hall 3340
Greeley, CO 80639
Email: Melissa.Henry@unco.edu

General Purpose of the study: The purpose of this project is to implement an evidence-based melanoma screening algorithm utilizing SAMScore to identify patients at high risk for melanoma in a primary care setting by primary care providers in an effort to facilitate early detection and initiate treatments to minimize the complications related to melanoma.

Procedure: You will be given a bright yellow sheet of paper with total of seven questions by the medical assistants. You will be asked to complete the questionnaire independently while you are waiting to see the providers. You will also be asked not to put any patient identifiers on the sheet such as name, age, sex, or ethnicity. You will then hand your completed paper to the provider to review your risk for melanoma. Only the providers, the medical assistants, and the student project lead will have a record of the data collected. The data collected will be confidential. The original document will be copied, and the copy will be scanned to your medical record. The original document will be stored in a confidential folder behind the nurses' station for the student to collect. The collected data will be destroyed once the project is completed. The project lead will review your chart for age, gender, risk factors for melanoma or skin cancer, documentation of melanoma or skin cancer screening, and intervention or education regarding melanoma or skin cancer.

Disclosure risk: Potential risks to participants in this project are minimal. Risk includes potential patient embarrassment to undress or lift clothing for providers to assess the skin for melanoma or skin cancer. There is a minimal risk of identifying you as a participant since the collected document will not have any patient identifiers.

Direct benefits: Direct benefits as a participant include identification as high or low risk for melanoma or skin cancer, early detection of skin lesions if any, and appropriate interventions. Early identification of a melanoma is a lifesaver. Another benefit in participating in the project is increased awareness of the risk factors for

melanoma and learning primary and secondary prevention measures for melanoma or other skin cancers.

Participation: Participation in this project is voluntary. If you wish to not participate in the project, you are free to do so at any time. You may simply verbalize your wish to withdraw from the project by notifying the medical assistant or the providers at the clinic. Your decision to participate or not participate will not affect you or your treatment at the clinic.

Confidentiality: Your confidentiality will be protected. There will be no patient identifiers attached to your completed document. The completed document will be kept safe in a confidential folder at the back of the nurses' desk. Only the medical assistants, the providers and the project lead will have access to the data collected.

Participation is voluntary. You may decide not to participate in this study and if you begin participation you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in loss of benefits to which you are otherwise entitled. Having read the above and having had an opportunity to ask any questions, please sign below if you would like to participate in this research. A copy of this form will be given to you to retain for future reference. If you have any concerns about your selection or treatment as a research participant, please contact Nicole Morse, Office of Research, Kepner Hall, University of Northern Colorado Greeley, CO 80639; 970-351-1910.

_____ _____

Participant Printed Name: Signature:

_____

Date:

APPENDIX C

LETTER FROM SALUD FAMILY HEALTH CENTER, ESTES PARK, COLORADO

Salud
Family Health Centers
EXCELLENCE. EVERY PATIENT. EVERY TIME.

Stanley J. Brasher
Administrative and
Training Center
203 South Rolfe Avenue
Fort Lupton, CO 80621
(303) 892-6401

Wednesday,
May 1, 2019

MISSION
To provide a quality, integrated health care home to the communities we serve.

CORE VALUES
Commitment
Compassion
Creativity & Innovation
Dignity
Integrity
Quality & Excellence
Teamwork

LOCATIONS
Brighton
Brighton Women's Center
Commerce City
Community Reach Center
Estes Park
Fort Collins Blue Spruce
Fort Collins West
Fort Lupton
Fort Morgan
Frederick
Longmont
Mobile Unit
Sterling
Trinidad

Dr. Kathleen Dunemn

Program Coordinator

University of Northern Colorado - Nursing Department

Greeley, CO 80639

Subject: Melanoma screening workflow algorithm for at-risk population in primary care

Dear Ms. Dunemn

Sapana Shakya FNP student is taking initiative to develop a melanoma screening workflow algorithm for at-risk population in primary care. Salud family Health Center in Estes park is willing to partner in the endeavor under the supervision of Hannah Fields MD, Medical Director. We give permission for such project. Sapana and our team will inform you about the developments of the project.

Thank You,

Hannah Fields MD, MSc

Medical Director

Marianne L. Dungan MSN, RN-BC

Marianne Dungan MSN, RN-BC

Center Director

saludclinic.org
(303) MY SALUD

APPENDIX D

CLINIC INSTITUTIONAL REVIEW BOARD APPROVAL

Morse, Nicole

From: Shakya, Sapana <shak5662@bears.unco.edu>
Sent: Sunday, August 11, 2019 6:24 PM
To: Henry, Melissa; Morse, Nicole
Subject: Fwd: Research Project

Sapana Shakya

Begin forwarded message:

From: Kandi Buckland <kbuckland@saludclinic.org>
Date: August 1, 2019 at 5:11:27 PM MDT
To: "shak5662@bears.unco.edu" <shak5662@bears.unco.edu>
Subject: Research Project

Good afternoon Sapana,

This message is to inform you that Salud has approved your research project for Estes Park. We wish you the best and will be anxious to hear your findings.

Kandi Buckland
Chief Operations Officer

Kandi Buckland, MPA, RN
Chief Operations Officer

Salud Family Health Centers

Salud Family Health Centers
203 South Rollie Ave
Fort Lupton, CO 80621
www.saludclinic.org
kbuckland@saludclinic.org

Our Mission: To provide a quality, integrated health care home to the communities we serve.

Connect with us

MySalud Online

APPENDIX E

INSTITUTIONAL REVIEW BOARD APPROVAL

UNIVERSITY OF
NORTHERN COLORADO

Institutional Review Board

DATE:	August 1, 2019
TO:	Sapana Shakya
FROM:	University of Northern Colorado (UNCO) IRB
PROJECT TITLE:	[1465670-2] Screening for Melanoma for At-risk Population: A practice guide
SUBMISSION TYPE:	Amendment/Modification
ACTION:	APPROVAL/VERIFICATION OF EXEMPT STATUS
DECISION DATE:	August 1, 2019
EXPIRATION DATE:	August 1, 2023

Thank you for your submission of Amendment/Modification materials for this project. The University of Northern Colorado (UNCO) IRB approves this project and verifies its status as EXEMPT according to federal IRB regulations.

We will retain a copy of this correspondence within our records for a duration of 4 years.

If you have any questions, please contact Nicole Morse at 970-351-1910 or nicole.morse@unco.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Northern Colorado (UNCO) IRB's records.

APPENDIX F

PERMISSION E-MAIL FROM DR. BRIGITTE DRENO TO USE SELF-ASSESSMENT OF MELANOMA RISK SCORE

BD Brigitte DRENO <brigitte.dreno@atlanmed.fr>
Wed 4/3, 3:35 AM

Yu can use it without any problem
And it is free
Best regards

Professeur Brigitte Dréno
brigitte.dreno@atlanmed.fr
Chef de service de Dermato-Cancérologie
Directeur Unité Thérapie Cellulaire et Génique
Vice Doyen à la Recherche à la Faculté de Médecine de Nantes

CHU Nantes - Place Alexis Ricordeau
44093 Cedex 01 - FRANCE
Tel : +33 2 40 08 31 18

BD Brigitte DRENO <brigitte.dreno@atlanmed.fr>
Thu 4/11, 12:21 AM

Dear Spana Shakya

You cna use the samscore free of any taxe
it I sonly in English and French
Best regards

Professeur Brigitte Dréno
brigitte.dreno@atlanmed.fr
Chef de service de Dermato-Cancérologie
Directeur Unité Thérapie Cellulaire et Génique
Vice Doyen à la Recherche à la Faculté de Médecine de Nantes

CHU Nantes - Place Alexis Ricordeau
44093 Cedex 01 - FRANCE
Tel : +33 2 40 08 31 18

APPENDIX G

NO SIGNATURE CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH

NO SIGNATURE CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH
UNIVERSITY OF NORTHERN COLORADO

Project Title: Screening for Melanoma for At-risk Population: A practice guide
Researcher: Sapana Shakya, RN, BSN, FNP-DNP student
-Phone Number: xxx-xxx-xxxx e-mail: shak5662@bears.unco.edu

I am conducting a scholarly project to improve the number of melanoma screening for at risk population in a primary care clinic by the primary care providers. As a participant in this project, you will be asked to complete pre-, post- and post-post survey questionnaires. The pre-survey questionnaires will be given to you to complete prior to "the lunch and learn session". The post-survey questionnaires will be given to you to complete after "the lunch and learn session". The post-post survey questionnaires will be given to the providers only at the end of the implementation of the project. All three questionnaires consist of multiple-choice questions, fill in the blanks and open- ended questions. The questionnaires will assess your understanding of self-assessment of melanoma risk score (SAMScore) and the project algorithm. Each questionnaire will take approximately 3-5 minutes to complete.

For the survey questionnaires, you will not provide your name, but will be asked to provide survey identification which includes numerical format of the birthday month and date. Therefore, your responses will be confidential. Only the project lead and the medical director of the clinic will have access to the completed survey questionnaire and written feedback will be used to make changes to the project as needed. The result of the survey questionnaires will be presented to the project chair, committee members and other students or members who attend the project lead's final defense at the University of Northern Colorado. All the original survey questionnaires will be stored in a confidential folder inside the office of the medical director of the clinic and will be destroyed at the end of the project implementation.

Risks to you are minimal. You should not feel anxious or frustrated taking the survey questionnaires since the survey questionnaires are straight forward and easy to understand. The benefits to you include increased awareness and knowledge on melanoma, melanoma screening, and interventions to prevent melanoma.

Participation is voluntary. You may decide not to participate in this study and if you begin participation you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in loss of benefits to which you are otherwise entitled. Please take your time to read and thoroughly review this document

and decide whether you would like to participate in this research study. If you decide to participate, your completion of the research procedures indicates your consent. Please keep or print this form for your records. If you have any concerns about your selection or treatment as a research participant, please contact Nicole Morse, Office of Research, Kepner Hall, University of Northern Colorado Greeley, CO 80639; 970-351-1910.

APPENDIX H

INDIVIDUAL INVESTIGATOR AGREEMENT FORM FOR MEDICAL ASSISTANTS

Individual Investigator Agreement

Name of Institution with the Federalwide Assurance (FWA): University of Northern Colorado

Applicable FWA #: FWA00000784

Individual Investigator's Name:

_____

Specify Research Covered by this Agreement: Screening for Melanoma for At-risk Population: A practice guide

UNC PIs: Sapana Shakya and Advisor, Dr. Melissa Henry

(1) The above-named Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.

(2) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(3) The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(4) The Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.

(5) The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.

(6) The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(7) The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

(8) The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB/IEC.

(9) The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.

(10) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.

(11) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.

(12) This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.

(13) The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Investigator Signature: _____ Date _____

Name: _____ Degree(s): _____
(*Last*) (*First*) *(Middle Initial)*
Address: _____ phone #: _____

_____
(*City*) (*State/Province*) (*Zip/Country*)

FWA Institutional Official (or Designee): _____ Date _____
Dr. Mark Anderson, Provost

Address: 501 20th Street, Greeley, Colorado 80639; 970-351-2305

APPENDIX I

SELF-ASSESSMENT OF MELANOMA RISK SCORE

Please **DONOT** put any patient identifier **(NO NAME/AGE/GENDER)** on this paper

Answer each question by checking the appropriate square.

1. What type of skin do you have?
    - Skin-type I: Very fair skin, blond or red hair, light eyes (blue or green), never tan and always sunburn after sun exposure.
    - Skin-type II: Fair skin, blond or light brown hair, light eyes (blue or green), usually sunburn.
    - Skin-type III: Dark skin, brown hair, light to medium eye color.
    - Skin-type IV: Olive skin, dark brown hair, brown eyes.
    - Skin-type V: Brown skin, black hair, black eyes.
    - Skin-type VI: Black skin, black hair, black eyes.
2. Do you have freckles?
    - Yes
    - No
3. How many moles do you approximately have on both arms?
    - More than 20
    - Fewer than 20
4. Have you had one or more episodes of severe blistering sunburn during childhood or teenage years?
    - Yes
    - No
5. Did you live more than 1 year in a country where sunshine is high (Africa, French West Indies, South of United States, Australia)?
    - Yes
    - No
6. Have you been diagnosed with melanoma in the past (It is a skin cancer, arising in melanocytes, skin cancer that make skin pigment?
    - Yes
    - No
7. Has any of your first-degree relatives (parents, children, brother or sister) ever had melanoma?
    - Yes
    - No

According to the SAMScore, a patient is considered at risk for melanoma if at least one of these 3 criteria is verified:

First criterion: Presence of at least 3 risk factors among the 7 following risk factors: phototype I or II, freckling tendency, number of melanocytic nevi >20 on both arms, severe sunburn during childhood or teenage years, life in a country at low latitude, a history of previous melanoma, a history of melanoma in a first-degree relative.

Second criterion: A subject under 60 years of age and a number of melanocytic nevi >20 on both arms

Third criterion: A subject of 60 years old or over and a freckling tendency

APPENDIX J

RETROSPECTIVE CHART REVIEW
DATA COLLECTION

RETROSPECTIVE CHART REVIEW DATA COLLECTION

Number of Annual visits	**Number of Establish visits**

Melanoma Screening	**Total Number of Patients**
Yes	
No	

APPENDIX K

INSTITUTIONAL REVIEW BOARD APPROVAL (AMENDMENT)

UNIVERSITY OF
NORTHERN COLORADO

Institutional Review Board

DATE:	September 12, 2019
TO:	Sapana Shakya
FROM:	University of Northern Colorado (UNCO) IRB
PROJECT TITLE:	[1465670-3] Screening for Melanoma for At-risk Population: A practice guide
SUBMISSION TYPE:	Amendment/Modification
ACTION:	MODIFICATION APPROVED/VERIFICATION OF EXEMPT STATUS
DECISION DATE:	September 12, 2019
EXPIRATION DATE:	August 1, 2023

Thank you for your submission of Amendment/Modification materials for this project. The University of Northern Colorado (UNCO) IRB approves this project modification and verifies its continued status as EXEMPT according to federal IRB regulations.

We will retain a copy of this correspondence within our records for a duration of 4 years.

If you have any questions, please contact Nicole Morse at 970-351-1910 or nicole.morse@unco.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Northern Colorado (UNCO) IRB's records.

APPENDIX L

INTERVENTION CHART REVIEW
DATA COLLECTION

INTERVENTION CHART REVIEW DATA COLLECTION

Number of Annual visits	**Number of Establish visits**	**Number of patients qualified for the project**	**Number of patients not qualified for the project**

Patient Numbers	**Age**	**Gender**	**+SAM**	**-SAM**	**ICD 10**	**Keywords**	**Intervention/Education**
P1							
P2							

APPENDIX M

PRE-SURVEY QUESTIONNAIRE (PROVIDERS)

PRE-SURVEY QUESTIONNAIRE (Providers)

Providers: Please fill out the following questionnaire to assist the project lead in identifying current practice and provide barriers/feedbacks/suggestions for melanoma screening in primary care.

1. Do you currently screen patients for melanoma or skin cancer during their annual wellness visits?
   - Yes
   - No

2. What percentage approximates the number of patients you currently screen?
   - 100%
   - 75%
   - 50%
   - 25%
   - 0%

3. Have you heard or learned about SAMScore for melanoma screening?
   - Yes
   - No

4. If answered Yes to question 2, where did you hear or learn about SAMScore? If answered No to question 2, Go to question 7.

   _____

5. How many risk factors on the SAMScore are needed for the patient to be considered at risk for melanoma?
   - 1
   - 2
   - 3
   - 4

6. Please check the appropriate boxes for the positive SAMScore
   - At least 3 of the 7 risk factors
   - Older than 60 with more than 20 nevi on both arms and freckles
   - Younger than 60 with more than 20 nevi on both arms
   - Older than 60 with freckling tendency

7. The ICD 10 code and key words in plan section of the SOAP note will be used by the project lead to evaluate the objectives.
   - True
   - False

8. Have you heard or learned about melanoma early detection provider toolkit through OSHU or any toolkit for melanoma screening?
    - Yes
    - No

9. Would you intend to use melanoma early detection provider toolkit as a resource for melanoma screening?
    - Yes
    - No

Barriers/Feedbacks/Suggestions to melanoma screening in primary care:

APPENDIX N

POST-SURVEY QUESTIONNAIRE (PROVIDERS)

POST-SURVEY QUESTIONNAIRE (Providers)

Providers: Please fill out the following questionnaire to assist the project lead in identifying your intention, understanding of the algorithm and SAMScore and provide barriers/feedbacks/suggestions for melanoma screening in primary care.

1. After participating in the melanoma screening "lunch and learn session", do you intend to change your current screening practice for melanoma or skin cancer by incorporating SAMScore or evidence-based melanoma algorithm to a greater number of patients during
   annual wellness visits?
   a. Yes
   b. No

2. How many risk factors on the SAMScore are needed for the patient to be considered at risk for melanoma?
   a. 1
   b. 2
   c. 3
   d. 4

3. Please check the appropriate boxes for the positive SAMScore
   a. At least 3 of the 7 risk factors
   b. Older than 60 with more than 20 nevi on both arms and freckles
   c. Younger than 60 with more than 20 nevi on both arms
   d. Older than 60 with freckling tendency

4. The ICD 10 code and key words in plan section of the SOAP note will be used by the project lead to evaluate the objectives.
   - True
   - False

5. Do you intend to use melanoma early detection provider toolkit as a resource for melanoma screening?
   a. Yes
   b. No

Barriers/Feedbacks/Suggestions to melanoma screening in primary care:

APPENDIX O

POST-POST SURVEY QUESTIONNAIRE
(PROVIDERS)

POST-POST SURVEY QUESTIONNAIRE (Providers)

Providers: Please fill out the following questionnaire to assist the project lead in identifying providers intention to utilize the algorithm and resources.

1. Do you intend to continue to screen patients for melanoma or skin cancer during their annual wellness visits?
    c. Yes
    d. No

2. Do you intend to use the melanoma screening algorithm developed for this practice or different melanoma early detection provider toolkit as a resource for melanoma screening in the future?
    a. Yes
    b. No

Barriers/Feedbacks/Suggestions to melanoma screening in primary care you encountered during the melanoma screening pilot project:

APPENDIX P

PRE-SURVEY QUESTIONNAIRE
(MEDICAL ASSISTANTS)

PRE-SURVEY QUESTIONNAIRE (Medical assistants)

Medical assistants: Please fill out the following questionnaire to assist the project lead in identifying your understanding of project lead's melanoma screening algorithm and SAMScore and provide barriers/feedbacks/suggestions to improve melanoma screening in primary care.

1. Have you heard or learned about SAMScore for melanoma screening?
    - Yes
    - No

2. If answered Yes to question 1, where did you hear or learn about SAMScore?

    _____

3. The inclusion criteria for the patients to have the SAMScore includes.
    - Patients younger than 35 and older than 75 for acute visits
    - Patients aged 35-75 presenting for their annual physical
    - Able to read, write and speak English
    - English and Spanish speakers

4. The exclusion criteria for the patients to not have the SAMScore includes.
    - Patients younger than 35 and older than 75 for acute visits
    - Patients aged 35-75 presenting for their annual physical
    - Able to read, write and speak English
    - English and Spanish speakers
    - Well women visits

5. Medical assistants will make a copy of the Original SAMScore filled out by patients, copied SAMScore will be scanned into the electronic health record and the original will be stored securely in a folder for the project lead to collect.
    - True
    - False

Barriers/Feedbacks/Suggestions to melanoma screening in primary care:

APPENDIX Q

POST-SURVEY QUESTIONNAIRE
(MEDICAL ASSISTANTS)

POST-SURVEY QUESTIONNAIRE (Medical assistants)

Medical assistants: Please fill out the following questionnaire to assist the project lead in identifying your understanding of project lead's melanoma screening algorithm and SAMScore and provide barriers/feedbacks/suggestions to improve melanoma screening in primary care.

1. The inclusion criteria for the patients to have the SAMScore includes.
    - Patients younger than 35 and older than 75 for acute visits
    - Patients aged 35-75 presenting for their annual physical
    - Able to read, write and speak English
    - English and Spanish speakers

2. The exclusion criteria for the patients to not have the SAMScore includes.
    - Patients younger than 35 and older than 75 for acute visits
    - Patients aged 35-75 presenting for their annual physical
    - Able to read, write and speak English
    - English and Spanish speakers
    - Well women visits

3. Medical assistants will make a copy of the Original SAMScore filled out by patients, copied SAMScore will be scanned into the electronic health record and the original will be stored securely in a folder for the project lead to collect.
    - True
    - False

Barriers/Feedbacks/Suggestions to melanoma screening in primary care:

APPENDIX R

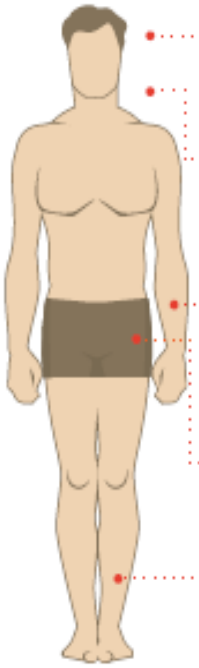
HANDOUT FROM AMERICAN ASSOCIATION OF DERMATOLOGY

Detect.

How to check your spots

SKIN CANCER SELF-EXAMINATION

Checking your skin means taking note of all the spots on your body, from moles to freckles to age spots. Ask someone for help when checking your skin, especially in hard to see places.



1. Examine body front and back in mirror, then right and left sides, arms
2. Examine back of neck and scalp with a hand mirror. Part hair for a closer look at your scalp.
3. Bend elbows, look carefully at forearms, back of upper arms, and palms.
4. Check back and buttocks with a hand mirror.
5. Finally, look at backs of legs and feet, spaces between toes, and soles.

Download the Academy's Body Mole Map at spotme.org to record your spots during your next skin self-exam.

What you're looking for on your skin

THE ABCDEs OF MELANOMA

Melanoma is the deadliest form of skin cancer. However, when detected early, melanoma can be effectively treated. You can identify the warning signs of melanoma by looking for the following:

A ASYMMETRY — One half is unlike the other half.

B BORDER — Irregular, scalloped or poorly defined border.

C COLOR — Varied from one area to another; shades of tan and brown, black; sometimes white, red or blue.

D DIAMETER — While melanomas are usually greater than 6mm (the size of a pencil eraser) when diagnosed, they can

E EVOLVING — A mole or skin lesion that looks different from the rest or is changing in size, shape or color.

Example:

OTHER TYPES OF SKIN CANCER

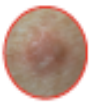
When checking your skin, please look for signs of these other suspicious spots.

Precancerous Growth

Actinic Keratoses (AK): Dry, scaly patch or spots.

Skin Cancer

Basal Cell Carcinoma (BCC): Flesh-colored, pearl-like bumps or a pinkish patch of skin.



Squamous Cell Carcinoma (SCC): Red firm bumps, scaly patches or sores that heal and then return.

If you find any spots on your skin that are changing, itching, or bleeding, make an appointment to see a board-certified dermatologist.

Live.

Visit spotme.org to:

- Learn more about skin cancer
- Find a dermatologist in your area

WHEN CAUGHT EARLY, SKIN CANCER
IS HIGHLY TREATABLE

AAD | SPOT me

APPENDIX S

PERMISSION E-MAIL FROM AMERICAN ASSOCIATION OF DERMATOLOGY TO USE HANDOUT

Daniya Ali (American Academy of Dermatology)
Apr 3, 3:15 PM CDT

Dear Sapana,

Thank you for contacting the Academy's Member Resource Center. The AAD website has a variety of free resources for you utilize for educational purposes. Please feel free to click the link below to access free handout

https://www.aad.org/public/spot-skin-cancer/free-resources

You may also purchase any of our AAD pamphlets by browsing the link below:

https://www.aad.org/aad-store

Lastly, if you are interested in hosting a SPOTme® Skin Cancer Screening Program, you may search our database for a physician that would be willing to participate in your event, by clicking the link below:

Find A Dermatologist

You would need to contact the dermatologist directly to see if they wish to volunteer.

If we can be of any further assistance, please feel free to contact us via phone at 888-462-3376 or via email at mrc@aad.org.

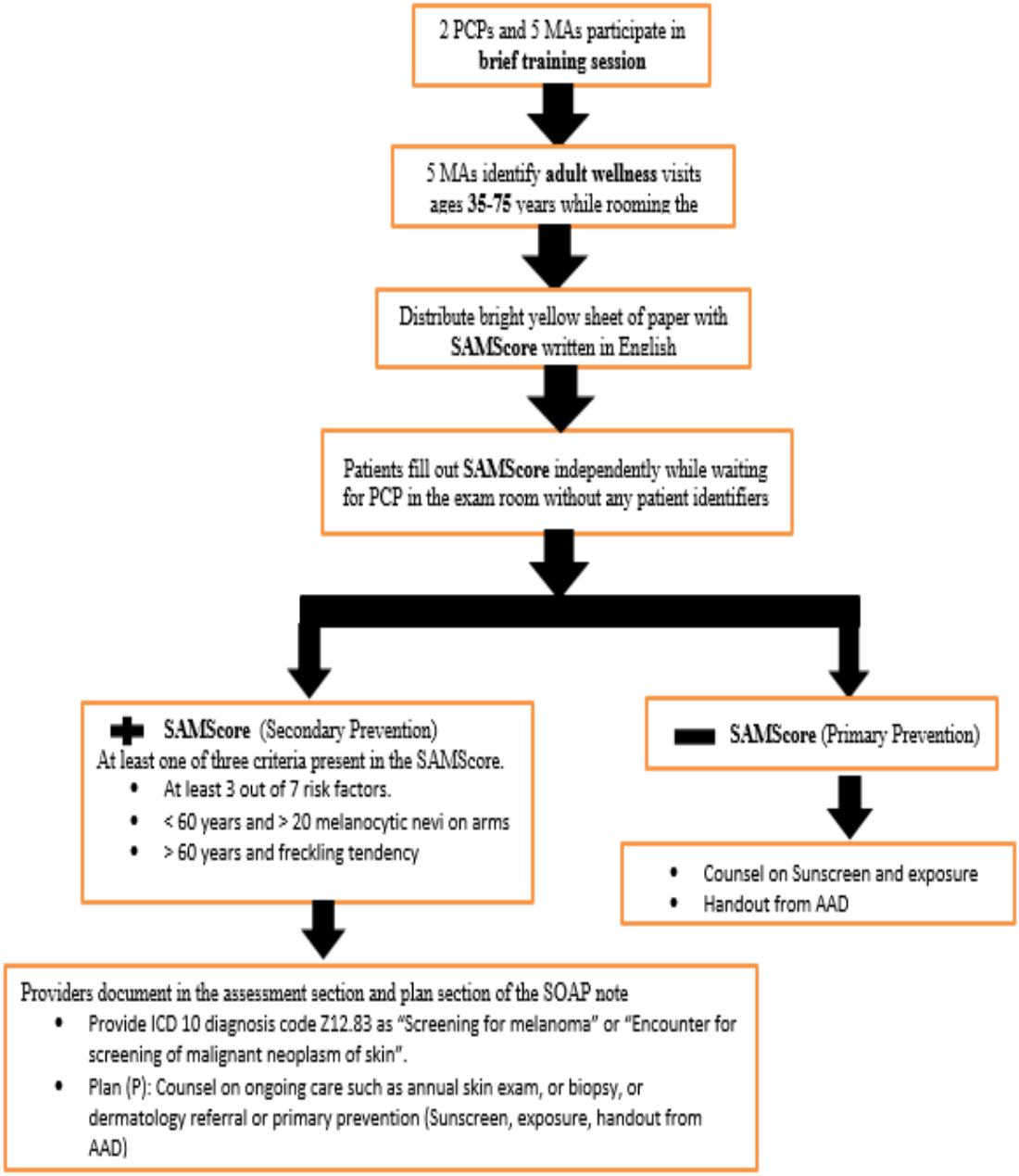
Sincerely,

Daniya Ali
Member Resource Center Representative
American Academy of Dermatology
9500 W Bryn Mawr Ave
Rosemont, IL 60018
866-503-7546 toll free
847-240-1859 fax
847-240-1280 Intl

APPENDIX T

MELANOMA SCREENING WORKFLOW ALGORITHM FOR PROVIDERS

Melanoma screening workflow algorithm for at-risk population in primary care



APPENDIX U

MELANOMA SCREENING WORKFLOW ALGORITHM FOR MEDICAL ASSISTANTS

Melanoma screening workflow algorithm for Medical Assistant at the clinic