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SKIN CANCER SCREENING IN THE PRIMARY CARE SETTING

by

EMILY ELIZABETH LEWANDOWSKI

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Approved by

First Reader

Allison Larson, M.D.
Assistant Professor of Dermatology

Second Reader

Oren Berkowitz, Ph.D., MSPH, PA-C
Assistant Professor of Medicine

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ABSTRACT

Introduction

Skin cancer is the most common cancer in the United States and melanoma is the fifth most common kind of cancer. The incidence of melanoma has been increasing over the past thirty years. This type of cancer can be detected using a visual skin examination. Survival is related to the thinness and stage at the time of diagnosis. Clinicians find thinner, earlier stage melanomas compared to those found by patients and significant others.

Review of the Literature

The average American visits their primary care provider twice annually and skin conditions are the number one reason Americans younger than sixty-five visit their primary care physician. However, the majority of residents in the United States are not comfortable with performing the full body skin examination required to screen for melanoma. Medical schools in the United States spend one percent of the curriculum on dermatologic conditions. In fact, the United States Preventative Services Task Force does not support regular skin cancer screening by primary care providers since there is limited evidence that primary care physicians perform adequate skin examinations.

Methods

This curriculum is aimed at teaching internal medicine and family medicine interns and primary care physician assistants and nurse practitioners the full body skin cancer

screening examination as well as the ability to differentiate between benign and malignant skin lesions. A pre- and post-course examination of benign versus malignant lesions will be distributed and the scores will be analyzed using a paired T-test. A pre- and post-course Likert scale will be dispersed to evaluate how clinical practice changes based on this course. Mean and standard deviation for the overall Likert scale as well as individual parts of the scale will be calculated and a paired T-test will be used to analyze how the course changed clinical practice of the clinicians. Additionally, standardized patients will be provided for the participants to practice the full body skin examination.

Conclusion

This study is unique in that it is teaching primary care medical interns as well as physician assistants and nurse practitioners the full body skin examination. Limitations include a small sample size, voluntary participation in the setting of a busy work schedule, and pushback from clinicians since performing full body skin exams are not recommended at this time.

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LIST OF ABBREVIATIONS

ABCDE ..... Asymmetry, Border irregularity, non-uniform Color, Diameter, Evolution

BU ..... Boston University

SCREEN ... Skin Cancer Research to Provide Evidence for the Effectiveness of Screening in Northern Germany

USPSTF .....United States Preventative Services Task Force

INTRODUCTION

Background

Skin cancer is the most common type cause of cancer in the United States of America[1], and melanoma skin cancer is the fifth most common kind of cancer in the United States[2]. Unlike most cancers, the incidence and mortality of melanoma has been increasing over the past three decades[2]. The overall lifetime risk for the development of melanoma in the United States of America is one in fifty-two for men and one in seventy-seven for women[2]. In 2016, it was estimated that 76,400 people are diagnosed with melanoma and 10,100 die of melanoma annually[1].

Risk factors for the development of melanoma include age[2], gender[2], skin type[3], immunocompromised state[4], personal or family history of melanoma[3], and presence of dysplastic nevi[3]. White men age sixty-five and older are at high risk of developing melanoma[2]. Ninety-eight percent of those who develop melanoma have at least one risk factor[5].

Diagnosis of skin cancer involves direct visualization of skin. One of the most commonly taught skin cancer assessment techniques is the ABCDE mnemonic[6]. This technique involves looking for asymmetry, border irregularity, non-uniform color, diameter greater than six millimeters, and evolution of a skin lesion. Both patients and clinicians can use this mnemonic to identify potentially cancerous skin lesions; however, clinicians find significantly thinner skin cancers than those identified by the patient or a patient's significant other[7].

Treatment and prognosis of skin cancer are related to the type of lesion as well as the stage at which the lesion is identified. Non-melanoma skin cancer typically does not result in significant morbidity or mortality[1], but it is usually treated with surgical excision, Mohs micrographic surgery, radiation, curettage, and electrodessication to decrease the risk of metastasis[8]. The morbidity and mortality of melanoma is greater than that of non-melanoma skin cancer. Prognosis is related to the thickness of the lesion at diagnosis[9]. Early-stage melanoma is typically treated with surgery whereas metastatic melanoma requires a combination of chemotherapy, radiation therapy, and immunotherapy[10].

Statement of the Problem

It has been shown that clinicians find significantly thinner lesions compared with the lesions found by the patient himself/herself or the patient's significant other[7]; however, the vast majority of primary care residents (seventy-five percent) have never been trained in the full body skin examination[11]. In fact, almost three-quarters of medical students report that they are not skilled in performing a full body skin examination[12].
Only thirty-one percent of primary care providers perform skin examinations on all of their patients[13] despite the fact that diagnosing melanoma at an earlier stage provides a significant survival benefit[9].

In 2009, the United States Preventative Services Task Force stated that there was insufficient evidence to recommend skin cancer screening by primary care providers[8]. One of the cited arguments was insufficient evidence that primary care providers can

accurately diagnose melanoma[8]. There have been studies examining the difference between lesions identified by dermatologists and primary care providers. Dermatologists identified significantly thinner and earlier-stage melanomas compared with primary care providers[14]. However, there is a shortage of dermatologists relative to the demand[15] and the average American visits his or her primary care provider twice per year[2]. Therefore, primary care providers can act as the triage providers and refer suspicious lesions to dermatologists.

Hypothesis

Implementing a skin cancer screening curriculum for internal medicine and family medicine interns, physician assistants, and nurse practitioners will result in improved comfort in performing full body skin examinations and increased knowledge about what to do if a suspicious lesion is found on a patient.

Objectives and specific aims

The objective of implementing a skin cancer screening curriculum is for primary care providers to identify earlier stage, thinner skin cancers. Here, we will seek to integrate a skin cancer screening curriculum for internal medicine and family medicine interns, physician assistants, and nurse practitioners at Boston Medical Center. This study has two specific aims:

1. Comparing pre- and post-course scores (average) of benign versus malignant lesions

2. Comparing pre- and post-course survey scores regarding the comfort level of primary care providers with the full body skin examination

REVIEW OF THE LITERATURE

Overview

Melanoma skin cancer

Melanoma is the fifth leading cause of cancer in the United States of America[2]. Unlike most other cancers, the incidence and mortality of melanoma has been increasing over the past three decades[2]. There has been a three-fold increase in the incidence of melanoma since 1975[2]. In 1975, the incidence of melanoma was 8.2 to 9.4 per 100,000 and this number rose to 24.2 to 35.4 in 2010[7]. The incidence is estimated to increase 3.1 percent per year for males and 3.4 percent per year for females[16]. The overall lifetime risk for the development of melanoma in the United States is 1 in 48[2]. The lifetime risk for men is 1 in 52 and is 1 in 77 for women in the United States[14]. In 2016, it was estimated that 76,400 people in the United States of America are diagnosed with melanoma and 10,100 die of melanoma annually[1].

Certain populations are at higher risk of developing melanoma than others. Many studies have explored the factors that increase one's chance of developing melanoma. Older men are at increased risk of melanoma[2]. Since 1975, the risk of developing melanoma has doubled in men fifty to fifty-nine years old and quadrupled in men sixty to sixty-nine years old[2]. The risk has increased seven-fold in men older than eighty years old[2]. An immunocompromised state confers a three- to six-times increased risk of developing melanoma[4]. Those with genetic immunodeficiency syndromes are six times more likely of developing melanoma, while those with acquired immunodeficiency states

have a four times increased likelihood of developing melanoma[4]. Other melanoma risk factors include the presence of dysplastic nevi, personal or family history of melanoma, fair skin, and inability to tan[3]. Of those who develop melanoma, ninety-eight percent have at least one risk factor, seventy-five percent have two or more risk factors, thirty-two percent have at least three risk factors, and five percent have four to five risk factors[5]. The more risk factors, the greater the likelihood of developing melanoma. Those with four to five risk factors have a 4.4 times increased likelihood of developing melanoma than those with one risk factor[5].

Atypical lesions are found grossly (figure 1) and the diagnosis of melanoma is confirmed by biopsy and histopathology. Biopsy is important for staging and prognosis of the melanoma (table 1). Survival is related to the thickness of the lesion at diagnosis. As tumor thickness increases, survival decreases[9]. Ten-year survival for patients with tumors less than or equal to 1.00 millimeter thick is ninety-two percent, and eighty percent for those with tumors 1.01 to 2.00 millimeters thick[9]. Patients with melanomas 2.01 to 4.00 millimeters thick have a ten-year survival of sixty-three percent, and those with tumors greater than 4.00 millimeters thick have a fifty percent ten-year survival[9]. It is of great survival advantage to diagnose and treat thin, early-stage melanomas.

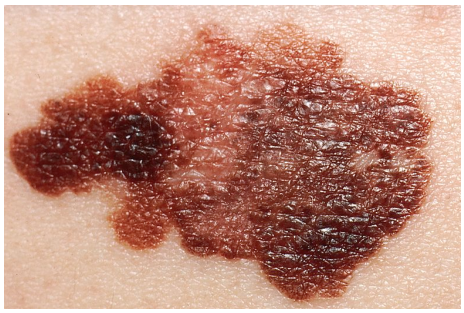

Figure 1: Melanoma[17]

Table 1: 2009 American Joint Committee on Cancer staging and prognosis of melanoma[9].

Stage	Tumor Depth	Nodal Involvement	Metastases	5-Year Survival	10-Year Survival
In situ	0 mm (non-invasive)	None	None		
IA	≤ 1.00 mm without ulceration	None	None	97%	93%
IB	≤ 1.00 mm with mitoses or ulceration OR 1.01-2.00mm without mitoses or ulceration	None	None		
IIA	1.01-2.00mm with ulceration OR 2.01-4.00mm without ulceration	None	None	79-82%	
IIB	2.01-4.00mm with ulceration OR > 4.00mm without ulceration	None	None	68-71%	
IIC	> 4.00mm with ulceration	None	None	53%	39%
III	Any thickness	Yes	None	40-78%	33-52%
IV	Any thickness	Any nodal involvement	Yes	One-year survival rates: 33-62%	

Non-melanoma skin cancer

Non-melanoma skin cancer is a broad category encompassing basal cell carcinoma and squamous cell carcinoma. It is leading type of cancer in the United States of America and accounts for more than ninety-eight percent of all skin cancers[1]. Non-melanoma skin cancer rarely results in death or morbidity, accounting for less than 0.1 percent of patient deaths[1]. Doran et al. estimated the average years of healthy life lost to non-melanoma skin cancer – sixteen days in males and six days in females[18]. However, there is risk of metastasis and death as well as continued local growth and destruction; thus, these cancers must be treated[8]. Non-melanoma skin cancer risk factors are included in table 2.

Table 2: Non-melanoma skin cancer risk factors[8].

Risk Factors for Non-Melanoma Skin Cancer
UV exposure
Number of sunburns
Actinic keratosis
Organ transplantation
Fair complexion
Arsenic exposure
Family history of skin cancer

Basal cell carcinoma (figure 2) is the most common type of skin cancer[8]. It is primarily found on sun-exposed areas of the skin, for example the head and neck[8]. Lesions are slow-growing and may spread to surrounding tissues if untreated[8]. Although basal cell carcinoma rarely results in death, it accounts for a large amount of healthcare resources simply due to its high prevalence[8].

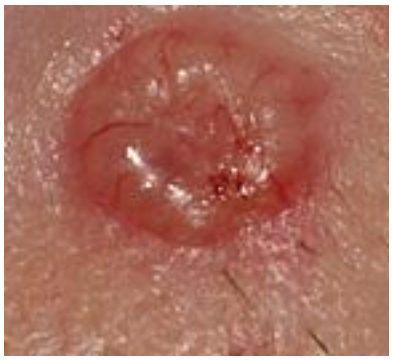

Figure 2: Basal cell carcinoma[19]

Squamous cell carcinoma (figure 3) tends to occur in fair-skinned people with increased amounts of sun exposure[8]. Squamous cell carcinoma tends to arise from actinic keratoses, leukoplakia, or old scars[8]. Metastasis occurs in 0.5-16 percent of cases[8].

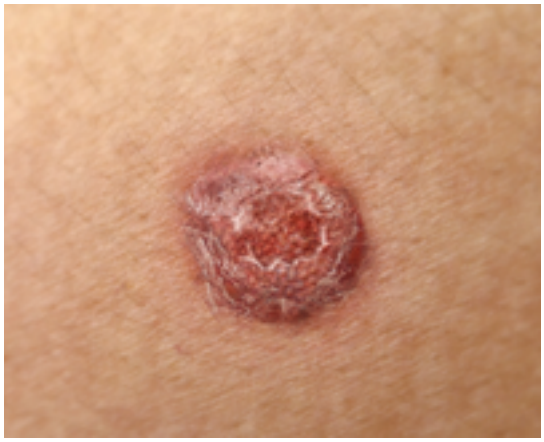

Figure 3: Squamous cell carcinoma[20]

Diagnosis

Skin cancer is detected through a visual skin examination. Both the patient and the clinician can participate in the detection of skin cancer, although multiple studies have shown that clinicians find significantly thinner, earlier stage skin cancers than those detected by the patient or the patient's significant other[7].

There are multiple methods for performing the skin examination. One approach is to examine down the anterior portion of the body and then back up the posterior of the body[7]. Another possible method includes examination of the face, head, neck, and scalp followed by examination of the arms and hands, chest, abdomen, anterior legs and feet, and lastly posterior legs and feet[7]. It is recommended to pay particular attention to high-risk melanoma sites, including the trunk for men and trunk and legs for women[7]. Photography can help clinicians document the evolution of lesions[7].

The ABCDE mnemonic (table 3) is an important algorithm for detecting malignant skin lesions. It is the most commonly taught skin examination technique[6]. The Unites States Preventative Services Task Force reported that the ABCDE mnemonic has a sensitivity of 50-97% and a specificity of 96-99%[8].

Table 3: ABCDE mnemonic for detecting worrisome pigmented lesions[8]

ABCDE	Definition
A	Asymmetry
B	Border irregularity
C	non-uniform Color
D	Diameter > 6 mm
E	Evolving over time

Dermoscopy can aid in a clinician's assessment of benign versus malignant lesions. Clinicians can assess the pigmentation and structure of a lesion[7]. Melanoma tends to show more colors and structures that are asymmetrically distributed in the lesion compared to benign lesions[7].

Treatment

Treatment for skin cancer depends on the stage at which the cancer is found. If skin cancer is found at an early stage, it can be cured by surgery alone[10]. Different surgical techniques for excision of non-melanoma skin cancers include Mohs micrographic surgery, curettage and electrodessication, and cryosurgery[1]. Early-stage melanoma is treated by wide local excision. Lymph node sampling may be performed depending on the lesion's stage.

Metastatic melanoma requires a more aggressive treatment[10]. It requires a combination of chemotherapy, radiation therapy, targeted molecular therapy, and/or immunotherapy[10]. In 2011, new immunotherapy was added to the treatment of metastatic melanoma[10]. Ipilimumab augments the immune response against melanoma, which results in prolongation of life[10]. Other therapies that inhibit mutated versions of the BRAF protein include vemurafenib and dabrafenib, which also have been shown to significantly increase survival[10]. Even with treatment, medial survival is less than one year in patients with distant metastasis[10].

Existing research

Screening has helped reduce the mortality of the most common cancers[2]. Mammography for breast cancer, digital rectal exams and prostate screening antigen for prostate cancer, and colonoscopy for colorectal cancer have aided in early detection of some of the most common cancers in the United States[2]. There is a lack of randomized control trials to suggest that these screening methods decrease mortality; however, observationally, mortality has decreased for these cancers[2].

Patients at high-risk of developing melanoma represent at least half of the United States population[21]. Of the high-risk population, only twenty-four percent have had one total body skin examination in their lifetime, and only eleven percent have had a total body skin examination in the previous year[21]. When surveyed, eighty-one percent of dermatologists reported performing full body skin examinations on their patients, compared with only fifty-nine percent of family practitioners and fifty-six percent of internists[22]. It is controversial whether clinicians should be screening for melanoma. The American Cancer Society recommends routine screening for individuals twenty years old and older during their routine annual health exam[21]. The American College of Obstetrics and Gynecology recommends skin cancer screening only for high-risk individuals[21].

The National Conference to Develop a National Skin Cancer Agenda identified melanoma as a disease that meets criteria for screening – its incidence is increasing, there is an asymptomatic period, there are available screening tools, and it is a disease that can be detected and treated early[23]. They recommend that primary care providers examine at least the exposed areas of skin for cancer. If an unusual lesion is identified, offices should

provide a protocol for follow up and biopsy[23]. Primary care providers are also recommended to counsel all patients regarding sun protection[23].

The American Academy of Dermatology recommends annual total body skin examinations[21]. Screening of high-risk individuals, such as those with a family history of melanoma or those with clinically atypical nevi, may require more frequent screenings[3].

The American Academy of Dermatology provides skin cancer screenings free of charge by volunteer dermatologists to numerous communities in the United States. This screening program started in 1985. Between 1985 and 1994, seven hundred forty-three thousand screenings have been performed and eight thousand people have been diagnosed with suspected melanoma as a result of this program[24]. There have been studies looking at the stage and thickness of melanomas found as a result of these screenings. These lesions were compared against the Surveillance, Epidemiology, and End Results data. The Surveillance, Epidemiology, and End Results data represents about ten percent of the United States population and it is considered a representative sample of the melanoma diagnoses in the United States[24]. Between 1989 and 1994, 98.9% of the lesions identified by the American Academy of Dermatology screening program were stages I and II[24]. Eighty-seven percent of the lesions were less than or equal to 1.50 mm while only 1.9% of the lesions were greater than or equal to 4.00 mm[24]. The median thickness of melanoma lesions was 0.30 mm[24]. There were fewer advanced-stage lesions identified in the American Academy of Dermatology screenings compared with the Surveillance, Epidemiology, and End Results data – 8.3% versus 16.9% respectively[24]. These results suggest that screening for melanoma results in an earlier stage at diagnosis,

which confers a survival advantage. This study also looked at the number of melanomas identified by screening. Melanoma was identified in 129 people per 100,000 screened[24]. When looking at the high-risk population of men fifty years old and older, the diagnostic yield for melanoma increased to 240 per 100,000[24]. This suggests that identifying and screening high-risk populations will decrease the number needed to screen and possibly make screening more cost-effective.

In 2009 and again in 2016, the United States Preventative Services Task Force (USPSTF) stated that there was insufficient evidence to recommend routine melanoma screening by clinicians. In 2009, the USPSTF claimed that there were two gaps in the literature: limited evidence that screening for melanoma improved survival and insufficient evidence that primary care providers are adequate at performing a screening examination for melanoma[8]. The USPSTF cites that no randomized control trials have been conducted to compare the morbidity and mortality of melanoma patients who were screened versus unscreened[8]. This is understandable given the questionable ethics of such a study.

In 2016, the USPSTF again investigated the current evidence regarding screening for melanoma. Again, the USPSTF stated that there was insufficient evidence to recommend screening for melanoma[1]. This time, however, the USPSTF cited the inability to conclude that the benefits of screening outweighed the harms[1]. The only study the USPSTF found demonstrating the benefits of skin cancer screening in reducing mortality due to melanoma was the SCREEN program out of Germany[1]. Evidence regarding harms of screening is also lacking[1]. Possible adverse effects of visual screening for melanoma

included overdiagnosis, overtreatment, and cosmetic or functional adverse events[1]. The USPSTF does state that clinicians need to understand the research and its limitations, and the recommendation is not meant to be a one-size-fits all. Clinicians should make decisions based on the patient and clinical scenario[1].

In 2003-2004, a skin cancer screening project was conducted in Northern Germany, called the SCREEN (Skin Cancer Research to Provide Evidence for the Effectiveness of Screening in Northern Germany) project. Participating providers, both dermatologists and primary care physicians, underwent an eight-hour training course covering the epidemiology, etiology, and diagnosis of melanoma as well as instruction on performing the full body skin examination[25]. After one year, incidence rates of melanoma increased by about thirty percent in the screened population while the overall incidence in Germany itself remained stable[25]. Of the melanomas detected in the SCREEN project, more than ninety percent of the invasive lesions were less than one millimeter thick, indicating that screening was finding more cancers at a lower stage[25]. Malignant melanoma mortality rates decreased by about fifty percent over a ten year period in the screened region of Germany while the rates remained constant in Germany as a whole[25].

After the promising results from the SCREEN program, Germany instituted a national skin cancer screening program in which all adults aged thirty-five and older were screened for melanoma every two years[25]. The incidence of melanoma increased by twenty-eight percent in Germany[25], which was to be expected as increased surveillance would lead to a greater number of new diagnoses. Disappointingly, the mortality rate in Germany has not decreased as was expected following the SCREEN pilot study[25]. There

are some factors that might contribute to the lack of mortality benefit seen in the nationwide screening program, including less intensive skin cancer screenings than those used in the SCREEN program and the need of a longer time to see results in such a large population[25]. Interestingly, the incidence and mortality rates in the region of Northern Germany where the SCREEN project took place have returned to the pre-SCREEN project levels[25]. It is possible that the mortality benefit seen in the pilot study was simply the result of normal variation.

There is an interesting phenomenon called melanoma of unknown primary. Between one and four percent of melanoma patients are identified with metastatic disease without ever being diagnosed with a primary cutaneous melanoma[28]. The underlying etiology is unknown, but one possible explanation is that providers are missing the primary lesion on physical exam[28]. Another interesting observation about melanoma of unknown primary is that these patients seem to have a survival advantage over other patients with metastatic melanoma with a known primary lesion – sixteen months versus eleven months, respectively ($p < 0.001$)[28]. Lee et al. hypothesized that the immune systems in those with melanoma of unknown primary may be superior to those with melanoma of known primary[28]. If the immune system rid the body of the primary lesion, the immune system may also be strong enough to partially fight the metastatic lesions. Despite the fact that these patients have a survival advantage, they still have stage IV disease and survive only a median of sixteen months[28]. Imagine the survival advantage for those patients who had a cutaneous primary lesion, if it had been instead detected at an early stage.

There is a fair amount of evidence on the ability of primary care providers to diagnose melanoma. Studies have shown that physicians find thinner melanomas than those picked up by patients themselves or their significant others. Geller et al. compared the thickness and stage of melanomas found by physicians, patients, and significant others[26]. Sixty-nine percent of lesions found by physicians were less than or equal to one millimeter thick, significantly thinner than those found by significant others and patient-detected (fifty percent [$p = 0.04$] and thirty-three percent [$p < 0.001$], respectively)[26]. Ten percent of physician-found lesions were late-stage, compared with twenty-eight percent of significant other-detected lesions ($p = 0.02$) and thirty-five percent of self-detected lesions ($p = 0.001$)[26]. The most important prognostic factor in melanoma is the depth of the lesion. Five-year survival of melanoma in situ is ninety-nine percent compared with forty-five to seventy-nine percent in lesions 1.01-2.0 millimeters[27]. Therefore, if physicians detect thinner melanomas than those found by a patient's significant other or by the patient themself, we would expect increased physician screening to subsequently increase five-year survival from melanoma.

Multiple studies have examined the difference between lesions detected by dermatologists versus primary care physicians. Pennie et al. explored thickness and stage at diagnosis as well as survival and mortality in dermatologists versus non-dermatologists[14]. Dermatologists detected significantly thinner melanomas compared with non-dermatologists (0.86 millimeters thick versus 1.00 millimeters thick, respectively [$p < 0.05$])[14]. Dermatologists also detected significantly more melanomas at stage 0 or I compared with non-dermatologists who found more melanomas at stages III

and IV ($p < 0.01$)[14]. Survival was superior in the dermatology group than in the non-dermatology group at six months, two years, and five years ($p < 0.05$)[14]. A lower cancer-related mortality rate was associated with dermatologists compared with non-dermatologists[14].

The 2009 USPSTF recommendation stated that there is insufficient evidence regarding the accuracy of primary care providers in the diagnosis of melanoma[8]. There is, in fact, a large amount of evidence regarding the length of dermatology training in both medical school and residency programs, and the result is dismal. Most surveys report a small amount of time spent on dermatology in medical school and most residents feel uncomfortable performing the full body skin examination.

Moore et al. examined the amount of dermatology exposure in fourth year medical students in seven medical schools in the United States[12]. Twenty-three percent of medical students had never seen a full body skin examination performed, twenty-six percent had never received training in the full body skin examination, and forty-three percent had never performed a full body skin examination[12]. Sixty-nine percent of fourth year medical students agreed that there was too little emphasis on the full body skin examination during their medical training[12]. Twenty-eight percent of students reported that they were skilled in the full body skin examination, a number that decreases to nineteen percent if the student had not completed a dermatology elective rotation[12]. Increased skill level in the full body skin examination was associated with observing, training, and practicing the examination[12]. A staggering seventy-two percent of

graduating medical students self-report that they are not skilled in performing the full body skin examination[12].

Buster et al. reported that less than one percent of the undergraduate medical education is devoted to dermatology (about sixteen to twenty-two hours)[29]. Less than forty percent of primary care residents report that their medical education adequately prepared them to diagnose and treat common skin conditions[29]. Hansra et al. reported that twenty-eight percent of residents felt adequately prepared to treat common dermatologic conditions[15]. Participation in a dermatology elective rotation during medical school increased the percentage of residents who felt adequately prepared to diagnose and treat common dermatologic conditions[15].

Wise et al. surveyed four residency programs to determine the skill level of the residents in performing the full body skin examination[11]. Seventy-five percent of residents had never been trained in the full body skin examination, fifty-five percent had never observed a full body skin examination, and fifty-seven percent had never practiced the full body skin examination[11]. Fifteen percent of primary care residents reported that they were skilled in the full body skin examination[11].

If the majority of residents are not confident in their full body skin examination and think their medical training inadequately prepared them to diagnose common dermatological skin conditions, how many primary care providers actually perform a full body skin examination? Kirsner et al. found that thirty-one percent of primary care providers perform full body skin examinations on every patients[13]. Of those who do not

perform full body skin examinations on all their patients, thirty-one percent report examining high-risk patients[13].

Oliveria et al. examined the barriers to performing the full body skin examination in both primary care physicians as well as dermatologists[22]. Primary care physicians reported that their biggest barriers to performing the full body skin examination were time constraints and competing comorbidities[22]. Of note, dermatologists took significantly more time to perform a full body skin examination compared with family practitioners and internists[22]. Dermatologists reported that skill in the full body skin examination and medical training were facilitating factors to their willingness to performing a full body skin examination[22]. All specialties cited patients having one or more skin cancer risk factors as being a facilitating factor in performing the full body skin exam[22].

Primary care physicians report time as a major barrier to performing full body skin examinations. How much time does it take? There is controversy in the literature regarding this subject. Hantirah et al. reported a mean time of just over six minutes to complete a full body skin examination[30]. A longer examination was associated with older age of patient ($p = 0.024$) and the use of tools ($p < 0.0001$). In this study, the full body skin examination included a general visual examination as well as any necessary special examinations but did not include history taking or counseling[30]. Zalaudek et al. recorded a median duration of seventy seconds to perform the full body skin examination[31]. Including dermoscopy in the examination was associated with a significantly increased examination time of one hundred forty-two seconds ($p < 0.001$)[31]. In fact, an increased

number of nevi on the patient was associated with a decreased time to complete a full body skin examination, which was attributed to pattern recognition[31]. Of note, this study was performed by dermatologists with an interest in skin cancer; also, the scalp, genitals, mucus membranes, and conjunctiva were excluded from the full body skin examination[31].

Do physicians need to perform a full body skin examination on all patients? In the free screenings performed by the American Academy of Dermatology, greater than thirty percent of the lesions were located on the posterior of the patient[24]. Other sites included the upper limb, lower limb, back, head and neck, chest, and abdomen[24]. The majority of melanomas were found on the trunk in men and on the posterior legs in women[7]. However, recently melanoma of the trunk has been increasing in incidence in women younger than forty years old[32]. Additionally, patients who receive a full body skin examination are more likely to be diagnosed with suspected melanoma than those who receive a partial examination (OR = 1.4, 95% CI 1.3-1.6)[5]. Clearly, there is an advantage to examining all aspects of the skin surface.

There is not good quality evidence on a recommended interval of time between screenings. The nationwide German screening project screened individuals every two years[25]. Watts et al. conducted a systematic review and reported low-level evidence that individuals with atypical nevi should have regular full body skin examinations every six to twelve months and consensus-based evidence that individuals at high risk should be monitored twice per year for life[3].

Most cost-effectiveness analyses compare one-time screens to screening every two years. Losina et al. reported that it was cost-effective to screen the general United

States population fifty years old and older once and every two years for individuals with a history of melanoma in first-degree relatives[33]. Freedberg et al. reported that screenings would be cost-effective if greater than or equal to ninety-four percent of lesions found on screenings were localized[34]. In this study, localized was defined as melanoma in situ or melanoma of any thickness as long as there was no spread to lymph nodes or distant metastases[34]. Goldsmith et al. reported that ninety-eight percent of lesions found by the American Academy of Dermatology free screening program were stages I and II[23]. These data altogether confirm that screening is cost-effective, especially when screening those at high-risk for developing melanoma.

Tsao et al. examined the costs of treating different stages of melanoma[35]. Stages I and II cost about five percent of the total annual cost of melanoma in the United States while stage III comsumes thirty-four percent of the cost and stage IV consumes fifty-five percent of the total annual cost[35]. Eighty percent of melanomas account for ten percent of the total annual cost of treating melanoma and twenty percent of patients consume ninety percent of the total annual cost[35]. If physicians find thinner melanomas than those found by patients, then screening by physicians should decrease the number of stage III and IV melanomas and thus decrease the annual cost to treat melanoma.

Why primary care physicians and not dermatologists? There is a shortage of dermatologists in the United States relative to the demand[15]. The average American visits his or her primary care provider twice per year[2]. Men older than fifty years old – a high-risk group for the development of melanoma – average three to four primary care visits per year[2]. Melanoma risk is associated with not having a regular dermatologist (OR = 1.4,

95% CI 1.3-1.5)[5]. Thus, it makes sense to have the primary care providers function as the triage providers for dermatologists – referring the patients who need to be further evaluated.

Some countries have employed the use of teledermatologists to account for the shortage of dermatologists. Aldridge et al. found that one third of melanomas would be missed if a full body skin examination was not performed[36]. Simply sending pictures of index lesions to a teledermatologist may result in many of these lesions being missed[36].

Skin disorders are the number one reason why patients visit their doctor[37]. St. Sauver et al. found that skin conditions are the most common presenting complaint of patients less than sixty-five years old[37]. For the patients sixty-five years old and older, skin disorders represent the third most common presenting complaint[37]. If a patient is presenting with a skin condition, it is quite reasonable that a physician would check the patient's skin, so why not take the opportunity to examine the patient head-to-toe.

McCleskey et al. reported on the efficacy of online modules in the education of residents and physician assistant students[38]. Higher pre-test scores were associated with having taken a prior dermatology elective ($p = 0.003$)[38]. All scores significantly improved after completion of the curriculum ($p < 0.01$)[38]. There was no difference in scores between residents and physician assistant students (pretest $p = 0.09$, post-test $p = 0.40$)[38]. Participants also took the same post-test months later to assess long-term knowledge retention[38]. The scores were slightly lower than those of the immediate post-test ($p = 0.012$), but the average of the long-term follow up post-test was higher than that of the

pre-test indicating that the dermatology knowledge was retained[38]. Interestingly, post-test scores were not associated with a prior dermatology rotation ($p = 0.38$)[38].

Wise et al. surveyed residents regarding their comfort in the full body skin examination and their input on how to adequately incorporate teaching the full body skin examination into residency programs[11]. Thirty-seven percent of residents preferred core curriculum classes while only seventeen preferred departmental lessons and eight percent thought grand rounds sessions would be ideal[11].

An ongoing study through the University of Pittsburgh Medical Center is exploring the effect of training primary care residents in skin cancer screening[39]. The primary care residents are participating in a one and a half hour online training module. Ferris et al. have found that primary care residents who had completed the online training module were significantly more likely to provide annual skin examinations to their patients than those who had not completed the training ($p < 0.001$)[39]. Primary care residents who had completed the online training were significantly more likely to diagnose melanomas than their colleagues who had not completed the training ($p < 0.001$)[39]. Melanomas found by the primary care residents who had completed the training were significantly thinner ($p = 0.023$) and more likely to be in situ (but not statistically significant, $p = 0.168$) compared with those who had not completed the online training module[39].

METHODS

Study design

This study will be a curriculum seeking to teach medical residents, physician assistants (PAs), and nurse practitioners (NPs) the full body skin examination as well as identification of benign versus malignant skin lesions.

Study population and sampling

Subjects will be recruited from post-graduate year 1 internal medicine and family medicine residents as well as PAs/NPs at Boston Medical Center. There are fifty-six internal medicine, twelve family medicine interns, and about twenty-four primary care PAs/NPs at Boston Medical Center. The population in this study is representative of the primary care and family medicine interns as well as PAs/NPs in the United States.

Intervention

Participants will participate in three one-hour long sessions during the noon conference allotted for Internal Medicine and Family Medicine interns as well as PAs/NPs. Learning objectives will include:

1. Discuss the importance of performing the body skin examination
2. Describe the epidemiology of benign versus malignant skin conditions
3. Discuss the risk factors for the development of skin cancer
4. Classify benign skin lesions
5. Classify malignant skin lesions

6. Prepare patient education and counseling on preventative practices
7. Evaluate when referrals to a specialist are warranted
8. Evaluate skin lesions based on the ABCDE mnemonic

A pre-test and pre-course survey will be emailed prior to the course that must be completed before the first session. The pre-test will contain ten images and participants will be asked to identify the skin lesion images as "benign" or "malignant." The survey will contain questions regarding the participant's clinical practice.

Participants will be asked to perform a full body examination on standardized patients during the first and third sessions. A different standardized patient will be used for each session so the participants can become comfortable with different skin types. Standardized patients will have a lesion for the provider to find – a benign nevus, actinic keratosis, seborrheic keratosis, et cetera. If the standardized patient does not have a skin lesion, a lesion will be applied to the foot of the standardized patient using makeup. The standardized patients will provide qualitative oral feedback to the participants. Feedback will include the comfort level of the provider as observed by the standardized patient, identification of skin lesions, and length of time taken to perform the full body skin examination. This will be for the purpose of practicing the full body examination and will not be included in the data analysis

The second session will consist of a lecture that will contain both elements of the full body examination as well as identification of benign versus malignant skin lesions.

Study variables and measures

The pre-test, immediate post-test, and six-month post-test will be an online module where the participant will be asked to identify benign versus malignant skin lesions. Links will be emailed to participants one week prior to the course, immediately after the course, and then six months after completion of the course. There will be a total of ten questions and the participant will receive his/her score at the end of the test. The questions will be randomized from a bank of fifty images. The test will include 4-6 malignant lesions, including early-stage and late-stage melanomas, squamous cell carcinomas, and basal cell carcinomas. The 4-6 benign lesions will include lesions such as actinic keratosis, lichen planus, seborrheic dermatitis, seborrheic keratosis, and dermatofibroma. No retries of the test will be allowed. Pre-test scores will be compared with both the immediate post-test as well as the six-month post-test to assess the immediate effectiveness of the course as well as the long-term retention of the material.

Surveys will be included in the emailed link at the end of all of the tests. The survey prior to the course and the six-month survey will contain the same questions to assess the change in clinical practice (table 4). Means and standard deviations will be calculated. Clinical significance will be defined as an increase of 1 point from the pre-course Likert score to the post-course Likert Score. The immediate post-course survey will be directed at assessing the effectiveness of the course itself (table 5).

Table 4: Pre- and six-month post-survey

Measure	1 point	2 points	3 points	4 points	5 points
How do you decide on whom you perform full body skin examinations?	I never perform full body skin examinations	Time permitting	If the patient has a specific concern	All high-risk patients	I perform full body skin examinations on all of my patients
How comfortable do you feel in performing a full body skin examination?	Very uncomfortable	Somewhat uncomfortable	Neither comfortable nor uncomfortable	Somewhat comfortable	Very comfortable
In the past 6 months, how many referrals have you made to dermatology?	0	1-3	4-7	8-10	> 10
In the past 6 months, how many skin lesions have you documented?	0	1-3	4-7	8-10	> 10
In the past 6 months, how many skin cancers have you identified?	0	1-3	4-7	8-10	> 10

Table 5: Immediate post-course survey

Measure	1 point	2 points	3 points
Did this course convey the importance of the skin examination?	Ineffective	Neither effective nor ineffective	Effective
How effective was this course at improving your skills in performing the full body skin examination?	Ineffective	Neither effective nor ineffective	Effective
To what degree did your confidence improve in your ability to identify benign versus malignant skin lesions?	Ineffective	Neither ineffective nor effective	Effective
Will this course change your practice	No	Maybe	Yes
Comments and suggestions for improvement			

Recruitment

All Boston Medical Center post-graduate year 1 Internal Medicine and Family Medicine residents as well as Hospitalist PAs/NPs will be invited to participate in this curriculum. All participants will receive the same instruction. Attendance will be voluntary, but strongly encouraged. Standardized patient encounters will be offered on several days to maximize providers' ability to participate in this intervention. The lecture-based didactic portion, session two, will be given four separate times at the noon conference in the Ambulatory Medicine block to capture different subsets of interns as they change rotations.

Data collection

Data will be collected using an emailed link to an online module. Participants will be presented a skin lesion and asked to identify said lesion as "benign" or "malignant." At the end of the ten-question test will be a survey. Pre-course and six-month post-course surveys will be the same, aimed at assessing how the course changed clinical practice (table 4). The immediate post-course survey will be aimed at assessing the effectiveness of the course and improving the course in the future (table 5). Participants will receive immediate feedback on the correct answers to the skin lesion questions after submitting the surveys. All questions must be answered and once an answer is submitted, it may not be changed.

Data analysis

Scores from the pre-test will be compared with the immediate post-test as well as six-month post-test scores. Average and standard deviation will be calculated for all of the tests. The scores will be analyzed using a paired T-test to assess participants' ability to identify benign versus malignant lesions both immediately after the course and long-term retention of the material.

Pre-course and six-month post-course surveys will be analyzed to assess how the course changed clinical practice using a paired T-test for the Likert scale. Overall Likert score with mean and standard deviation will be calculated. Mean and standard deviations will be calculated for individual components of the Likert scale: the determining factors for performing a full body skin examination (question 1), the comfort in performing a full body skin examination (question 2), and the number of referrals/suspicious lesions documented/skin cancers identified (questions 3, 4, 5). An increase of 1 from the pre-course survey to the post-course survey in any section of the Likert scale will be considered a clinically significant difference.

It is expected that the pre-course quiz average will be 60% or lower and the post-course quiz average will be 85% or higher. With a sample size of 68 interns and 24 PAs/NPs, the calculated power is 0.97.

Immediate post-course surveys will be reviewed to assess the success of the course in meeting the learning objectives, and to help improve the course in the future.

Timeline and resources

Summer 2017

IRB submission and approval

Development of curriculum for lecture

Book standardized patients

Fall 2017

Development of pre-course and post-course tests and surveys

Training of standardized patients

Spring 2018

Dispersal of email links with pre-course test and survey

Twelve one-hour sessions at noon conference

Dispersal of email links with immediate post-course test and survey

Fall 2018

Dispersal of email links with six-month post-course test and survey

Data analysis

Manuscript preparation

Winter 2018

Submit manuscript for peer review

Institutional Review Board

This study will be submitted to the Boston Medical Center Institutional Review Board for exemption for educational studies under 45 CFR 46 101 (b) criteria.

CONCLUSION

Discussion

This study is aimed at improving skin cancer screening in primary care. There are some limitations of this study. First of all, there is a limited amount of family medicine and internal medicine interns and PAs/NPs at Boston Medical Center, making the sample size small. Another potential limitation is the responses to the emailed surveys. Participation is completely voluntary and with the busy schedules of clinicians, surveys may not be returned, further limiting the amount of data.

One obstacle for this study is the United States Preventative Services Task Force report that there is insufficient evidence for primary care providers to perform the full skin examinations[1]. This could be problematic both in the approval process for the study as well as clinician participation. From the proposal aspect, why should there be a study about whether teaching the full skin examination improves both comfort with the examination and detection of suspicious skin lesions if primary care providers will not get reimbursed for performing the examination? From the clinician standpoint, why should time be spent learning something that is not even recommended in clinical practice? One of the cited reasons the United States Preventative Services Task Force does not recommend the full skin examination is due to insufficient evidence that primary care physicians can accurately perform a skin examination[8]. The hope is that teaching clinicians the full skin examination and identification of benign versus malignant skin lesions will provide the evidence that the United States Preventative Services Task Forces argues is lacking.

Why not go to the source and teach students? The aim of this study is to teach clinicians who are practicing in primary care. Medical students and PA/NP students can enter any field and by the time they start practicing, they still may not have practiced a full body skin examination on a patient by the time they enter residency or clinical practice. Residents and PAs/NPs can begin practicing full body skin examinations immediately after the course and integrate the examination into their clinical practice. The practicing primary care providers can then teach students who are rotating on an internal medicine or family medicine rotation. Therefore, the purpose of this study is not only to teach the examination, but also to have the practicing clinicians integrate skin cancer screening into their exam and teach future clinicians.

Although there is a current study exploring the benefit of teaching residents skin cancer screening, this is the first study including both practicing residents and practicing PAs/NPs, making this study unique.

Summary

Melanoma is a leading cause of cancer in the United States and its incidence is increasing[2]. Prognosis for melanoma is related to stage and thinness of the lesion at diagnosis[9]. Although clinicians find thinner, earlier stage melanomas than patients themselves or patients' significant others[7], medical schools only dedicate one percent of undergraduate medical school education to dermatology[29]. The majority of primary care residents have not been trained in the full body skin examination for melanoma screening[11] and the minority are comfortable with diagnosing common dermatologic

complaints[15]. There is a shortage of dermatologists relative to the demand[15]; thus, it is the responsibility of the primary care provider to triage skin lesions and refer suspicious lesion to the dermatologist.

This project is aimed at creating a curriculum that will teach residents and PAs/NPs the full body skin examination as well as identification of benign versus malignant skin lesions. The results of this study will attempt to increase the number of clinicians who are not only comfortable with performing the full body skin examination, but also have an understanding of benign versus malignant lesions should they find a lesion in clinical practice.

Clinical and/or public health significance

In both the outpatient and inpatient realms, full body skin examinations are important; however, according to the United States Preventative Services Task Force, primary care providers do not perform adequate full body skin examinations[1]. It is the hope that this study will show that primary care providers are capable of performing the full body skin examination as well as identifying malignant lesions. Another goal is that these clinicians will take with them the confidence to perform full body skin examinations and the tools to identify potentially cancerous lesions. It is the ultimate goal that the clinicians who participate in this study will modify their practice to include the full body skin examination on their patients.

LIST OF JOURNAL ABBREVIATIONS

Acta Derm Venereol	Acta Dermato Venereologica
Ann Med.	Annals of Medicine
Arch Dermatol	Archives of Dermatology
Br J Dermatol	British Journal of Dermatology
Cancer Epidemiol Biomarkers Prev	Cancer Epidemiology Biomarkers & Prevention
Clin Dermatol	Clinics in Dermatology
Curr Oncol	Current Oncology
Dermatol Clin	Dermatologic Clinics
Dtsch Ärztebl Int	Deutsches Ärzteblatt International
J Am Acad Dermatol	Journal of the American Academy of Dermatology
JAMA	The Journal of the American Medical Association
J Clin Aesthetic Dermatol	The Journal of Clinical and Aesthetic Dermatology
J Clin Oncol	Journal of Clinical Oncology
J Gen Intern Med	Journal of General Internal Medicine
Mayo Clin Proc	Mayo Clinic Proceedings
Prev Med	Preventative Medicine

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CURRICULUM VITAE

Emily Elizabeth Lewandowski

Born 1989

lewandowskiee@gmail.com

207-577-4412

137 Fuller Street Apt 2

Brookline, MA 02446

Education:

Boston University – Boston, MA

Masters of Science in Physician Assistant Studies – expected August, 2017

Kenyon College - Gambier, OH

Bachelor of Arts - May, 2011 – Magna Cum Laude with High Honors in Biology

GPA: 3.70/4.0

Honors Project: The effect of larval stage, midgut region, and dietary Protein concentration on Aminopeptidase N isoform mRNA expression in *Manduca sexta* caterpillars

University of Southern Maine – Lewiston, ME

Employment:

Critical Care Technician, Central Maine Medical Center – Lewiston, ME (January 2013-Present)

EMT-Basic, United Ambulance Service – Lewiston, ME (October 2012-Present)

Bates College Assistant Swim Coach – Lewiston, ME (August 2011-May 2012)

Kenyon College Summer Science Scholar - Gambier, OH (June-July, 2010)

Results presented at the Ohio Physiological Society Meeting (October 2010) Biology/Chemistry/Math Tutor, Kenyon College - Gambier, OH (Fall 2009-May 2011)

Tour Guide, Kenyon College Science Department – Gambier, OH (June 2010-May 2011)

Activities/ Volunteer Work

Kenyon College Varsity Swim Team (August 2007-February 2011)

2-time All-American

Academic All-American (2008, 2009)

Junior Class Committee and Senior Class Committee (August 2009-May 2011)

Organized events and fundraisers for the class

Relay for Life Team Captain (April 2009, 2010, 2011)

Awards/ Honors

Associate Member of Sigma Xi Scientific Research Society

Member of American Chemical Society

Member of American Association for the Advancement of Science

Affiliate Member of International Union of Pure and Applied Chemistry (IUPAC)

NCAA Post Graduate Scholarship Nominee