

# **TOTAL BODY SKIN EXAMS IN THE PRIMARY CARE SETTING**

by

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A brief submitted to the Faculty of the University of Delaware  
in partial fulfillment of the requirements for the degree of  
Doctor of Nursing Practice

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Colossians 3:17

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## ABSTRACT

A Total Body Skin Examination (TBSE) for the detection of skin cancer or precancerous lesions are not the standard of care in primary care during wellness screenings. More recent evidence, however, supports their use in primary care noting a significant reduction in time (years) of diagnosis and lesion thickness. In the following practice improvement project, a TBSE was performed on all patients presenting for an annual physical exam at a local primary care clinic. The incidence of referral was documented. Ultimately, TBSEs proved to successfully identify patients with suspicious skin lesions and refer them when necessary. The project change ultimately suggests and supports more recent evidence that primary care providers are able to adequately identify and refer for concerning dermatologic skin lesions such as melanoma and non-melanoma skin cancers.

## Chapter 1

### INTRODUCTION

In 2015, the United States Preventative Services Task Force (USPSTF) released their recommendation for skin cancer screening. They determined that there existed insufficient evidence for the implementation of an annual total body skin examination (TBSE) for any demographic/age group (Final Update, 2015). This decision was met with resistance by many professional bodies including the American Academy of Dermatology Associates (AADA) and the Skin Cancer Foundation (Torres, 2016). The USPSTF noted in its final report that a visual screening exam has the ability to recognize all three forms of skin cancer (melanoma, basal cell carcinoma, and squamous cell carcinoma), but its use can exacerbate misdiagnosis, overdiagnosis and cosmetic adverse effects from biopsy or treatment (Final Update, 2015).

The AADA publicly criticized the USPSTF and expressed their disappointment in the recommendations (Torres, 2016). The AADA cited specifically their successful identification of both non-melanoma skin cancer (NMSC) and melanomas through their total body skin exam SPOTme campaign, which began in 1985. Since its fruition, the campaign has identified skin cancer in 11% of asymptomatic screened individuals (Torres, 2016). The AADA also noted that melanoma, merkel cell carcinoma (MCC), squamous cell carcinoma (SCC), and basal cell carcinoma (BCC) not only have the potential to result in death or other morbid conditions related to metastasis, but can also cause locally invasive complications requiring costly and substantial surgery (Lebwohl, 2015).

Of concern is that in their analysis, the USPSTF did not include a significant workplace time study by Lawrence Livermore National Laboratories that found a reduction in thicker melanomas (and therefore morbidity) and lower expected death rates compared to standard practice with the implementation of a TBSE. There was no explanation for the reason this significant study was excluded (Lebwohl, 2015). Additionally, the AADA brings to light that the studies referenced by the USPSTF discussing cosmetic effects lack strength, as their comparative features are outdated and do not reference current practice (Lebwohl, 2015). Lastly, it is important to note that the analysis by the USPSTF lacked any input from a dermatologist and therefore represented a knowledge deficit to the highly specialized field (Lebwohl, 2015).

## **1.1 Background**

One person dies of melanoma every hour, with over 10,000 individuals dying in 2016 alone (Johnson et al., 2017). Between the years 2009 and 2013, the mortality rate from melanoma alone was 2.7 per 100,000 (Johnson et al., 2017). Its incidence continues to increase. In the last forty years, the incidence of melanoma alone has increased by almost 200% and has become the fifth most invasive cancer in men and seventh most in women (Johnson et al., 2017). While it is more prevalent in older adults, melanoma is also the most common cancer in young adults, and skin cancer (melanoma, MCC, SCC, and BCC combined) is the most common form of cancer in the United State of America (USA) (Guy et al., 2015).

Melanoma specifically results in the largest amount of skin cancer related deaths each year (Johnson et al., 2017). Thinner melanomas (lesions <1mm) have a lower case-based mortality rate compared to thicker lesions (>4mm) but the incidence of thinner

melanomas is much greater resulting in a sheer greater number of deaths compared to thick melanomas (Guy et al., 2015).

## **1.2 Significance**

Those individuals that die from melanoma lose on average 20.4 years of otherwise expected, or potential life (Guy et al., 2015). Melanoma incidence rates have doubled between the years 1982 and 2011 and are expected to continue to rise through 2030 with the annual cost to treat melanoma expected to more than triple (a 252.4% increase) by 2030 (Guy et al., 2015). The division of Cancer Prevention & Control, run through the Centers for Disease Control (CDC), estimates that a comprehensive skin cancer prevention program would prevent at least 20% of melanoma cases and decrease associated costs by 2.7 billion dollars between the years 2020 and 2030 (Guy et al., 2015).

### **1.2.1 Delaware**

Delaware specifically, ranks fifth in the United States between the years 2009 and 2013 for malignant melanoma; specifically, second in men and fifth in women nationally (Cancer Incidence, 2017, p.80). Delaware is noted to have a statistically significant higher incidence of melanoma compared to the United States as a whole (Cancer Incidence, 2017, p. 81). In a comparison of the years 1999-2003 and 2009-2013, incidence rates of melanoma increased 78% in Delaware compared to only 14% across the USA (Cancer Incidence, 2017, p. 812). Even more significantly, diagnosis of malignant melanoma at a distance stage is increasing in Delaware. The United States as whole has more malignant melanoma diagnosed at the local stage (Cancer Incidence,

2017, p. 85-86). It is also notable that Caucasians accounted for 98% of malignant melanoma cases in the state between 2009 and 2013 (Cancer Incidence, 2017).

In New Castle County the average incidence rate of malignant melanoma between the years 2009 and 2013 was 28.9 per 100,000. This is significantly higher than the United States' incidence rate of 21.8 per 100,00 and in line with Delaware's total average incidence rate of 30.1 per 100,00 (Cancer Incidence, 2017, p.81).

### **1.3 Current Practice**

Approximately 66% of medical students and 75% of primary care residents felt as though they had inadequate training to perform a TBSE due to lack of both formal education and on-the-job continuing education (Johnson et al., 2017). Conversely, 79% of advanced practice nurses were confident in their ability to perform TBSEs but only 48% were confident in their ability to identify a suspicious lesion (Loescher, Harris & Curiel-Lewandrowski et al., 2011).

When surveyed, only half of primary care providers (PCPs) viewed TBSEs as “very important” (Johnson et al., 2017). This, in addition to disparaging beliefs by a vast number of medical bodies, results in TBSE not being part of a general physical examination by PCPs. The American Academy of Family Physicians released practice guidelines in accordance with the USPSTF, which likely contributed to the small number of TBSEs that take place in practice. While the USPSTF still encouraged clinicians to discuss skin health and prevention with their adolescent and adult patients due to increasing rates of skin cancer diagnoses across the USA, there is no physical exam in the majority of practices (Crawford, 2015).

As expected, dermatologists reported screening individuals at a significantly higher rate compared to family practitioners and internists (Oliveria et al., 2011). Family practitioners noted time constraints, competing comorbidities, and patient embarrassment or in some cases reluctances, as the main barriers to TBSEs (Oliveria et al., 2011). Nurse practitioners, however, are entering the workforce at a faster rate than physicians and providing an increasing amount of primary care, including annual physicals (Loescher et al., 2011). While not general practice in the USA, other governing medical bodies such as those in Australia, Germany, New Zealand, The Netherlands, and Great Britain recommended at least annual skin examinations for certain individuals (demographics differ per county) (Johnson et al., 2017).

#### **1.4 Population**

In general, melanoma incidence rates increase with age and are most significant in non-Hispanic, whites. For younger individuals, aged 15-49 white women have a higher incidence, whereas after age 50, men exhibit a higher incidence (Guy et al., 2015). This remained true in the state of Delaware between the years 2009 and 2013, with 58% of malignant melanoma cases belonging to males (Cancer Incidence, 2017). While incidence is higher in whites, specifically Fitzpatrick Skin Prototype Classification 1-III (Appendix A), individuals of color should not be ignored, left unscreened, or uncounseled. For there still exists a risk to individuals with darker skin. Additionally, many are not aware of their risk for developing skin cancer such as melanoma and often experience multiple burns that go unnoticed (Guy et al., 2015).

## **1.5 Vulnerability**

In the high-risk patient population identified by Johnson et al. (2017) (non-Hispanic, white men and women aged greater than sixty-five years; individuals with a history of sunburn; or individuals with a family history of skin cancer) only 24% of individuals reported having a TBSE in their lifetime. As determined by the data from the National Cancer Institute Surveillance, Epidemiology and End Results (SEER) registry, the most vulnerable age group for melanoma or skin cancer are individuals aged 35-75 (Johnson et al., 2017). More specifically, individuals with a personal history of basal cell carcinoma, squamous cell carcinoma, actinic keratosis, ongoing immunocompromise, a family history of melanoma in at least one first degree relative, a hereditary predisposition, a physical feature such as light colored skin (as defined as Fitzpatrick Skin Types I-III- see Figure 1 (Appendix A)), blonde hair, red hair, more than 40 moles, more than 2 atypical moles, freckles, sun damaged skin, or UV radiation (weather from sunburns or indoor tanning) necessitate an annual TBSE (Johnson et al., 2017).

### **1.5.1 Needs**

The AADA, the Skin Cancer Foundation, and recent evidence both in the USA and internationally, report overwhelming support for TBSEs. Notwithstanding the recommendations and evidence, this practice fails to be implemented at the primary care level, with only eight percent of patients seen by a PCP in a twelve-month period receiving a skin examination and only 24% of high-risk patients having been screened for skin cancer (Johnson et al., 2017). This screening appears best placed within a primary care visit as they outnumber dermatology visits nearly nine-fold (Gordon, 2014), and may have improved accessibility over a specialist appointment.



It is important to note that between the years 2000 and 2010, there has been an increase in the use of TBSE seen largely amongst non-Hispanic whites (Amrock & Meydani, 2013). Melanoma incidence, however, has increased across the majority of ethnic groups. This puts minorities at an increased risk for delayed diagnosis and higher mortality (Amrock & Meydani, 2013).

## **1.6 PICOT Question**

A PICOT (population, intervention, comparison, outcome, time) question is often the technique used in evidence-based practice to outline a clinical related question (Melnik & Fineout-Overjolt, 2015). It is helpful in developing literature search strategies and identifying key words. The PICOT question, in this context, is a foreground question. A foreground question is a question that surrounds a refined, limited body of evidence specific to the evidence-based question and is developed either through a problem focused trigger or a knowledge focused trigger (Dang & Dearholt, 2017). In this case, the lack of screening for skin cancer was identified through a knowledge-focused trigger by identifying problems in a variety of scholarly publications. Therefore, the evidence-based practice problem question in relation to skin cancer screenings is as follows:

"How will the implementation of an annual total body skin examination (TBSE) affect the incidence of referrals for suspicious skin lesions (consistent with melanoma, basal cell carcinoma, and squamous cell carcinoma) in the adult population between ages 18-75 in a primary care office during a 15 week time period?"

### **1.6.1 Specific elements of the PICOT**

Population: Adults between the ages of 18 and 75

Intervention: Total body skin exam during an annual physical exam office visit.

Comparison: NA

Outcome: incidence of referrals for suspicious skin lesions (consistent with melanoma, basal cell carcinoma, and squamous cell carcinoma)

Setting: A primary care office located in Newark, DE

Time: a 15-week time period

## **1.7 Theoretical Framework**

Donald Pathman sought to enhance clinician uptake of information and help transition evidence into practice (White, Dudley-Brown, & Terhaar, 2016. P.45). The translative theory, known as Pathman's Pipeline, was originally designed to address physician adherence to guidelines. The key elements of the pipeline, awareness, agreement, adoption, and adherence display the natural flow of adherence to new knowledge. The pipeline visually displays the flow of knowledge through the seven faucets, which are said to represent the seven stages of evidence to action (clinical awareness, acceptance, applicable, able, act on/adopt, agree, and adhere) (White et al., 2016, p. 45).

While an accurate description, the pipeline was modified by Diner et al. (2007) who added "leaks" along the pipeline to depict barriers of translation (Appendix B). These barriers include both micro and macro variables such as competing influences, marketing tactics, information overload, and even patient compliance (White et al., 2016, p.46). Additionally, there are added strings on the valves of the leaks displaying key elements that can help to prevent or deter such "leaks" or barriers to implementation, such as increasing pragmatic clinical trials, community evidence-based education and more (White et al., 2016, p.209). One of the most important elements to his theory of

translation, however, is the acknowledgement that the developed model would need individualization for each situation where it is applied (White, et al., 2016, p. 45).

### **1.7.1 Relation to Project & Use for Translation**

Pathman's Pipeline has immense relation to the implementation of TBSEs during routine physicals in the primary setting as the current evidence is at the beginning of the pipeline and requires individualization for the project. In other words, the current stage of research, in relation to TBSE, is depicted on the pipeline as the water chamber of 'high quality clinically relevant evidence'. The pipeline however serves as a directional key and displays the first step in advancing this evidence-based knowledge as awareness and directs stakeholders to make others aware but also seeks to develop acceptance by increasing interdisciplinary education and appropriate delivery of relevant practice. The evidence-based research needs to descend the pipeline and begin its implementation into interdisciplinary education clearly defining the demographics and integrate such into the standard of care for primary care. The pipeline will help clinicians anticipate the needs of the community and practice and better anticipate ways to combat such issues to ensure the success of implementation.

The pipeline specifically is relevant to the implementation of TBSEs as there are many barriers due to differing standards and research published at present. The pipeline's focus on barriers or "leaks" to adaptation or translation makes it particularly appropriate. Ultimately, Pathman's Pipeline is a fit model for the implementation of TBSE within primary care practices with appropriate provider buy-in. The model is appropriate for this project implementation where TBSE's are performed in a private practice with one

practitioner who has total buy-in. The pipeline will aid the provider in facing the many barriers with early implementation of new research.

## Chapter 2

### REVIEW OF THE LITERATURE

#### 2.1 Search

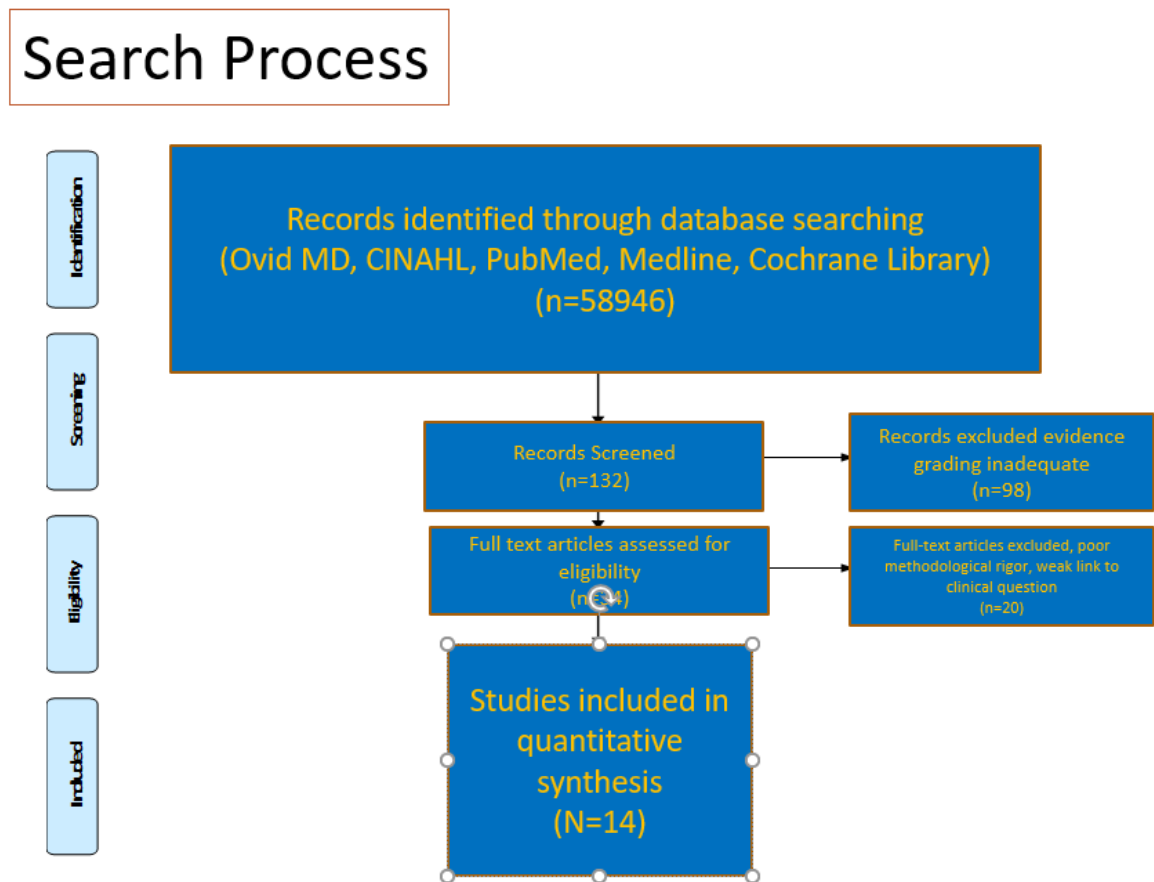
For the search for applicable literature relating to TBSEs in primary care, five databases including Pubmed, Medline, CINAHL, Cochrane Library, and Ovid MD were utilized. In all databases, as demonstrated below, search terms started off broad and became more narrow or specific with every search. In the case of Ovid MD, broad searches such as “total body skin exam” were too broad, yielding over 5000 responses. The first 20 responses yielding the greatest percentage of “hits” with the keyword were reviewed and ultimately provided two very applicable research articles. With almost every other database however, “total body skin exam” seemed too specific, and results were not applicable. Additionally, in research studies, not everyone uses the terminology TBSE, but rather “skin cancer screenings,” “Full body exams,” and “visual skin cancer exams,” are often used interchangeably and thus searches needed to utilize different terminology.

As proper terminology was utilized, and filters applied, searches became more applicable. Searches that yielded a large number of results, such as “Skin cancer screening AND primary care/ F: published in the last 5 years” on PubMed, still yielded 800 plus results. Only the first 50 most applicable searches were referenced, as after such there was a clear trend of searches being off topic and only containing a single key word. Even still, two very prominent articles were able to be utilized from this large search.

In the selection of appropriate literature, every article was analyzed for validity, reliability, and applicability (Melnyk & Fineout- Overholt, 2015, p. 132). Ultimately 14

articles were chosen. As the topic of skin examinations in primary care is a relatively new concept, there was not an abundance of applicable studies found in the search process.. After finding these fourteen studies, every search seemed to yield the same results, ceasing the search. A preferred reporting items for systematic reviews and meta-analysis (PRISMA) diagram depicting the search process is displayed below.

Figure 2.1 PRISMA Diagram for TBSEs



Below is the documented search process utilizing 5 different databases for evidence accumulation.

Table 2.1 Search history from PubMed Database

Query/ Filters	Results Returned	Chosen for Review of Literature
Total body skin exam	14	0
Skin cancer screening	50934	0
Skin cancer screening AND primary care	913	0
Skin cancer screening AND primary care/F: published in the last 5 years	886	2
Melanoma Screening AND primary care	913	1
Melanoma Screening AND primary care/F: published in the last 5 years	2	0
Whole body skin exam AND melanoma/ F: published in the last 5 years	5	0

Table 2.2 Search history from Medline Database

Query/ Filters	Results Returned	Chosen for Review of Literature
Total body skin exam	22	0
Total body skin exam AND primary care	36	2
Melanoma AND primary care	241	0
Melanoma screening AND primary care	29	0
Melanoma screening AND primary care/ F: published in the last 5 years	15	1

Table 2.3 Search history from CINAHL Database

Query/ Filters	Results Returned	Chosen for Review of Literature
Total Body Skin Exam	6	0
Skin cancer screening AND primary care	35	2
Skin cancer screening AND primary care/ F: published in the last 5 years	18	
Skin cancer screening AND PCP / F: published in the last 5 years	2	1
Skin cancer screening AND Primary care provider / F: published in the last 5 years	3	1

Table 2.4 Search history from Cochrane Library

Query/ Filters	Results Returned	Chosen for Review of Literature
Skin cancer F: published in the last 5 years	59	0
Skin cancer screening F: published in the last 5 years	12	0
Melanoma Screening Skin Cancer F: published in the last 5 years	4	0
Primary care AND skin cancer screening	14	0

Table 2.5 Search history from OvidMD

Query/ Filters	Results Returned	Chosen for Review of Literature
Total body skin exam	5517	2
Total body skin exam / F: published in the last 5 years, journals	175	0
Skin cancer competency	4	2



## 2.2 Review and Synthesis

Since the USPSTF released their guidelines in 2015, additional evidence continues to shed more light on the importance of TBSEs. Details of each study referenced are located in alphabetical order on the Matrix Table (Appendix C).

Research by Ferris et al. (2017) found that in those screened by their PCP for skin cancer, the incidence of melanoma was more than half that of unscreened patients. Additionally, thickness rates of invasive melanomas were found to be lower by a statistically significant amount in screened patients compared to unscreened patients (Ferris et al., 2017; Wakiyama et al., 2017). It is also important to note that the average age of diagnoses was two years younger (62 rather than 64) for screened patients (Ferris et al., 2017). A skin care prevention program promoting and implementing skin cancer screening has been estimated to prevent 20% of melanoma cases (Guy et al., 2015). In a pilot study by Katalinic, Eisenmann & Waldmann, (2015) melanoma mortality rates decreased by 47% in men and 49% in women with the implementation of a skin screening exam. While a reduction in mortality has been duplicated, it is important to note that it has not been duplicated to such a significant extent.

Most incidental skin cancers that are found are located on the head, neck, and back. The head and neck are often exposed during a PCP physical exam but the back, unless a patient is placed in a gown, is almost never visualized (Kingsley-Loso et al., 2015). The TBSE leads to detection of earlier stage melanomas and seeks to decrease disease-specific mortality (Shellenberger, Nabhan, & Kakaraparthi, 2016).

### **2.2.1 Age**

Recent research has suggested that there exists a clear decrease in morbidity in patients aged 35 years and older screened by the primary care physician for skin cancer (Johnson et al., 2017). Screening, however, is necessary for all age groups and skin cancer is not only a disease of old age. Increased use of tanning lamps and beds contribute to melanoma diagnosed a younger age in both men and women, but particularly women (Lazovich et al., 2016).

### **2.2.2 Over Diagnosis**

The USPSTF guidelines suggest that screening for skin cancer could result in over diagnosis and result in potential harm (Final Update, 2015). Ferris et al. (2017) found that screening likely detects thin melanomas, however more people die from melanomas thinner than 1mm than from those thicker than 4mm. This is largely due to a much greater incidence rate. Thus, if there were to be an uptick in referrals it would be for a thinner lesion.

There still exists the concern that unnecessary referrals would result from such screening. This, however, is not the case according to Swetter et al., (2017) for determining the effect of screenings; research concluded that there was not a statistically significant increase in the number of referrals or unnecessary skin surgeries with total body skin screenings. This is largely due to the fact that skin cancers are not failing to be detected with screenings but are being diagnosed in earlier stages (thus having an effect on morbidity and mortality) (Swetter et al., 2017; Weinstock et al., 2016).

The key is that it is not the PCP's role to diagnose the skin cancer, but to assess and refer the at risk or lesion-bearing patient to a specialist for diagnosis (Kingsley-Loso

et al., 2015). Even if a lesion is benign, there is still a benefit to an exam by a specialist as 6.9% of patients referred to a dermatologist had one or more additional incidental cutaneous malignancies and 13.1% had one or more biopsied lesions. Basal cell carcinomas specifically often develop in multiples over time therefore screening using only lesion-direct screening increasing the risk of missing potential or actual skin cancers (Hoorens et al., 2016).

### **2.2.3 Training**

As noted in the background section, some studies have identified that medical students perceive a lack of training in medical school regarding skin examinations. In a large randomized trial on skill mastery, Robinson et al. (2018) suggests that training helps in the proper diagnosis and referral. Hartnett & O’Keefe’s (2016) study about nurse practitioners noted that sufficient training can be completed with a 15-minute web tutorial. Such training, however, is not necessary to achieve successful/impactful results as a large proportion of practitioners in Ferris et al.’s (2017) study had no skin cancer identification training. It is important to note that incidence of melanomas thicker than 0.75mm decreased with heightened awareness alone and even more drastically with the implementation of screening, regardless of training (Schneider, Moore, & Mendelsohn, 2008).

### **2.3 Summary**

The study by Robinson et al. (2018) represents the only randomized trial at the time of research on the topic. The remaining evidence utilized for this synthesis consisted of: observational reports, quasi-experimental studies, cross sectional studies, retrospective chart reviews, literature reviews, mixed methods reports, and expert

opinion. As a vast amount of randomized control trials or systematic reviews are lacking in relation to TBSEs, a wide variety of evidence has been analyzed throughout this process to demonstrate the support of evidence as expounded upon above and have served helpful in concluding the benefit of TBSEs.

#### **2.4 Project Recommendation**

The review of literature supports the value and relevance of the PICOT question to implement a TBSE in the primary care setting. Implementation of the TBSE will not only increase awareness of skin cancer in the patient but seek to decrease morbidity and mortality.

The overall goal of this evidenced-based practice change project is to close the gap in practice by providing a TBSE as part of a comprehensive physical exam. This goal is clearly supported by the research findings presented by Johnson et al. (2017), Ferris et al. (2017), Weinstock et al. (2016), Katalinic et al. (2015), Kingsley-Loso et al., (2015), Lebwohl, (2015), & Schneider et al. (2008).

## Chapter 3

### METHODOLOGY

Total body skin exams (TBSE) are extensively prevalent in the highly specialized setting of dermatologic care. Community dwelling adults, however, often do not have the necessary exposure to such specialists. The practitioners whom they do have access and exposure to, primary care practitioners, are not routinely performing such assessments. As previously noted, only eight percent of patients seen by their PCP receive a TBSE (Johnson et al., 2017). The number of PCPs performing biopsies of suspicious lesions is even less. As Enamandram (2015) notes, more than 10% of skin biopsies performed by family physicians were malignant. This staggering statistic does not represent the additional number of non-biopsied malignancies found and referred to dermatologists by PCPs. Skin examinations, noted as a value-delivering intervention, are not only minimally invasive and inexpensive, but proven to reduce morbidity, mortality, and even health care expenditure by detecting malignancies at an earlier stage (Enamandram, 2015).

This project implemented a total body skin exam, defined as an “evaluation of the entire skin surface (scalp, face, ears, neck, chest, abdomen, back, buttocks, genitals, upper and lower extremities, hands, feet, eyes (iris and sclera), oral mucosa, hair and nails)” (Johnson et al., 2017, p.15) into a routine physical examination as the standard of care within a single provider primary care practice. A referral to a specialist was made, if deemed appropriate, from the TBSE. After the visit, the project lead placed a call to the patient in an effort to document follow-up with the specialist. After completion of the implementation, a retrospective chart review from the previous years’ matching time

period was reviewed to compare and contrast dermatologic referrals. The remainder of this section will detail the methodology in which this project was implemented.

### **3.1 Setting**

The implementation of the TBSE, as part of an annual physical, took place in the Nurse Managed Primary Care Center (NMPCC) located at 540 South College Avenue, Suite 130 in Newark, DE. This practice is in an academic setting in the university of Delaware and is a clinical education site for undergraduate and graduate nursing students. A single practitioner at the location, Beatrice Gaynor, PhD, APRN, FNP-BC implemented the practice change with appropriate patients (detailed below). Dr. Gaynor worked one day each week at the NMPCC and saw on average 1-2 annual physicals per day. The retrospective data collection occurred on patients seen for an annual physical or routine wellness exam at the same location by the same provider in the preceding year over the same timeframe.

### **3.2 Participants**

Any patient, new or established, presenting to the practice for an annual physical or routine wellness examination between the predetermined ages of 18-75 was offered a TBSE as part of the standard general physical exam. There was no contraindication for race, gender, weight or any other personal modifiable or non-modifiable factor.

The form of data collection utilized for this project was combination of judgmental sampling and convenience sampling. This was due to the fact that participants were being screened based on specific qualifiers, in this case, their age, which resulted in the sample being considered “judgmental”. The patients were also obtained through

convenience sampling, as any patient who met the qualifications and sought preventative/annual care at the practice was included.

### **3.3 Implementation Plan**

The implementation of the TBSE practice change project screened all individuals between the ages of 18 and 75 who presented for an annual physical exam and agreed to have the TBSE. As a modified skin exam is often included in a physical exam, a more thorough exam does not add a significant amount of time to the provider's exam. Since a TBSE was to be the standard of care for all patients, there was no need for a consent form.

The process proceeded as detailed below. It is important to note that current standards of care remain included in the detailed process for clarity.

1. The patient checked in for his/her appointment at the front desk verifying "annual physical" as the reason for the appointment
2. The patient was taken back to an exam room at their scheduled appointment time
3. Upon rooming the patient, if the patient was scheduled for an annual physical per the electronic medical record (EMR), a undergraduate nursing student/volunteer asked the patient to remove his/her clothing and provided the patient with a gown to be worn for the appointment
4. The patient was seen by the primary care provider and received an annual physical assessment and offered a TBSE as the standard of care
5. The results of the TBSE were documented under the integumentary section of the physical exam section in the EMR
6. A referral was made if determined necessary by the provider of care

7. At least two weeks after the appointment, a call was placed to the patient to verify if follow up to specialist had been scheduled/attained
8. At the end of each week, data was reviewed by means of a chart review, completed by the project lead. Necessary information was extracted to a password protected excel document.
9. The data was reviewed and ultimately synthesized with descriptive statistics.
10. During the implementation process, a retrospective chart review was performed on synchronous dates from the year prior. All annual physical or annual wellness visits of patients between the ages 18-75 were analyzed. The age, race, gender, and referral status were documented.

### **3.4 Project Timeline**

Official project implementation began September 2<sup>nd</sup>, 2019 and closed December 13<sup>th</sup>, 2019. This time-period was selected to allow for a maximum amount of time for data collection within the time constraints of the academic semester. During its implementation, the project lead collected data by chart review.

It is important to note that project development began in the summer of 2018 with the development of the PICOT question and literature review and continued through to its implementation date.

### **3.5 Ethical Considerations**

This project holds ethical considerations to the highest standards and has taken every means possible to ensure the rights of individuals are protected and ensured. This is exemplified in the project lead's collaborative institutional training initiative (CITI)



certification. Such is often considered the standard of care for work including human subjects (which this project includes). Additionally, prior to its implementation, this practice change project was submitted to the University of Delaware's Institutional Review Board (IRB) (Appendix D). The IRB determined the project to be not human subject research and was approved to proceed. Any changes in protocol were approved prior to their implementation by the IRB (Appendix E).

The project lead ensured in data collection that no personal information was removed from the electronic medical record and that participants remained unrecognizable. HIPAA guidelines were maintained. As implementation of the exam was a standard of care, consent was not required. Patients rather, as with any other exam, had the right to refuse a TBSE. If such was the case, refusal was documented and noted within the chart and data. There were no noted conflicts of interest with this project.

### **3.6 Data Collection & Analysis**

As the provider of care implemented the screening, the project lead (PL) was not required to be at the practice daily. Rather, the project lead collected data weekly. The project lead had access to the EMR, reviewed the charts of the above-noted practitioner and obtained the race, gender, age, and TBSE result from the patient's chart. The project lead took this information and transferred it to a password protected excel document. The PL did not remove identifying information such as name, addresses, date of birth, medical record number or medical conditions from the medical record and only collected the age, race, and gender of the patient in addition to whether or not they were referred to dermatology for a suspicious lesion.

The analysis of the data obtained sought to demonstrate the incidence of referrals from primary care with appropriate screening. The 15-week time period was expected to yield sufficient data to demonstrate significance. Descriptive statistics sought to describe or summarize features of the collected information. The descriptive statistics included the sample size, the demographic or clinical characteristics (noted above in collection) and their relative proportions.

### **3.7 Project Evaluation**

Evaluation of the project occurred every week during implementation. This occurred by a check in between the PL and the provider of care. Stakeholder evaluation was strongly taken into consideration upon completion and weighed heavily in the evaluation process.

On a more microscopic level, the project was evaluated in regard to time, quality of data, quantity of data, satisfaction of the stakeholders, and satisfaction of the project lead in its evaluation.

### **3.8 Project Budget**

The budget for this project was \$0.00. The provider of care agreed to implement the TBSE as a routine standard of care screening. The PL operated at no cost. The implementation of TBSEs in the primary care setting helped to identify skin abnormalities and malignancies earlier in their stages thus potentially contributing to a reduction in healthcare expenditure and improved outcomes over time.

### **3.9 Project Close Out**

The project close-out date was December 13<sup>th</sup>, 2019. Stakeholder feedback was collected upon project close. Following project close out, the dissemination plan was initiated.

### **3.10 Dissemination plan**

After the project completion, dissemination of the project will commence with the written project brief (Moran, Burson, & Conrad, 2017). Additionally, other means of deliverables will include a PowerPoint assisted presentation at the University of Delaware School of Nursing in the spring of 2020. Publication of the findings will be considered. It is important to recognize that evidence will not progress without effective dissemination of the findings to appropriate stakeholders and without proper notoriety within the field (Moran, Burson, & Conrad, 2017).

## Chapter 4

### RESULTS

#### 4.1 Descriptive Statistics

The following section will review the data from the completed project.

Of the patients evaluated during the 15-week implementation period, 17 patients were eligible for and offered a Total Body Skin Exam (TBSE) during their annual physical exam. Of the 17 patients, 11 accepted a complete TBSE, 5 accepted a limited (genital differed) TBSE, and one declined the exam all together. The demographic breakdown of the 16 individuals who were examined included three males, thirteen females; all were Caucasian non-Hispanic; age range from 18 to 73 years old. Table 4.1 below provides details on the patients and their specific results.

Table 4.1 TBSE Patient Results

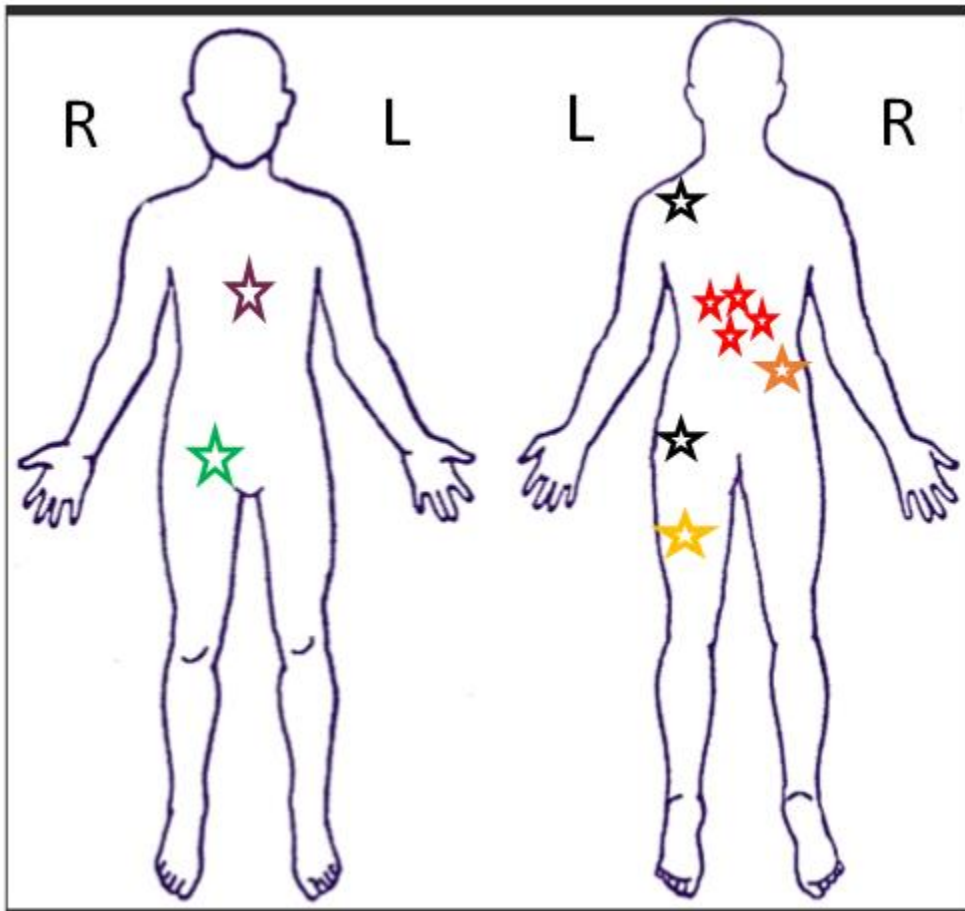
Pt #	Age	Gender	Race	Negative TBSE	Positive TBSE	Specific + Result
1	61	F	Ca	X (GD)		
2	73	F	Ca	X		
3	54	F	Ca		X	Upper back lesion: Brown/black with irregular borders Buttock Lesion:2cm lesion regular borders
4	18	F	Ca	X (GD)		
5	41	F	Ca	X (GD)		
6	44	F	Ca		X	4mm tan, dry, crusting 2mm raised lesion with irregular borders to right back
7	57	F	Ca	X		
8	58	F	Ca	X		
9	70	F	Ca		X	2mm lesion with uneven edges and multiple colors to left posterior leg
10	23	M	Ca	X		
11	58	F	Ca		X	Skin tag >5mm
12	22	M	Ca		X	1CM dark brown and black lesion with irregular borders to right groin
13	65	F	Ca	X (GD)		
14	26	F	Ca	X		
15	21	M	Ca	X (GD)		
16	57	F	Ca		X	Multiple new seborrheic lesions to back

**Table 4.1 Key**

- GD: Genitalia Deferred
- F: Female
- M: Male
- Ca: Caucasian non-Hispanic

Of the sixteen individuals who received an exam, six individuals (37.5%) yielded a positive result indicating that their exam yielded a suspicious skin lesion that warranted referral to a dermatologist. No patients who had a “genitalia deferred” exam screened positive. Of the six patients who had positive results, 5 were female and one was male. The ages of the patients who screened positive ranged from 22 to 70 years old. The locations of the suspicious skin lesions included the left upper back, the right lower back, the middle back, left buttock, left leg, middle chest, and right groin area. Some patients had more than one concerning lesion. A depiction of the sites and brief description of the lesions can be seen below in figure 4.1.

Figure 4.1 Locations of Suspicious Skin Lesions on Patients who Screened Positive During TBSE



Key	
★	= Positive Patient 1: Dark brown and black lesion with irregular borders
★	= Positive Patient 2 : Tan, dry, crusting lesions, irregular, raised 2mm
★	= Positive Patient 3: Brown black lesion, irregular borders, 2mm
★	= Positive Patient 4: Skin tag >5mm
★	= Positive Patient 5: 1CM lesion, dark brown, irregular borders
★	= Positive Patient 6: Multiple new seborrheic keratosis on back

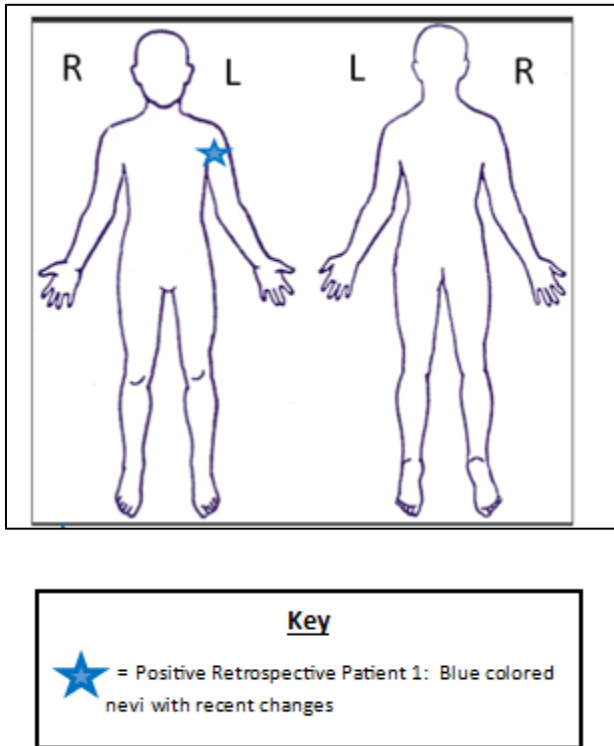
## 4.2 Retrospective Review

Throughout the data collection time, a retrospective chart review was completed simultaneously of all the physical exams performed by Dr. Beatrice Gaynor during the same time period (September 2<sup>nd</sup>- December 13) one year prior, in 2018. The results of this retrospective review helped to answer the PICOT question which was the driving purpose of this practice change project: "How will the implementation of an annual total body skin examination (TBSE) affect the incidence of referrals for suspicious skin lesions (consistent with melanoma, basal cell carcinoma, and squamous cell carcinoma) in the adult population between ages 18 and 75 in a primary care office?". Although nothing can be said definitively about the patients, it can be inferred that there were more referrals during the practice change project than in the same time frame the previous year.

In the chart review, during the same time period in the preceding year, 13 total patients received annual physical exams by Dr. Beatrice Gaynor at the NMPCC. Of those 13 exams, only one patient was referred to dermatology due to a suspicious skin lesion. Perhaps the most interesting finding is that the patient's suspicious lesion was on her left arm, visible with clothing on. The visual representation of location clearly displays how easily skin lesions may be missed without a full body examination and the patient removing their clothes.



Figure 4.2 Location of Suspicious Skin Lesion in Retrospective Review.



When comparing Figure 4.1 and Figure 4.2, it is easy to see how many suspicious skin lesions consistent with melanoma or non-melanoma skin cancer are located in areas not clearly visible when wearing clothes. If you were to reference Figure 4.2 again, of the six patients who screened positive, if a patient did not change into a gown, it can be estimated that only one lesion (the lesion on the back left shoulder- one of patient 1's lesions) may have been identified, assuming the provider moved clothing when assessing lung sounds. Additionally, if patients were placed in gowns but lower body and genitalia regions were not examined, three total lesions would likely have been missed (patient 5, patient 3 and patient 1).

### **4.3 Total Body Skin Examination Follow Up**

A follow-up was conducted with the patients who screened positive and were referred for additional treatment. A total of up to three calls were placed in attempt to reach these patients. Three out of the six positive TBSE screens were successfully contacted. Calls were placed 1-8 weeks post office visit. All three patients had failed to follow up but acknowledged that they were planning to make an appointment. Some used reasoning such as “my insurance changes at the end of the year and therefore I’m waiting to schedule for when I have the new insurance”, others stated “after the holidays I’ll do it.” None of the three patients expressed a lack of desire to follow-up despite the fact none of them had. While this result was discouraging, it is important to realize this happens very frequently in primary care, and that TBSEs and dermatology referrals are not immune. The results of this follow-up, while small, display areas of opportunity for providers going forward again, not only in referrals, as a result of TBSEs, but for primary care providers and patient accountability for follow-up.

### **4.4 Interpretation of Findings**

The findings are best interpreted after visualization of their results. As depicted, the majority, if not all areas of suspicious skin lesions were found in locations easily hidden by clothes. This implies that, for practitioners who do not undress their patients, likely all of these lesions would have been missed unless specifically accounted for by the patient. Additionally, if a patient were not in a gown, it is likely that at least three skin lesions, the ones described as “Positive Patient 3: brown & black with irregular borders, 2mm”, “Positive Patient 5: 1CM lesions, dark brown, irregular borders” and “Positive Patient 1: dark brown and black lesion with irregular borders (to the left lower buttock)”

would have likely been missed. When reading the description of all the lesions, concern grows; 2 millimeters, 1-centimeter, irregular borders, multi-colored. All signs of potential skin cancers that easily could have been missed even by a practitioner performing a thorough exam with diligence.

Ultimately, the provider performing the TBSE identified individuals with suspicious skin lesions and referred them to higher care when appropriate. The identified lesions were in expected areas, with a large percentage on the back, but multiple lesions were in inconspicuous places such as the groin and buttock which are not often examined unless indicated. Therefore, the TBSE proved successful at identifying lesions all over the body and throughout any age or gender. Evidence by Kingsley-Loso et al. (2015) supports that a significant percentage of primary care patients referred to dermatologists for suspicious skin lesions have either precancerous, cancerous, or multiple abnormal lesions and require the specialty care.

#### **4.5 Limitations in Data Collection**

The project lead had full access to current and retrospective patient charts at the project site and encountered no difficulty in abstracting the elements necessary for the practice change project. Time was the largest limiting factor in data collection. It is important to note that due to this limitation, and since the project was enacted in a university setting, the ultimate benefit of the TBSE cannot be determined. Time limitations had far reaching effects, including accurate follow-up and impact measurement. As a result, specialist (in this case dermatology) follow-up was unable to be collected or recorded (something that often happens in the primary care setting).

Additionally, the size of the clinic was also a limiting factor in data collection.

While the clinic is a successful clinic, it sees a smaller number of patients each day compared to most primary care clinics. This ultimately resulted in a smaller total sample size for collection.

## Chapter 5

### INTERPRETATION OF THE DATA

#### 5.1 Discussion

The results of the implementation of TBSEs yields many points of discussion. First it is important to further analyze the patients as a whole. For example, the only patient that refused a TBSE did so because the patient expressed that they already saw a dermatologist regularly and had a TBSE performed within the last year. A goal of primary care is prevention through screening, this patient refusing the exam in fact does not affect the project change numbers, but rather underscores the goals of the project. In many cases primary care practices and providers serve to screen patients and refer as necessary. If, for example, a patient with diabetes chooses, based off preference or recommendation, to see an endocrinologist to manage their diabetes, the primary care practitioner does not re-run all of the same tests but rather defers to the specialist. This is the same protocol in relation to TBSE. Therefore, if a patient reports being followed by dermatology with active TBSEs (this would not apply if a patient has seen dermatology solely for a separate disease process such as acne) the PCP can rest assured to not repeat the exam. Therefore, the one patient in this practice change was not in reality considered “lost” to the practice study but rather already followed and up to date on care.

Secondly, of the ten patients who screened negative, three (30%) self-reported to be followed by dermatology annually or more frequently. While this information was not directly derived from patients, this percentage could have been higher, but its importance significance regardless can not be understated. A logical inference can be made, that since patients are followed by a proper specialist, they have less suspicious skin lesions

due to proper care and prevention. This is supported by the remaining patients as well. For example, similarly, of the five patients who refused genitalia exams (and also had negative partial TBSEs), at least two self-professed to have regular or recent follow up/visits with gynecology. This supports the notion of adequate preventative care ensuring patients are healthier and able to make informed treatment decisions.

In contrast, of the six patients who screened positive, none had an established dermatologist. This supports the inference above and at a minimum supports the notion of screening in primary care as a means to target patients who do not have the ability or knowledge of need to see a specialist such as a dermatologist. In fact, one of these patients self-reported that he had not seen a primary care provider (or any other specialist) in at least 12 years. This supports the literature findings that this screening appears best placed within a primary care visit as they outnumber dermatology visits nearly nine-fold (Gordon, 2014) and may have improved accessibility over a specialist appointment.

## **5.2 Barriers & Advantages**

Discussion would not be complete without the dialog surrounding the barriers and advantages of implementing this project change. What worked and what didn't? What got in the way? During discussions with the implementing provider, Dr. Beatrice Gaynor, there were both modifiable and nonmodifiable barriers for implementation. The nonmodifiable barriers included patient characteristics such as extensive thick hair, or nail polish. These things prevented a thorough and complete TBSE to be completed by hindering visualization of certain body parts. Additionally, some patients presented with ulterior motives for the exam. For example, some patients presented for a physical

because they need it for work or school. As a result, they were less interested in their health and more interested in getting in and getting out of the office. While this was mentioned by patients on more than one occasion, it did not result in any TBSEs from being completed. As for modifiable barriers, there was one primary barrier and that was the medical assistants, or rather, lack thereof. This will be discussed below in the limitations section however it is also important to note as a barrier. The nursing students, which are utilized as medical assistants in the clinic often forgot to put patients in gowns or properly screen the visit type. This added an additional step for the provider, ultimately delaying the visit and resulting in less time for examination. Time is a noteworthy barrier to implementation of this practice change.

### **5.3 Project Limitations**

The limitations of the project largely surround the site where the implementation took place. While the site provided adequate data, it provided biased data based on the demographics of the client population. Of the 16 patients, 13 (81.25%) were female and all were Caucasian, non-Hispanic. While it has been established that non-Caucasian individuals such as African Americans or Hispanic Americans do suffer from skin cancer, it is also understood that Caucasian individuals, particularly those with Fitzpatrick Skin Phototype classification 1-III (Appendix A) have higher risks of developing skin cancer (Amrock & Meydani, 2013). Since all patients examined were Caucasian, this could have arbitrarily increased the incidence of suspicious skin lesions noted. If the project were to be duplicated, a clinic with a more diverse patient population would help to yield more representative data.

Secondly, as the NMPCC is a small practice, time and numbers became limiting constraints. Only one provider out of four agreed to implement the TBSEs, and that provider worked at the clinic one day a week. As a result, data collection had the opportunity to be much larger than it was but was constrained by the limiting number of providers. Additionally, as the project change was enacted as part of a University program, it inherently met university time constraints of semesters and deadlines. Additionally, the time constants of the semester resulted in less than complete follow-up with patients. Although many specialists who examine patients referred by the NMPCC, dermatology specialists rarely send acknowledgements of the referral or corresponding results (C. Haines, personal communication, 2019). Due to the compressed time frame of the project, patients had not yet made appointments for the specialist.

#### **5.4 Sustainability of the Project**

The work implemented will at a minimum, be sustained by the site mentor, Dr. Beatrice Gaynor. Dr. Gaynor decided to join the DNP project team and implement the practice change out of a sincere belief in the importance of the project. With the results seen in the implementation phase, Dr. Gaynor is committed to maintaining the implementation of TBSE during annual physicals of her patient population.

Informal dissemination occurred to the staff at the NMPCC throughout the duration of the project. As TBSE should not impact a cost increase to the practice, there should be no concern for financial factors negatively affecting its sustainability. Ultimately, all providers choose to practice differently and other constraints such as time remain a concern for some. As the NMPCC is a unique setting where patients often have



longer appointments than traditional primary care settings, its sustainability will be supported by the ability to carry out these exams with quality.

For future associated projects, implementation should occur in locations with strong support staff (nurses or medical assistants). A patient being “prepped” properly will nearly eliminate the additional exam time which will be more of a concern to a busier practice. Sustainability will be reinforced by collecting additional aggregate data to disseminate and present to practitioners to show the comparative effects of implementation of the project.

### **5.5 Significance of the Change Project**

The project clearly affected the clients of the Nurse Managed Primary Care Center (NMPCC) most directly. The practitioner implementing the project had the opportunity to advance the patients’ health and identify potentially lethal skin abnormalities, making their care more thorough.

More broadly, the project affected Delaware residents; a state whose malignant melanoma rates place the state 5<sup>th</sup> in the USA or incidence. Additionally, compared to the rest of the USA, melanomas in Delaware are diagnosed at a much later stage (Cancer Incidence, 2017). The project was implemented in Newark, New Castle County, Delaware, one of the most populated cities in the state. Increasing this practice change throughout the County and eventually the state will ensure its impact to all Delawareans.

Ultimately, the project answered the PICOT question as referrals for suspicious lesions were increased even in this very small population. While it reached a small number of individuals, these individuals received the benefit of being identified with suspicious skin lesions that likely would not have been addressed without a TBSE.

## **5.6 Implications for Advanced Practice**

As discussed initially, the Centers for Disease Control (CDC) estimates that a comprehensive skin cancer prevention program would prevent at least 20% of melanoma cases and decrease associated costs by 2.7 billion dollars between the years 2020 and 2030 (Guy et al., 2015). If TBSEs become the standard of care for primary care providers during annual physicals throughout the United States for skin cancer, the opportunities to affect cost and morbidity related to melanoma and non-melanoma skin cancers are great. Nurse practitioners who are trained in evidence-based practice have the potential to lead this wave of practice change through example.

Additionally, there remain opportunities to bill for TBSEs. “Encounter for screening of malignant neoplasms” (ICD 10: Z12.83) can be used by practices that want to bill separately for the exam. By doing so, especially in a state like Delaware who is losing primary care providers due to lack of reimbursement, additional coding could service practices well.

## **5.7 Dissemination**

The dissemination of the DNP Project Total Body Skin Exams in the Primary Care Setting will be at the local and regional level. As the project is being sustained at the NMPCC in Newark Delaware, a part of the University of Delaware, dissemination will occur at the local level both at the clinic itself and at the University’s School of Nursing. More specifically, formal dissemination will occur to the School of Nursing during the project presentation in hopes of advancing the knowledge and ease of TBSEs within the nursing community. This will engage key stakeholders and active participants in the nursing community. The TBSE should be considered as part of the physical exam

curriculum in the nurse practitioner program.

A poster presentation will be submitted and presented at Christiana Care's "Tell It In a Poster" nursing research week event. As Christiana Care health system sees inpatient, as well as outpatient individuals, presentation at such an event will draw practitioners from primary care who are the target audience. Additionally, the project will be submitted to be presented at Nursing Grand Rounds at Christiana Care as a means to reach more individuals within the organization.

Submission will also be made to The Journal for Nurse Practitioners. As the official journal for the American Association of Nurse Practitioners, dissemination to such a source has the potential for large reaching effects. As it is a generalized journal, not a specialty focused journal, the submission of the DNP project dissemination will be appropriate to target generalized practitioners.

## **5.8 Conclusion**

Ultimately, while the practice change remained small, its current and future impact cannot be understated. As time remains a factor for all healthcare practices and examinations, certain exams like a TBSE can not only be completed efficiently with proper workflow, but effectively.

This change project highlighted the lack of transparency between the dermatology specialists and the primary care practices, at least in this geographic location. There is a need to close the loop of care amongst the providers with dissemination of medical information, rather than rely on patient disclosure of skin exams, frequencies, and results. A fully integrated universal EMR would be the solution, albeit in the future. For the current concern, perhaps the Delaware Coalition of Nurse Practitioners could spear head

a movement to encourage and facilitate seamless transfer of medical information between all providers of care.

For myself as the project lead and a future advanced practice healthcare provider, this project change was challenging but nonetheless rewarding. It demonstrated the importance of a thorough examination and efficiency of staff. When both are aligned, a provider of care has the maximum potential to provide each patient with well-rounded, all-encompassing, and quality care.

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## Appendix A

### THE FITZPATRICK SKIN PHOTOTYPE CLASSIFICATION

Table 1: The Fitzpatrick skin phototype classification<sup>17-18</sup>

Skin type	Unexposed skin colour	Constitutive characteristics	History of sunburn	Ultraviolet radiation sensitivity	Continuous ultraviolet radiation exposure needed for sunburn (SED)
I	White	Fair skin, blue or light eyes and freckles	Always burns on minimal sun exposure	Extremely sensitive	2-3
II	White	Red or blonde hair, blue, hazel or brown eyes and freckles	Burns very readily	Very sensitive	2.5-3
III	White/light brown	Brown hair and blue, hazel or brown eyes	May burn on regular sun exposure with no protection	Moderately sensitive	3-5
IV	Light brown	Brown hair and dark eyes	Burns rarely	Relatively tolerant	4.5-6
V	Brown	Brown eyes and dark brown or black hair	Despite pigmentation, may burn surprisingly easily on sun exposure	Very variable	6-20
VI	Black	Brown eyes and dark brown or black hair	Rarely burns, although sunburn is difficult to detect on very pigmented skin	Relatively insensitive	6-20

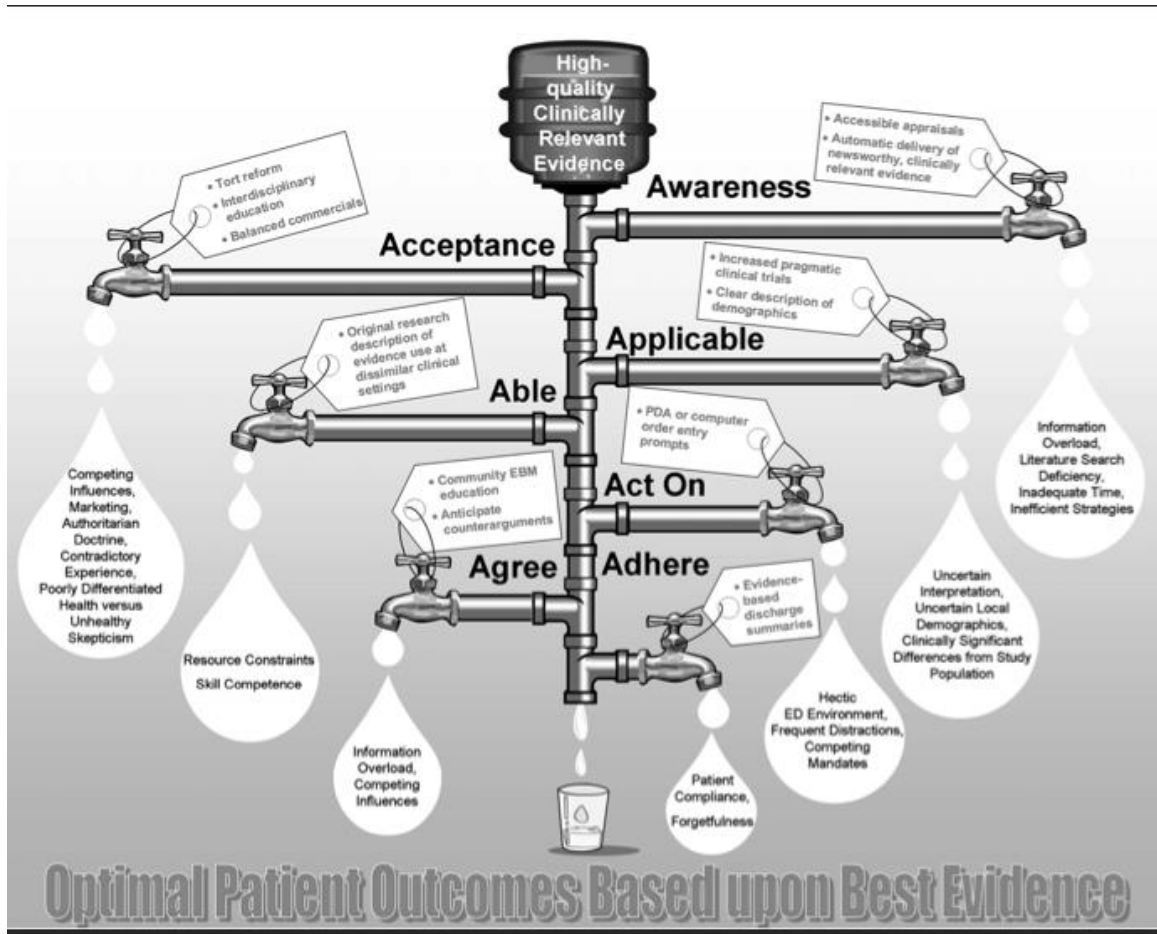
SED, standard erythemal dose

(Makgabutlane, Caradee, & Wright 2015).

*Note:* Image licensed under creative commons 2.0

## Appendix B

### PATHMAN'S PIPELINE



Diner, B. M., Carpenter, C. R., O'Connell, T., Pang, P., Brown, M. D., Seupaul, R. A., ... & KT-CC Theme IIIa Members. (2007). Graduate medical education and knowledge translation: role models, information pipelines, and practice change thresholds. *Academic Emergency Medicine*, 14(11), 1008-1014.

## Appendix C

### MATRIX TABLE

Author/Date	Conceptual Framework	Design/Method	Sample/Setting	Major Variables Studied & Their Definitions	Measurement	Data Analysis	Findings	Appraisal Worth to Practice
Ferris, L. K., Saul, M. I., Lin, Y., Ding, F., Weinstock, M. A., Geller, A. C., ... & Kirkwood, J. M. (2017). A large skin cancer screening quality initiative: description and first-year outcomes. <i>JAMA oncology</i> , 3(8), 1112-1115.	None	Level V-A  Observational evaluation of a prospectively implemented QI initiative. X2 test utilized for discrete variables. Logistical regression for odds ratio	<ul style="list-style-type: none"> <li>• "A large health care system in western Pennsylvania".</li> <li>• 333753 total patients (53196 received TBSE, 280539 did not)</li> </ul>	IV: Adult patient over the age of 35 who saw a UPMC-employed PCP for an office visit in 2014 and had a documented screening status for skin cancer DV1: incidence of melanoma DV2: thickness of melanoma (IV=independent variable, DV=dependent variable)	Incidence and degree of melanoma in comparative groups	<ul style="list-style-type: none"> <li>• Descriptive statistics used to report demographic characteristic</li> <li>• X2 test for discrete variables and Wilcoxon rank-sum test for continuous variables</li> <li>• Logistic regression used to estimate odds ratio</li> </ul>	Large scale screening is feasible in the US and can increase detection of thinner melanomas.	Largest scale study presented on said topic at present. Findings significant enough to change USPSTF guidelines.

Author/Date	Conceptual Framework	Design/Method	Sample/Setting	Major Variables Studied & Their Definitions	Measurement	Data Analysis	Findings	Appraisal Worth to Practice
Guy Jr, G. P., Thomas, C. C., Thompson, T., Watson, M., Massetti, G. M., & Richardson, L. C. (2015). Vital signs: melanoma incidence and mortality trends and projections —United States, 1982–2030. MMWR. Morbidity and mortality weekly report, 64(21), 591.	None	Level V-A  Analysis of current melanoma incidence and mortality data with statistical evaluation to project melanoma incidence, mortality, and cost.	<ul style="list-style-type: none"> <li>The entire United States</li> <li>Data obtained from the National program of cancer registries and the surveillance epidemiology and end results (SEER) program representing 99.1% of US population</li> <li>Death certificates from all 50 states/</li> </ul>	<ul style="list-style-type: none"> <li>Incidence of invasive melanomas</li> <li>Cost of melanoma treatment</li> </ul>	Incidence and cost of invasive melanoma treatment in the US.	<ul style="list-style-type: none"> <li>Cost estimates were adjusted using the per capita projected increase in national health expenditures through 2023.</li> <li>SEER data was utilized to calculate incidence rate projections</li> <li>Referrals made to census.gov/statistics</li> </ul>	<ul style="list-style-type: none"> <li>Melanoma incidence rate is 19.7 per 100000, highest amongst non-Hispanic whites.</li> <li>Death incidence from melanoma was 2.7 per 100000</li> <li>Melanoma incidence rates doubles since 1982 to 2011</li> <li>Skin cancer prevention program is estimated to prevent 20% of melanoma cases.</li> <li>Annual cost of treating melanoma with no intervention is estimated to increased 252.4% from 2011 to 2030.</li> </ul>	Extremely important statistics that discuss the severity of need for intervention related to melanoma.

Author/Date	Conceptual Framework	Design/Method	Sample/Setting	Major Variables Studied & Their Definitions	Measurement	Data Analysis	Findings	Appraisal Worth to Practice
Hartnett, P. D., & O'Keefe, C. (2016). Improving skin cancer knowledge among nurse practitioners. Journal of the Dermatology Nurses' Association, 8(2), 123-128.	Health promotion Model	Level II-A Quasi experimental study	<ul style="list-style-type: none"> <li>10 Nurse Practitioners in the Nebraska Nurse Practitioners Association</li> </ul>	<ul style="list-style-type: none"> <li>IV: 15 minute online educational Program</li> <li>DV: skin cancer identification competency score</li> </ul>	Does the implementation of a 15-minute online education model increase competency of providers on identifying skin cancer	<ul style="list-style-type: none"> <li>Paired t-test</li> <li>P&lt;0.0001</li> </ul>	<ul style="list-style-type: none"> <li>NPs can increase their knowledge and skin cancer lesion identification after a brief online educational program</li> </ul>	Lack of knowledge/experience is not a significant barrier
Hoorens, I., Vossaert, K., Pil, L., Boone, B., De Schepper, S., Ongenaes, K., ... Brochez, L. (2016). Total-body examination vs lesion-directed skin cancer screening. JAMA Dermatology, 152(1), 27-34. <a href="http://dx.doi.org/doi:10.1001/jamadermatol.2015.2680">http://dx.doi.org/doi:10.1001/jamadermatol.2015.2680</a>	none	Level II-B Population based cross-sectional study - quasi experimental	<ul style="list-style-type: none"> <li>2 socio-demographically similar regions</li> <li>TBSE implemented in community of 9325 inhabitants 18 years or older (Wichel, East Flanders, Belgium)</li> <li>Lesion Direct Screening implemented in 9484 adults 18 years or older in Nevele, East Flanders, Belgium</li> </ul>	<ul style="list-style-type: none"> <li>IV: TBSE screening</li> <li>DV: Lesion-direct screening</li> <li>DV: Incidence of skin cancer</li> </ul>	Comparing the incidence rates between TBSE and LDS and its effect/ yield in diagnosis of skin cancer	<ul style="list-style-type: none"> <li>Skin cancer detection rates per 100 participants did not differ significantly between the 2 groups (p=.4).</li> <li>LDS participants had significantly higher anxiety levels compared to TBSE participants (p &lt;0.01)</li> </ul>	<ul style="list-style-type: none"> <li>TBSE yielded a higher absolute number of skin cancers</li> <li>LDS was more time effective</li> </ul>	<ul style="list-style-type: none"> <li>Findings do not diminish the importance and significance of a TBSE but provide LDS as an alternative for health care systems with limited time</li> </ul>

Author/Date	Conceptual Framework	Design/Method	Sample/Setting	Major Variables Studied & Their Definitions	Measurement	Data Analysis	Findings	Appraisal Worth to Practice
Johnson, M. M., Leachman, S. A., Aspinwall, L. G., Cranmer, L. D., Curiel-Lewandrowski, C., Sondak, V. K., ... & Dellavalle, R. P. (2017). Skin cancer screening: recommendations for data-driven screening guidelines and a review of the US Preventive Services Task Force controversy. <i>Melanoma management</i> , 4(1), 13-37.	none	Level V - A  Literature Review	• n/a	• n/a	To compare the recommendations made by the USPSTF compared to proposed guidelines from other national and international organizations	<ul style="list-style-type: none"> <li>• Review of literature</li> </ul>	<ul style="list-style-type: none"> <li>• The steepest incline in mortality and thus the recommended age for screening begins at age 35</li> <li>• The literature review suggests that risk-based skin cancer screening is warranted and justifiable</li> </ul>	<ul style="list-style-type: none"> <li>• Skin cancer recommendations in the UD are not sufficient</li> </ul>

Author/Date	Conceptual Framework	Design/Method	Sample/Setting	Major Variables Studied & Their Definitions	Measurement	Data Analysis	Findings	Appraisal Worth to Practice
Katalinic, A., Eisemann, N., & Waldmann, A. (2015). Skin cancer screening in Germany: documenting melanoma incidence and mortality from 2008 to 2013. Deutsches Ärzteblatt International , 112(38), 629.	none	II-C	<ul style="list-style-type: none"> <li>Adults aged 35 years or older in the country of Germany who have health insurance</li> </ul>	<ul style="list-style-type: none"> <li>IV: bi-annual skin cancer screening</li> <li>DV: mortality rates/incidence</li> </ul>	Mortality rates across Germany after the implementation of a nationwide skin cancer screening program	<ul style="list-style-type: none"> <li>Data on the incidence of invasive malignant melanoma of their skin were extracted from the database of the association of population-based cancer registries in Germany</li> <li>Mortality rates were extracted from the official cause-of-death statistics</li> </ul>	<ul style="list-style-type: none"> <li>No detectable difference</li> <li>Differing results compared to pilot study</li> <li>PILOT STUDY: Impact in mortality rates through 2009: melanoma mortality declined by 47% per 100,000 men and by 49% per 100,000 women by 2008/2009.</li> <li>Impact of screening by PCP on melanoma tumor thickness and mortality rates.</li> </ul>	<ul style="list-style-type: none"> <li>Skin cancer screening yield more results with more intense (annual versus bi-annual) implementation and increased education</li> </ul>



Author/Date	Conceptual Framework	Design/Method	Sample/Setting	Major Variables Studied & Their Definitions	Measurement	Data Analysis	Findings	Appraisal Worth to Practice
Kingsley-Loso, J. L., Grey, K. R., Hanson, J. L., Raju, S. I., Parks, P. R., Bershaw, A. L., & Warshaw, E. M. (2015). Incidental lesions found in veterans referred to dermatology: the value of a dermatologic examination. <i>Journal of the American Academy of Dermatology</i> , 72(4), 651-655.	none	Level III-A  Retrospective chart review	<ul style="list-style-type: none"> <li>17174 veterans</li> <li>Veterans who had a consult from 2004-2012 and had a dermatologist exam at the Minneapolis VA within 18 months of referral.</li> </ul>	<ul style="list-style-type: none"> <li>IV: those referrals to dermatology from primary care</li> <li>DV: incidence of skin cancer.</li> </ul>	Determining the amount of incidental findings of skin cancer in those referred to dermatologist by PCP	<ul style="list-style-type: none"> <li>Statistical analysis of data</li> </ul>	<ul style="list-style-type: none"> <li>6.9% of patients referred by non-dermatologist had 1 or more incidental cutaneous malignancies</li> <li>13.1% of patients had 1 or more biopsied lesions</li> <li>Many were located on the head/neck (areas of observation for a PCP exam)</li> <li>Less than 5% of PCPs at Minneapolis ask patients to undress for exam.</li> </ul>	<ul style="list-style-type: none"> <li>Encouraging PCPS too specifically examine the back while performing auscultation could aid in detection</li> </ul>

Author/Date	Conceptual Framework	Design/Method	Sample/Setting	Major Variables Studied & Their Definitions	Measurement	Data Analysis	Findings	Appraisal Worth to Practice
Lebwohl, M. (2015). [Letter written December 28, 2015 to United State preventative Services Task Force]. Retrieved from <a href="http://www.uspreventiveservice.stakeforce.org/comment/collect/questionpage">www.uspreventiveservice.stakeforce.org/comment/collect/questionpage</a>	None	Level IV-A  Comments provided on behalf of the American Academy of Dermatology Association (Academy) to the USPSTF	• n/a	• n/a	n/a	• n/a	• n/a	• Raises legitimate concerns over the evidence used or rather, not utilized by the USPSTF
Robinson, J. K., Jain, N., Marghoob, A. A., McGaghie, W., MacLean, M., Gerami, P., ... & Martin, G. J. (2018). A Randomized Trial on the Efficacy of Mastery Learning for Primary Care Provider Melanoma Opportunistic Screening Skills and Practice. <i>Journal of general internal medicine</i> , 33(6), 855-862.	None	Level IA  Randomized educational trial	• 90 PCPs	<ul style="list-style-type: none"> <li>• IV: pretest/post test diagnostic accuracy</li> <li>• IV: Referral of concerning lesions</li> <li>• DV: Skin cancer screening training</li> </ul>	Does the implementation of skin cancer screening training affect skills and practice	<ul style="list-style-type: none"> <li>• A randomized number sequence was generated to assign PCPs to the intervention and control groups</li> <li>• Blinded until after pretest</li> <li>• ANOVAs via SPSS</li> </ul>	<ul style="list-style-type: none"> <li>• Patient care was improved by the training (increased referrals for melanomas, decreased referrals for benign)</li> </ul>	• Adds to benefit of training for TBSE

Author/Date	Conceptual Framework	Design/Method	Sample/Setting	Major Variables Studied & Their Definitions	Measurement	Data Analysis	Findings	Appraisal Worth to Practice
Schneider, J. S., Moore II, D. H., & Mendelsohn, M. L. (2008). Screening program reduced melanoma mortality at the Lawrence Livermore National Laboratory, 1984 to 1996. Journal of the American Academy of Dermatology, 58(5), 741-749.	none	Level IIIA Mixed Methods	<ul style="list-style-type: none"> <li>Thickness and incidence of melanomas were detected at three intervals: pre-awareness, early awareness and screening between the years 1969-1996 among LLNL employees</li> </ul>	<ul style="list-style-type: none"> <li>IV: Melanoma incidence</li> <li>IV: Melanoma Thickness</li> <li>IV: Mortality Rate</li> <li>DV: screening intervention</li> </ul>	Does the incidence or degree of melanoma decrease with heightened awareness and/or screening	<ul style="list-style-type: none"> <li>The expected annual number of death from melanoma among subjects was calculated using California mortality data</li> </ul>	<ul style="list-style-type: none"> <li>Incidence of melanomas thicker than 0.75mm decreased During the 3 periods from 22.1 to 15.13 to 4.62 (p=0.001 by chi-square)</li> </ul>	<ul style="list-style-type: none"> <li>Significant reduction in incidence and mortality noted</li> </ul>

Author/Date	Conceptual Framework	Design/Method	Sample/Setting	Major Variables Studied & Their Definitions	Measurement	Data Analysis	Findings	Appraisal Worth to Practice
Shellenberger, R., Nabhan, M., & Kakaraparthi, S. (2016). Melanoma screening: A plan for improving early detection. <i>Annals of medicine</i> , 48(3), 142-148.	none	Level V-A  Literature review	• n/a	<ul style="list-style-type: none"> <li>Key words include: "melanoma" "melanoma detection" "skin cancer"</li> <li>"Skin examination, "Mortality"</li> <li>"Cost effectiveness"</li> <li>"Primary care"</li> <li>"Internal medicine residency"</li> <li>"family medicine residency", "Skin examination education"</li> </ul>	N/A	<ul style="list-style-type: none"> <li>Reviewed Medline complete, PubMed, Cochrane library, Cochrane databases of systematic reviews, and clinical trials.gov 2015 data with keywords. Analyzed trials based on Newcastle-Ottawa quality assessment tool</li> </ul>	<ul style="list-style-type: none"> <li>Total body skin examinations can lead to the detection of earlier stage melanomas as well as disease-specific mortality.</li> </ul>	<ul style="list-style-type: none"> <li>Helps strengthen significance of TBSE</li> </ul>

Author/Date	Conceptual Framework	Design/Method	Sample/Setting	Major Variables Studied & Their Definitions	Measurement	Data Analysis	Findings	Appraisal Worth to Practice
Swetter, S. M., Chang, J., Shaub, A. R., Weinstock, M. A., Lewis, E. T., & Asch, S. M. (2017). Primary Care-Based Skin Cancer Screening in a Veterans Affairs Health Care System. JAMA dermatology, 153(8), 797-801.	none	Level IIB	<ul style="list-style-type: none"> <li>258 Patients</li> <li>Pilot intervention study at the Veterans Affairs Palo Alto Health Care System in patients aged 35 years and older scheduled for annual physical exam between June 2015 and August 2016</li> <li>6 PCPS undertook Internet Curriculum for Melanoma early Detection (INFORMED) training-5 screened patients during the following 14 months.</li> </ul>	<ul style="list-style-type: none"> <li>DV: INFORMED education provided to PCPs</li> <li>IV: incidence and quality of dermatology referrals</li> </ul>	If dermatology referral patterns and skin biopsies differ after skin cancer education and screening by PCPs.	<ul style="list-style-type: none"> <li>Bivariate comparisons were performed with x2 tests or Fisher exact tests for categorical variables and Wilcoxon rank sum test for continuous variables</li> <li>All tests were two-sided with <math>p &lt; .05</math>.</li> <li>SAS statistical software version 9.4</li> </ul>	<ul style="list-style-type: none"> <li>No significant differences were observed in the measure or proportion of referrals and skin biopsies <math>p=0.1</math></li> </ul>	<ul style="list-style-type: none"> <li>PCPs without specific melanoma training still have sufficient skill to complete TBSE</li> <li>Referral rates do not change/alter greatly with such.</li> </ul>

Author/Date	Conceptual Framework	Design/Method	Sample/Setting	Major Variables Studied & Their Definitions	Measurement	Data Analysis	Findings	Appraisal Worth to Practice
Wakiyama, T. P., França, M. L. M., Carvalho, L. P., Marques, M. E. A., Miot, H. A., & Schmitt, J. V. (2017). Initial basal cell carcinomas diagnosed in the National Campaign for Skin Cancer Prevention are smaller than those identified by the conventional medical referral system. <i>Anais brasileiros de dermatologia</i> , 92(1), 26-29.	none	IIB Cross sectional study with retrospective cohort component	<ul style="list-style-type: none"> <li>• 223 individuals with suspicious lesions from 2531 examinations</li> <li>• 116 basal cell carcinomas removed</li> <li>• 84 cases referred to surgery not from the national campaign</li> </ul>	<ul style="list-style-type: none"> <li>• IV: Skin care campaign</li> <li>• DV: lesion size</li> </ul>	Does the implementation of a national skin care campaign affect the profile of detected lesions	<ul style="list-style-type: none"> <li>• Parametric and nonparametric bivariate tests were used for continuous variables</li> <li>• Chi-square test for Fisher's exact test for categorical variables</li> <li>• <math>P &lt; 0.25</math> in bivariate analyses</li> <li>• <math>P &lt; 0.05</math> in multivariate analysis with odds ratio</li> </ul>	<ul style="list-style-type: none"> <li>• Primary lesions identified in the national campaigns were smaller than those referred to surgery by conventional routes of public health care</li> </ul>	<ul style="list-style-type: none"> <li>• Examinations yield substantial/significant results</li> </ul>
Weinstock, M. A., Ferris, L. K., Saul, M. I., Geller, A. C., Ristic, P. M., Siegel, J. A., ... & Kirkwood, J. M. (2016). Downstream consequences of melanoma screening in a community practice setting: first results. <i>Cancer</i> , 122(20), 3152-3156.	none	Level IIIA	<ul style="list-style-type: none"> <li>• 618 PCPs</li> <li>• 16472 patients 35 years or older</li> </ul>	<ul style="list-style-type: none"> <li>• IV: melanoma diagnosis</li> <li>• IV: Skin surgery</li> <li>• IV: Dermatology visits</li> <li>• DV: Skin exams from INFORMED trained PCPS</li> </ul>	Does the implementation of skin exams from PCPs cause harm (Increase unnecessary skin surgeries/burden dermatology visits).	<ul style="list-style-type: none"> <li>• statXact 4 for Windows</li> </ul>	<ul style="list-style-type: none"> <li>• Increased melanoma diagnoses but little impact on skin surgeries or dermatology visits</li> </ul>	<ul style="list-style-type: none"> <li>• Study contradicting suggestions made by USPSTF to warrant screening</li> </ul>

## Appendix D

### IRB APPROVAL



**Institutional Review Board**  
210H Hullen Hall  
Newark, DE 19716  
Phone: 302-831-2137  
Fax: 302-831-2828

DATE: July 24, 2019  
TO: Kristyn Keller  
FROM: University of Delaware IRB  
STUDY TITLE: [1464748-1] Total Body Skin Exams in the Primary Care Setting  
SUBMISSION TYPE: New Project  
ACTION: NOT HUMAN SUBJECTS RESEARCH DETERMINATION  
DECISION DATE: July 24, 2019

Thank you for your New Project submission to the University of Delaware Institutional Review Board (UD IRB). According to federal regulations, this project does not meet the definition of human subject research under the purview of the IRB.

The following definitions were used in making the NOT HUMAN SUBJECTS RESEARCH determination:

- **Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

No further action with the IRB Office is required at this time. Please consult with our office if any major changes to the reviewed project, relevant to the definitions above, were to be proposed.

A copy of this correspondence will be kept on file by our office. If you have any questions, please contact the UD IRB Office at (302) 831-2137 or via email at [hsrb-research@udel.edu](mailto:hsrb-research@udel.edu). Please include the study title and reference number in all correspondence with this office.

#### INSTITUTIONAL REVIEW BOARD

[www.udel.edu](http://www.udel.edu)

## Appendix G

### IRB APPROVAL LETTER



Institutional Review Board  
210H Hulihan Hall  
Newark, DE 19716  
Phone: 302-831-2137  
Fax: 302-831-2828

DATE: November 18, 2019  
TO: Kristyn Keller  
FROM: University of Delaware IRB  
STUDY TITLE: [1464748-2] Total Body Skin Exams in the Primary Care Setting  
SUBMISSION TYPE: Amendment/Modification  
ACTION: ACKNOWLEDGED  
EFFECTIVE DATE: November 18, 2019

The University of Delaware Institutional Review Board (UD IRB) has RECEIVED and ACKNOWLEDGED your submission for the review of the following documents:

- Amendment/Modification - Keller\_Kristyn\_20191113\_Official IRB ChangesTRACKED.doc (UPDATED: 11/13/2019)
- Amendment/Modification - Keller\_Kristyn\_20191113\_IRB AmendmentForm.docm (UPDATED: 11/13/2019)
- Application Form - Keller\_Kristyn\_20191113\_Official IRB ChangesCLEAN.doc (UPDATED: 11/13/2019)

There is no further action for you to take at this time. The UD IRB Office will contact you about any next steps required in the review process if pertinent.

If you have any questions, please contact the UD IRB Office at (302) 831-2137 or via email at [hsrb-research@udel.edu](mailto:hsrb-research@udel.edu). Please include the study title and reference number in all correspondence with this office.

#### INSTITUTIONAL REVIEW BOARD

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