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# Skin Cancer Screening



Medical Education Systems, Inc

TOLL FREE 1-877-295-4719

FAX (619) 295-0252

EMAIL: [Info@mededsys.com](mailto:Info@mededsys.com)

[www.mededsys.com](http://www.mededsys.com)

P.O Box 81831 San Diego, CA 92138-3939



# Screening for Skin Cancer: An Update of the Evidence for the U.S. Preventive Services Task Force

## Learning Objectives

Upon successful completion of this course, you will be able to:

- List the evidence of benefits and harms of screening for skin cancer in the general population
- List the sensitivity and specificity of skin self-examination (SSE) to detect new and changing moles with and without the aid of baseline digital photographs in patients with dysplastic nevi
- Identify those at highest risk for developing melanoma
- Identify how cancer prevention behavior change takes place

**Background:** Skin cancer is the most commonly diagnosed cancer in the United States. The majority of skin cancer is nonmelanoma cancer, either basal cell cancer or squamous cell cancer. The incidence of both melanoma and nonmelanoma skin cancer has been increasing over the past 3 decades. In 2001, the U.S. Preventive Services Task Force (USPSTF) found insufficient evidence to recommend for or against routine screening for skin cancer by using whole-body skin examination for early detection of skin cancer.

**Purpose:** To update the evidence of benefits and harms of screening for skin cancer in the general population. Tracy Wolff, MD, MPH; Eric Tai, MD, MS; and Therese Miller, DrPH  
3 February 2009 |

**Data Sources:** MEDLINE and Cochrane Library searches from 1 June 1999 to 9 August 2005 for English-language articles; recent systematic reviews; reference lists of retrieved articles; and expert suggestions.

**Study Selection:** English-language studies were selected to answer the following key question: Does screening in asymptomatic persons with whole-body examination by a primary care clinician or by self-examination reduce morbidity and mortality from skin cancer? Randomized, controlled trials and case-control studies of screening for skin cancer were selected. One author selected English-language studies to answer the following contextual questions: Can screening with whole-body examination by primary care clinicians or by self-examination accurately detect skin cancer? Does screening with whole-body examination or by self-examination detect melanomas at an earlier stage (thinner lesions)?

**Data Extraction:** All studies for the key question were reviewed, abstracted, and rated for quality by using predefined USPSTF criteria.

**Data Synthesis:** No new evidence from controlled studies was found that addressed the benefit of screening for skin cancer with a whole-body examination by a physician. One article of fair quality, which reanalyzed data from a 1996 study identified for the 2001 report for the USPSTF, provides limited but insufficient evidence on the benefit of skin self-examination in the reduction of morbidity and mortality from melanoma.

**Limitations:** Direct evidence linking skin cancer screening to improved health outcomes is lacking. Information is limited on the accuracy of screening by physicians or patients using real patients and lesions.

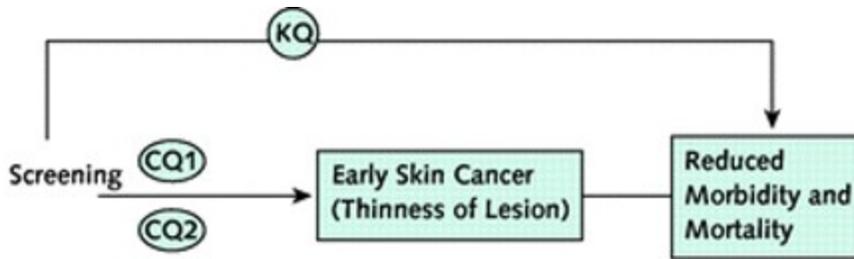
**Conclusion:** The limited evidence prevents accurate estimation of the benefits of screening for skin cancer in the general primary care population.

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Skin cancer is the most commonly diagnosed cancer in the United States (1). The majority of skin cancer is non-melanoma cancer, either basal cell cancer or squamous cell cancer (2). In the United States, melanoma of the skin is the sixth most common type of cancer in white men and women (3). The incidence of both melanoma and non-melanoma skin cancer has been increasing over the past 3 decades (4). Several preventive strategies, including routine screening, have been proposed by professional organizations.

The U.S. Preventive Services Task Force (USPSTF) last reviewed screening for skin cancer in 2001 and concluded that evidence was insufficient to recommend for or against routine screening for skin cancer by using wholebody skin examination for the early detection of cutaneous melanoma, basal cell cancer, or squamous cell cancer (5). The USPSTF made this statement after reviewing the available evidence and identifying 2 major gaps: the lack of quality evidence that links screening to improved health outcomes and limited information about the ability of primary care providers to perform adequate examinations in the context of usual care. To update its recommendation, the USPSTF determined that an update of the evidence would need to focus on these 2 issues.

On the basis of an analytic framework (Figure), the USPSTF determined that this evidence update would focus on a systematic review of the evidence of controlled trials on screening for skin cancer with morbidity and mortality outcomes to answer the following key question: Does screening in asymptomatic persons with whole-body examination by a primary care clinician or by self-examination reduce morbidity and mortality from skin cancer? In addition, the USPSTF asked for information concerning several contextual questions. The issues for this review that were identified as contextual questions that were nonsystematically reviewed are:



**KQ:** Does screening in asymptomatic persons with whole-body examination by a primary care clinician or by self-examination reduce morbidity and mortality from skin cancer?

**CQ1:** Can screening with whole-body examination by primary care clinicians or by self-examination accurately detect skin cancer?

**CQ2:** Does screening with whole-body examination or by self-examination detect melanomas at an earlier stage (thinner lesions)?

Figure. Analytic framework for screening for skin cancer.

Contextual Question 1. Can screening with whole-body examination by primary care clinicians or by self-examination accurately detect skin cancer?

Contextual Question 2. Does screening with whole-body examination or by self-examination detect melanomas at an earlier stage (thinner lesions)?

This CEU does not include evidence on counseling for skin cancer. The USPSTF previously reviewed the evidence for counseling; the evidence review and recommendation can be found at <http://www.preventiveservices.ahrq.gov>.

## Methods

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### Data Sources and Searches

We searched the English-language literature in MEDLINE to identify randomized, controlled trials (RCTs) or case-control trials published from 1 June 1999 to 9 August 2005 to answer the following key question: Can screening reduce morbidity and mortality from skin cancer? We used the terms *skin neoplasms*, *squamous cell neoplasms*, *basal cell neoplasms*, *melanoma*, and *mass screening*. In addition to the MEDLINE search, we identified further literature by reviewing reference lists of review articles and editorials and by consulting with experts. For the contextual questions, we performed targeted literature searches, reviewed the searches performed for other questions, identified studies from reference lists, and consulted with experts.

## **Study Selection**

Two reviewers independently reviewed the title lists, abstracts, and full articles for the key question. We excluded studies if they did not address skin cancer, did not report morbidity or mortality outcomes, were editorials or review articles, had no control group, or had a study population that included only persons with rare skin cancer syndromes. We also excluded studies if the intervention was not screening with whole-body visual examination by a physician or by the patient, was not performed in a primary care setting, or was designed to improve diagnostic ability (and not screening). We discussed studies selected by fewer than 2 reviewers and based selection on consensus. A third reviewer was consulted if necessary. For contextual question 1, 1 author selected studies published since June 1999 that provided information on accuracy of screening examinations by primary care clinicians or by patient self-examination. For contextual question 2, 1 author selected studies published since June 1999 that provided information on thinness of lesions detected by screening examinations.

## **Data Extraction and Quality Assessment**

For all citations that met the eligibility criteria for the key question, 2 reviewers independently reviewed, abstracted, and quality-rated the full articles. The 2 reviewers achieved consensus about article inclusion, content, and quality through discussion; a third reviewer resolved disagreements. We extracted data on the following items from the studies included for the key question: identification of case patients, case definition, selection of control participants, comorbid conditions, sun exposures, demographic characteristics of case patients and control participants, definition of screening examination, exposure to screening, rates of follow-up, and results. We performed quality evaluations of articles for the key question by using standard USPSTF methodology on internal and external validity (6). We evaluated the quality of RCTs and cohort studies on the following items: initial assembly of comparable groups, maintenance of comparable groups, important differential loss to follow-up or overall high loss to follow-up, measurements (equality, reliability, and validity of outcome measurements), clear definition of the interventions, and appropriateness of outcomes. We evaluated the quality of case-control studies on the following items: accurate ascertainment of cases, nonbiased selection of case patients and control participants with exclusion criteria applied equally to both, response rate, diagnostic testing procedures applied equally to each group, accurate measurement of exposure applied equally to each group, measurement of exposure accurate and applied equally to each group, and appropriate attention to potential confounding variables.

## **Data Synthesis and Analysis**

Data from the included studies was synthesized qualitatively in a narrative format.

## **Role of the Funding Source**

The general work of the USPSTF is supported by the Agency for Healthcare Research and Quality. This specific review did not receive separate funding.

## Results

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### Key Question

*Does screening in asymptomatic persons with whole-body examination by a primary care clinician or by self-examination reduce morbidity and mortality from skin cancer?*

We found no new evidence on the effectiveness of skin examination by a physician in reducing the morbidity or mortality of skin cancer. One article of fair quality by Berwick and colleagues (7), which reanalyzed data from a 1996 study identified for the 2001 report for the USPSTF (8), provides limited but insufficient evidence on the benefit of skin self-examination in the reduction of morbidity and mortality from melanoma.

Data on case patients ( $n = 650$ ) in Berwick and colleagues' study (7) were obtained from the Connecticut Tumor Registry, a National Cancer Institute Surveillance Epidemiology and End-Results (SEER) site. Control participants ( $n = 549$ ) were identified from the general public through random-digit dialing and were frequency-matched on age and sex. Nurses performed a limited skin examination to count nevi on the back and arms. Participants were followed biannually for a mean of 5.4 years.

Identification of case patients was probably fairly complete because of a state reporting mandate and the research team's active monitoring of dermatopathology laboratories. The response rate for case patients and control participants was 75% and 70%, respectively. The mortality tally was probably complete because the research team used several sources to identify deaths of the participants. Limitations of the research design include potential selection bias of case patients and control participants, lack of information on the initial comparability of the case patients and control participants, potential recall bias because information on many variables (including the history of any clinical screening) relied on patient report, and lack of information on masking of the nurse or dermatologist to the case status.

Of the original 650 case patients, 112 were excluded: 26 because of diagnosis from node or organ metastases, 95 with a diagnosis of lentigo maligno melanoma, and 1 without follow-up. This analysis showed no significant association between screening examination (by self-examination or by a physician) and death from melanoma in those with melanoma. On univariate analysis, the hazard ratio for skin self-examination was 0.6 (95% CI, 0.2 to 1.5) and for physician screening examination was 0.7 (CI, 0.4 to 1.3); this does not differ greatly from the 1996 analysis that had more participants and a slightly broader definition of the outcome. The authors report a significant association between "skin awareness" and death from melanoma (hazard ratio, 0.5 [CI, 0.3 to 0.9]) after controlling for other confounders. The authors defined skin awareness as a positive response to the question, "Did you ever think about your skin, how it looked, whether there were any changes, or whether there were any abnormal marks?"

## Contextual Question 1

*Can screening with whole-body examination by primary care clinicians or by self-examination accurately detect skin cancers?*

Accuracy of screening is an important link in the chain of evidence connecting screening in asymptomatic persons with improved health outcomes. Evidence for the accuracy of screening with whole-body examination by physicians or by patients is limited and inconsistent. A recent systematic review (9) using pictures of lesions reported a sensitivity that ranged from 42% to 100% and a specificity of 98%. The same systematic review reported a sensitivity of 70% to 91% and a specificity of 51% to 87% for appropriateness of referral or biopsy, using histopathology or expert consensus as the gold standard. Studies on the accuracy of skin self-examination reported sensitivity and specificity from 58% to 75% and 62% to 98%, respectively. The studies in physicians evaluated the accuracy of diagnosing pigmented lesions, not a screening examination, and many of the studies on self-examination were performed in selected patient populations. Therefore, these results may not be generalizable to a screening examination in the general population. In addition to the accuracy of a physician or patient examination, there is the uncertainty of the pathologist's reading of the biopsy specimen. There is some evidence of moderate disagreement among pathologists in reading skin biopsies (10, 11).

Several studies on diagnostic and referral accuracy of family physicians and general practitioners have been published since 2001 (12–14); these studies evaluated accuracy before and after educational interventions and generally concluded that educational interventions improve the diagnostic accuracy of skin cancer examinations. Most of these studies were performed outside the United States, and all used nonliving representations of lesions, including photographs and slides of lesions, limiting the applicability to screening accuracy in primary care.

A more recent, community-based RCT of screening in Australia (15) involving 16 383 whole-body skin examinations reported the specificity and positive predictive value of screening by a primary care physician for melanoma as 86% and 2.5%, respectively. The overall positive predictive value for all types of skin cancer was 29%. However, the researchers did not follow the participants with negative results, and therefore could not report the number of true-negative results or the true specificity.

Three published studies have evaluated the accuracy of skin self-examination (16–18). They generally showed variable specificity and sensitivity that was higher with greater size increases in lesions and higher with the use of photographs. Two of these studies assessed the accuracy, after artificial change of lesions, in the study participants' reports of the number or appearance of moles, and 1 study evaluated the accuracy of skin self-examination before and after education about the asymmetry, border, color, diameter (ABCD) criteria. Again, the applicability to primary care of studies of artificial change in lesions is questionable.

## Contextual Question 2

*Does screening with whole-body examination or by self-examination detect melanomas at an earlier stage (thinner lesions)?*

We found no RCTs that compared screened and unscreened participants with respect to thickness of melanoma lesions. We identified 1 study that looked at a screened population to evaluate lesion thickness at detection (19). This study of 639 835 participants who were screened during the American Academy of Dermatology Skin Cancer Screening Program from 1985 to 1999 compared the results of the American Academy of Dermatology screening efforts with the SEER registry. In the American Academy of Dermatology program, dermatologists performed screening examinations that were free and open to the public. Participants who had received screening through the American Academy of Dermatology program had a higher percentage of lesions smaller than 1.50 mm than cases documented in the SEER registry: 10% and 2%, respectively ( $P < 0.001$ ). Conclusions are limited because of self-selection in the American Academy of Dermatology program, the ecological nature of the study, and problems with generalizing screening by a dermatologist to screening by a primary care clinician. A study in Queensland, Australia, reviewed the characteristics of all histologically confirmed first melanomas in residents age 20 to 75 years (20). They found that the rate of thin lesions (<0.75 mm) detected by a physician (81%) was higher than the rate detected by nonphysicians (62%).

There is evidence from retrospective studies of patients with diagnosed melanoma that, although most melanoma lesions are first noticed by someone other than a physician, lesions detected by a physician are thinner. A study of 471 patients with newly diagnosed melanoma (1995 to 1998) in New York found that 57% of patients first detected the melanoma lesion and another 15% were found by someone other than a physician (primarily a spouse) (21). There was a significant association between physician detection and thickness of 0.75 mm or less. In an Italian study of 816 consecutive patients with melanoma (22, 23), identification by a dermatologist was associated with significantly thinner melanoma lesions than those identified by others (0.68 mm vs. 0.90 mm). Of note, melanoma lesions in participants who performed skin self-examination were also significantly thinner than in those who did not perform skin self-examination (0.77 mm vs. 0.95 mm); however, the definition of skin self-examination was not reported. A study of 102 patients seen at the Johns Hopkins Melanoma Center between June 1995 and June 1997 reported that the majority of lesions were detected by the patient (24). The mean lesion thickness was 0.23 mm for physician-detected lesions and 0.9 mm for self-detected lesions. Compared with self- or other-detected lesions, physician-detected lesions were associated with a higher likelihood of thinner lesions (relative risk, 4.0 [CI, 1.08 to 14.3] for lesions  $\leq 0.75$  mm versus those  $> 0.75$  mm).

## Discussion

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The direct evidence to support the benefits of a screening examination by a physician or patient in reducing morbidity and mortality is limited. We reviewed 1 new fair-quality case-control study of skin self-examination that used data from a study identified in the 2001 report for the USPSTF. We found no new studies on the benefits of screening by a physician that met our inclusion and exclusion criteria and were of appropriate quality.

The evidence on accuracy of screening has limitations. Several different methods have been used to study the accuracy of screening for skin cancer by physicians and by patients. Many studies measure accuracy through the use of photographs of lesions of known histopathology. Other studies measure accuracy by following the referral patterns and ultimate histopathology of lesions from real patients. Both of these methods have obvious problems. Using photographs of known lesions may test the accuracy of the diagnostic ability of a physician but does not necessarily assess the accuracy of a full-body screening examination. The use of referral patterns and histopathology assumes that a dermatologist's assessment of the need for biopsy and the resultant histopathology constitute the gold standard. Without appropriate follow-up of patients, this method probably underestimates the number of false-negative results.

There is limited evidence on whether screening by physicians or by patients identifies lesions that are thinner than those identified in usual care. Older ecological studies reported conflicting results on the association of thickness of melanoma and screening. Newer limited evidence from 1 large study of a self-selected screened population and from retrospective studies indicates that physician examinations and self-examinations identify thinner melanoma lesions. However, the retrospective studies do not report whether the lesions were detected during a screening examination or coincidentally during an examination for other reasons. Therefore, there are problems with using this evidence to generalize about the ability of screening examinations to identify thinner lesions in the general public. In addition, the majority of melanoma lesions are identified by the patient, friend, or spouse, and the question remains whether encouraging skin self-examination would identify more lesions or lesions at an earlier stage than are currently being identified by nonphysicians.

### Research Gaps

The literature on screening for skin cancer has several limitations. A major limitation is the lack of direct evidence linking skin cancer screening to improved health outcomes. An adequately powered, population-based RCT of screening demonstrating mortality outcomes would require approximately 800 000 participants because of the relatively low melanoma-related mortality rate in the United States. (7, 25) However, the incidence of melanoma and mortality are higher in Australia, requiring a smaller sample size. A 3-year RCT in 44 Australian communities ( $n = 560\,000$  adults age  $\geq 30$  years) had been planned by Aitken and colleagues (26). The intervention included promotion of screening through skin self-examination and physician examination. Unfortunately, the study was performed only in 9 control and 9 intervention communities because of lack of funding. The preliminary results may help inform future recommendations on skin cancer screening.

Further analyses are needed to evaluate whether routine referral to dermatologic specialists might be effective. Given the lack of direct evidence, modeling studies using available indirect evidence, including cost-effectiveness studies, may provide some information on the usefulness of screening as a preventive strategy.

Other limitations of the literature include a lack of large studies on accuracy of screening in the general population and a lack of information on whether screening in the general population would result in the identification of lesions at an earlier stage than regular care.

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## **Diagnostic Accuracy of Patients in Performing Skin Self-examination and the Impact of Photography**

### **Abstract**

**Objective** To determine the sensitivity and specificity of skin self-examination (SSE) to detect new and changing moles with and without the aid of baseline digital photographs in patients with dysplastic nevi.

**Design and Intervention** Patients had baseline digital photography and mole counts of their back, chest, and abdomen and were instructed to perform a baseline SSE. Print copies of the images were provided to the patient. Following the baseline examination, the appearance of existing moles was altered and new moles were created using cosmetic eyeliner. The number of moles altered and/or created totaled approximately 10% of each patients' absolute mole count.

**Setting and Patients** Fifty patients with 5 or more dysplastic nevi from the outpatient clinic at Memorial Sloan-Kettering Cancer Center, New York, NY.

**Main Outcome Measure** Skin self-examinations with and without access to the baseline photographs to identify the number of new and altered moles.

**Results** The sensitivity and specificity of SSE for detection of both altered and new moles without photography were 60.2% and 96.2%, respectively. Skin self-examination with photography yielded a sensitivity and specificity of 72.4% and 98.4%, respectively. The findings were similar when stratified by site (back vs chest or abdomen). The sensitivity and specificity for new moles were higher compared with altered moles.

**Conclusions** Access to baseline photography improved the diagnostic accuracy of SSE on the back and chest or abdomen and improved detection of changing and new moles. Our results suggest that baseline digital photography in tandem with SSE may be effective in improving the diagnostic accuracy of patients performing SSE. Susan A. Oliveria, ScD; Dorothy Chau, MD; Paul J. Christos, MPH; Carlos A. Charles, MD; Alvin I. Mushlin, MD; Allan C. Halpern, MD *Arch Dermatol.* 2004;140:57-62.

## INTRODUCTION

LESION THICKNESS (BRESLOW depth) has been identified as the most important prognostic factor for primary cutaneous melanoma, with survival inversely related to lesion thickness.<sup>1-4</sup> There is a direct relationship between survival of patients with melanoma and early detection. The 5-year survival rate for patients with melanoma smaller than 1 mm thick is 94% compared with 50% for melanomas larger than 3 mm thick.<sup>5</sup> This finding suggests that the identification and excision of thin lesions may be important in reducing mortality from melanoma.

The American Academy of Dermatology has recommended that individuals practice skin self-examination (SSE) to detect new and/or changing lesions.<sup>6</sup> Self-screening is important because self-detection by patients, spouses, and families is the most common way skin cancer is currently detected, even though SSE may not be performed routinely or thoroughly.<sup>7-9</sup> Results suggest that SSE is associated with a reduced risk of melanoma, and it is a moderately effective tool for detecting changes in mole size.<sup>10-12</sup>

During the past decades, atypical nevi (dysplastic nevi) have been identified as the strongest indicators of melanoma risk.<sup>13-18</sup> The presence of large numbers of clinically atypical nevi hinders self-examination and professional evaluation. Because the wholesale excision of these lesions is impractical, the present standard of care for individuals with dysplastic nevi is close observation and excision of changing lesions.<sup>19-21</sup> In individuals with large numbers of moles and/or dysplastic nevi, attempts to recognize new or changing lesions are aided by comparison of the clinical examination to pictures of the individual's skin at an earlier point in time.<sup>19, 22-24</sup> Providing patients with photographs offers a baseline measure and may encourage the patient to carefully watch lesions.<sup>25</sup> It has been suggested that patients may be able to better detect changes in their lesions if they have an opportunity to repeatedly view the original lesion with photographs.<sup>26</sup> In addition, through the application of computerized image analysis, digital imaging may offer an opportunity to identify new lesions or changes in lesions earlier and more accurately than standard photographically assisted follow-up.

The purpose of this study was to determine the sensitivity and specificity of SSE to detect new and changing moles in patients with dysplastic nevi. New and changing moles were artificially created with the use of cosmetic makeup. We also assessed the impact of making personal baseline digital photographs available to these patients at the time of SSE on diagnostic accuracy (ie, sensitivity and specificity).

## METHODS

### STUDY PARTICIPANTS

The study was conducted in the outpatient setting of the Pigmented Lesion Clinic of the Dermatology Service at Memorial Sloan-Kettering Cancer Center (New York, NY). Fifty patients 18 years or older with 5 or more clinical dysplastic nevi who were willing to have digital whole-body photography were recruited and informed consent obtained. Patients who were visually or physically impaired were not eligible for the study.

### CONDUCT OF THE STUDY AND DATA COLLECTION

#### Baseline Examination

Information was obtained from each participant at baseline using an in-person interview conducted and recorded by a research fellow (D.C.). Specifically, information was collected on age, sex, race/ethnicity, hair color at the age of 18 years, eye color, skin tone, tendency to burn, ability to tan, self-reported mole count, personal and family history of skin cancer, and SSE practices. As part of the baseline data collection, patients were asked to perform SSE with the aid of a full-length (35 x 127 cm) and hand-held mirror (16 x 19 cm). Patients who wore corrective glasses were instructed to wear them while performing their SSE. Digital photography and mole counts of the chest, abdomen, and back were performed on each patient by a research fellow ([Figure 1](#)).<sup>22</sup> Print copies of the images were provided to the patient.



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**Figure 1.** Body areas for digital photography and mole counts.

#### Procedures to Create and Alter Moles

This was an intervention study design whereby patients received the intervention (alteration or creation of moles) and served as their own comparison group. Following the baseline examination, the appearance of existing moles was altered and new moles were created using cosmetic eyeliner that was water soluble and nontoxic. Four different color shades of eyeliner were available, and the shade closest in color to the patient's typical nevi was used to minimize any color discrimination by the patient.

Each patient had approximately 10% of their moles altered and/or created on their back and chest or abdomen. To alter the size and shape of moles, a template was used to convert existing 5-mm moles to slightly more irregularly shaped 7-mm moles. To assess the ability of patients to identify focal changes in the color of moles, a 2-mm, dark brown mark was made in the confines of existing 5-mm moles. A template was used to create new 4-mm moles ([Figure 2](#), [Figure 3](#), [Figure 4](#), and [Figure 5](#)). Blindfolding of patients and sham drawing on multiple sites were used to ensure that the patients were unaware of the location of cosmetically altered moles and to preclude tactile recall of the sites of the altered and created moles.



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**Figure 2.** Unaltered mole.



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**Figure 3.** New 4-mm mole.



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**Figure 4.** A 2-mm, dark brown mark within the existing 5-mm mole.



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**Figure 5.** A 5-mm mole changed to an irregularly shaped, 7-mm mole.

### **Patient Assessment of New and Altered Moles**

Patients had the blindfolds removed and were then asked to perform SSE (with full-length and hand-held mirror) first without the aid of baseline digital photographs and subsequently with access to their personal photographs. The research fellow recorded the number and types (new vs altered mole) of changes correctly and incorrectly identified by the patient.

### **Statistical Analysis**

Descriptive statistics were used to characterize the study population. Sensitivity, specificity,  $\kappa$  statistic, 95% confidence intervals, and  $P$  values derived from the  $\kappa$  statistic are presented. Using the mole as the unit of analysis, the sensitivity and specificity of SSE to detect new and changing moles were calculated for SSE with and without the aid of baseline digital photographs. The reference standard was the lesion count and recorded number of moles changed and/or created.

The  $\kappa$  statistic was used to evaluate the diagnostic accuracy (sensitivity and specificity) of each SSE modality (eg, with and without baseline photography). In this context,  $\kappa$  is a weighted statistic that expresses the desirable properties of the test (eg, low probability of false results). The comparison of the  $\kappa$  statistic between each SSE modality and the resultant  $P$  value are based on an approach for the comparison of 2 diagnostic tests, each evaluated against the same gold standard (eg, actual number of moles physically altered and/or created) in the same study sample.<sup>27</sup> The positive predictive values (PPVs) and negative predictive value (NPVs) of SSE, with and without the aid of baseline digital photography, were also calculated using the Bayes theorem.<sup>28</sup>

The diagnostic accuracy of SSE can be affected by numerous factors. Stratified analyses were performed by age, sex, history of melanoma, melanoma risk factors, and SSE practices. We explored the potential effects on SSE accuracy of mole location (back vs chest or abdomen), type of mole detected (newly created moles vs altered existing moles), and total number of moles altered and/or created on the patient (dichotomized at median;  $\leq 5$  moles altered or created vs  $>5$  moles altered or created) by conducting stratified analyses.

## RESULTS

The participation rate for this study was 93% (50/54). Characteristics of the 50 patients who were recruited and completed the study are presented in [Table 1](#). There was a total of 3167 moles (median, 50; mean, 63) that contributed to the analyses; 108 moles were altered and 211 new moles were created. The number of altered or created moles per patient ranged from 2 to 27 based on the criteria of altering 10% of each patients' moles. Fifty-two percent of the patients had 5 or fewer moles altered or created, and 48% of the patients had more than 5 moles altered or created. The sensitivity and specificity of SSE for detection of both new and altered moles without photography were 60.2% and 96.2%, respectively, whereas SSE with photography yielded a sensitivity and specificity of 72.4% and 98.4%, respectively.

**Table 1. Patient Characteristics**

<b>Characteristic</b>	<b>Patients, No. (%) (N = 50)*</b>
Sex	
Male	20 (40)
Female	30 (60)
Age, y	
≤30	13 (26)
31-40	18 (36)
41-50	12 (24)
≥51	3 (6)
White race	50 (100)
Tendency to burn	
Easily or some	43 (86)
Rarely or never	7 (14)
Tendency to tan	
Deep or moderate	25 (50)
Mild or none	25 (50)
Eye color	
Blue or green	20 (40)
Hazel or brown	30 (60)
Hair color at age 18 y	
Blond or red	20 (40)
Brunette or black	30 (60)
Skin tone	
Very fair or fair	35 (70)
Medium or dark	15 (30)
Personal history of melanoma	
Yes	22 (44)
No	28 (56)
Family history of melanoma	
Yes	14 (28)
No	25 (50)
Family history of basal cell carcinoma	
Yes	18 (36)
No	21 (42)
Family history of squamous cell carcinoma	
Yes	4 (8)
No	29 (58)
No. of skin self-examinations in last 4 mo	
0	17 (34)
1-4	33 (66)
No. of moles altered and/or created for study protocol	
≤5 (range, 2-5; mean, 4; median, 4)	26 (52)
>5 (range, 6-27; mean, 9; median, 7)	24 (48)

\*Some percentages do not total 100% because of missing responses.

Table 1. Patient Characteristics

Sex differences were apparent, with men performing better than women without the aid of photographs. However, women had a higher sensitivity and specificity of SSE with the use of photographs compared with men. Results showed that patients with more than 5 moles altered or created had significant improvements in diagnostic accuracy with the aid of baseline photographs, although patients with 5 or fewer moles altered or created still gained some benefit from access to photography. The stratified analyses suggested that patients with fairer complexions (eg, light skin, eye, and hair color, tendency to burn, and ability to tan) had higher sensitivities both with (76.6%, 82.8%, 79.8%, 76.0%, and 78.7%, respectively) and without (59.9%, 70.5%, 67.5%, 60.5%, and 61.9%, respectively) the aid of photographs compared with patients who did not have these risk factors (with photography: 62.9%, 66.0%, 68.3%, 54.7%, and 66.5%, respectively; without photography: 60.8%, 53.8%, 56.1%, 58.4%, and 58.5%, respectively). There were no similar trends in the analyses stratified by family history of skin cancer or SSE practices. However, patients with a personal history of melanoma had higher sensitivities both with (80.0%) and without (65.8%) the aid of photography compared with patients with no such personal history (with photography: 67.8%; without photography: 56.8%).

We calculated the PPV and NPV for SSE with and without the aid of baseline photography. The stratified estimates for PPV and NPV for SSE with photography ranged from 70% to 90% and 97% to 99%, respectively. For SSE without the aid of baseline photography, the stratified estimates for PPV and NPV for SSE ranged from 54% to 67% and 96% to 98%, respectively. However, these estimates are highly dependent on the prior selected prevalence of altered or created moles and should therefore be interpreted with caution. The PPV and NPV results could differ in a population with a different prevalence of new and changing moles; in our study, we fixed the prevalence at 10%, since we created the new and changing moles.

## COMMENT

This pilot study determined the sensitivity and specificity of SSE to detect new and changing moles in patients with dysplastic nevi and also assessed the impact of making personal baseline digital photographs available to these patients at the time of initial self-examination. The sensitivity of SSE to detect both new and altered moles was 60.2% without photography and increased substantially to 72.4% with the aid of digital photographs. The results suggest that patients had high specificity (few false-positive results) both with and without access to photographs. The specificity was 96.2% without photographs and increased slightly to 98.4% with the aid of photographs.

Berwick et al<sup>10</sup> reported that SSE is associated with a reduced risk of melanoma, with the potential for a 63% reduction in mortality. A prospective study of the effectiveness of SSE is needed; however, the logistic constraints in conducting such a study are obvious. In a preliminary study by Muhn et al,<sup>11</sup> the efficacy of SSE to detect changes in mole size has been investigated in high-risk patients.<sup>11</sup>

The specificity of SSE was 62% and the sensitivities of detecting 2-mm and 4-mm changes were 58% and 75%, respectively. In a recent study by Dawid et al,<sup>12</sup> the ability of patients to identify real changes in melanocytic nevi was evaluated in 251 patients with 1431 melanocytic nevi. The sensitivity to detect enlarging nevi was low (10.9%), whereas the specificity was 99.2%. In a study by Edmondson et al,<sup>25</sup> the effect of instant photography as a method for screening melanoma during routine health examinations was assessed. Copies of the prints were given to patients for observation of any changes in the lesions of interest. Although the objective was not to study the effect of providing photographs to patients, the results showed that the possession of a photograph by the patient led to a diagnosis of melanoma in 2 instances.

Although the ultimate end point of interest in a screening study of this type would be melanoma, we defined new lesions and lesion change as intermediate outcomes because we believe these are the most important and relevant for self-directed prescreening and early detection. Limitations of the study are that SSE was not formally taught to the patients and the study was not restricted to patients who could adequately perform SSE. Patients who are taught SSE may receive more benefit. We only assessed the diagnostic accuracy of SSE performed on the back and chest or abdomen, and the results may not be generalizable to different sites on the body. Also, there can be other subtle changes related to margins, thickness, and texture that are not captured with this simplistic approach of creating new moles and altering existing moles using cosmetic eyeliner.

The design of the intervention for this study differs from the intervention design that would be observed in routine follow-up examination because the study population was a select, highly motivated group composed of patients at high risk for melanoma based on the presence of 5 or more dysplastic nevi. These patients expected an artificial alteration in a lesion, and the alteration and SSE to detect change were performed at the same appointment. Because the assessment of diagnostic accuracy of SSE occurred shortly after the baseline SSE, patients were relying on immediate rather than long-term recall of the location and characteristics of their moles, and there is the potential for an overestimate of the diagnostic accuracy. The research fellow who interviewed the patients and altered the patients' moles was also responsible for recording the patients' ascertainment of altered moles. Hence, there may be the potential for bias related to accuracy ascertainment. However, the research fellow was instructed to simply record the patients' responses with respect to ascertainment. Due to logistical constraints, it was not feasible to use a separate research fellow for accuracy ascertainment.

This study was conducted in an experimental, highly controlled situation and may not represent what would occur in a population-based setting. Sham-altered nevi may not represent what would occur in a real-world setting; however, this was designed as a pilot study. A prospective study is being planned, and the results will allow us to draw firm conclusions about the impact of digital photography on accuracy of SSE in high-risk patients.

The patient population was also highly motivated, with a high prevalence of dysplastic nevi (100%), history of malignant melanoma (65.8%), and previous performance of SSE (66.0%). These preliminary results likely represent the best case scenario, since our study population was highly motivated and had the advantage of an immediately antecedent baseline SSE.

The availability of baseline digital photographs improved the sensitivity and specificity to detect new and altered moles. Our results suggest that baseline digital photography as an adjunct to SSE improves the diagnostic accuracy of patients performing SSE. Providing patients with photographs may encourage patients to more carefully monitor their lesions and may enable patients to better detect suspicious changes in their lesions.

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## **Psychosocial Mediators of a Nurse Intervention to Increase Skin Self-examination in Patients at High Risk for Melanoma**

### **Abstract**

This prospective study examines psychosocial mediators of efficacious skin self-examination (SSE) intervention that includes provision of a whole-body digital photography book depicting the entire skin surface. Individuals ( $n = 100$ ) with established risk factors for melanoma were recruited from the Memorial Sloan-Kettering Cancer Center Pigmented Lesion Clinic during their initial dermatologist visit and were randomized to receive a photobook immediately ( $n = 49$ ) or 4 months after intervention delivery ( $n = 51$ ). Potential mediators included self-efficacy and response efficacy drawn from Social Cognitive Theory, melanoma worry, and SSE anxiety drawn from Self-Regulation Theory, and skin cancer knowledge, and skin awareness. Only self-efficacy was a significant mediator, accounting for 8% of the total effect of photobook enhancement on SSE adherence at 4 months. (*Cancer Epidemiol Biomarkers Prev* 2006;15(6):1212–6)

1. Jennifer L. Hay<sup>1</sup>,
2. Susan A. Oliveria<sup>2</sup>,
3. Stephen W. Dusza<sup>2</sup>,
4. Deborah L. Phelan<sup>2</sup>,
5. Jamie S. Ostroff<sup>1</sup> and
6. Allan C. Halpern<sup>2</sup>

± Author Affiliations

1. <sup>1</sup>Behavioral Sciences Service and <sup>2</sup>Dermatology Service, Memorial Sloan-Kettering Cancer Center, New York, New York

## Introduction

Melanoma is one of the most rapidly increasing cancers in the United States (1). Established risk factors for melanoma include strong intermittent sun exposure, large numbers of dysplastic nevi, cutaneous phenotype (red hair, blue eyes, and poor tanning ability; ref. 2), and a family history of the disease (3). Fortunately, there is a 95% survival rate if melanoma is diagnosed at a local stage (4), making early detection an important strategy for reducing melanoma mortality and morbidity. Skin self-examination (SSE) by patients is a potentially useful, but as of yet unproven, strategy to reduce incident and invasive diagnoses (5). Additionally, over half (53-68%) of melanomas are originally detected by the patients, spouses, or partners (6); thus, increasing individuals' ability to recognize new or changing lesions represents an important goal for early detection of melanoma, especially among those with melanoma risk factors (7). Even among those with a family history of melanoma, recent (last 12 months) screening rates vary widely (28-62%; refs. 8, 9). Novel intervention strategies to increase SSE use among those at high risk for developing melanoma are warranted.

Among those at high risk for developing melanoma, demographic predictors of adherence to SSE include being female, younger, and having a higher educational level (10). Medical factors related to SSE performance include having a history of skin cancer and greater sun sensitivity (10). Psychosocial predictors of SSE in high-risk populations include higher knowledge about SSE (10), high self-efficacy, or confidence that they can perform efficacious screening (8, 10), a positive attitude about SSE and the benefits of SSE, low levels of perceived barriers to SSE performance (10-12), and physician recommendation and counseling to perform SSE (12). Finally, increased SSE is related to ability to ask for help from a spouse or partner (8, 10) and increased levels of melanoma concern and risk perceptions (10, 11).

Prior research indicates that SSE educational interventions can increase SSE utilization and diagnostic accuracy. In the general population, Mickler et al. (13) found that the provision of an SSE educational brochure, videotape, or one-on-one instruction from a nurse practitioner led to sustained (3 weeks) increases in skin cancer knowledge, SSE use, and accurate discrimination of lesions compared with a no-intervention control group. In addition, the provision of photographic examples combined with written information about different types of skin lesions has also been shown to be a useful strategy to increase participants' ability to accurately discriminate benign from suspicious lesions. Among those at high risk for developing melanoma, dermatologic examination and nurse-provided SSE education increase knowledge and use of SSE sustained through 18 months (14).

The provision of digital photographs of the entire skin surface, in tandem with SSE education, may further enhance SSE over educational interventions alone. Digital photography has the potential to act as an at-home reminder to engage in monthly SSE, as well as a concrete point of comparison for patients as they search for new or changing skin lesions on their skin surface during SSE (15). The use of digital photography increases high-risk individuals' diagnostic accuracy (16) and, integrated into a nurse and dermatologist-provided educational intervention, results in significantly increased use of SSE after 4 months over the intervention alone (17).

In this study, we examine potential theory-based psychosocial mechanisms of the effect of digital photography on adherence to SSE.

In behavioral science, the relationship of an intervention on an intervening variable on a behavioral outcome is defined as mediation (18); whereas in epidemiology, this relationship is termed an intermediate end point effect (19). An understanding of the mechanisms through which provision of digital photography enhances SSE use has practical and theoretical importance, as this information could guide the development of additional enhancements for SSE interventions and booster interventions aimed at SSE maintenance. Additionally, clarification of the psychological processes through which digital photography leads to increased SSE would provide guidance concerning the development of other personal, hands-on aids for screening and provide evidence for or against theoretical approaches used to develop intervention enhancements. Unfortunately, even when health behavior theories are used to guide the development of intervention components, examinations of whether the expected theory-based constructs are actually responsible for behavior change are rarely conducted. The Task Force on Community Preventive Services (20) has advocated for further examination of the theoretical mechanisms responsible for community interventions aimed to reduce sun exposure; these recommendations are similarly warranted for SSE interventions provided in clinical settings.

## **Materials and Methods**

### **Sample**

As described previously (21), the sample included new patients recruited from the Memorial Sloan-Kettering Cancer Center outpatient Pigmented Lesion Clinic of the Dermatology Service. All new dermatology visits were assessed for presence and number of clinically dysplastic or atypical nevi by the physician during the clinical examination. Patients ages  $\geq 18$  years with five or more clinically dysplastic or atypical nevi who were willing to have digital whole-body photography and agreed to be randomized to an intervention arm were recruited and informed consent obtained ( $N = 100$ ). Among these participants, self-reported melanoma risk factors included a personal history of skin cancer (50%), a history of dysplastic moles (81%), and a history of previous skin biopsy (80%). Half of these individuals ( $n = 49$ ) were designated to receive their whole-body digital photography (photobook) to take home with them. We stratified by personal history of skin cancer during patient enrollment to ensure that this variable was equally distributed between the two intervention arms. Patients who were visually or physically impaired, had been previously photographed, or had previously received a photobook were not eligible. The participation rate for the study was 95%, with those refusing involvement in the study doing so because of time constraints or a lack of interest in research participation. This study was reviewed and approved by the Institutional Review Board at Memorial Sloan-Kettering Cancer Center.

### **Study Design and Description of the Intervention**

The intervention for this study (21) consisted of a 2-hour meeting with a dermatologist and a dermatologic nurse. As a preliminary step, an explanation of the study was provided; consent was obtained; and randomization to intervention A (photobook) or intervention B (no photobook) was completed. The first intervention module consisted of a dermatologist encounter where the physician explained the importance of SSE, instructed the patient to focus on size/color/shape of the lesions during SSE, and conducted a discussion of any changes that should prompt a dermatology visit, types of skin cancer, and sun protection advice. Next, the nurse asked each patient to remove all clothing and put on a robe.

The nurse then did whole body digital photography incorporating 27 body sectors, including close-ups of patients' moles. After patients changed back into their clothing, they viewed a 3-minute video on SSE: *Skin Cancer: Can you Spot it?* (22). Next, the nurse conducted a guided imagery exercise where she asked each patient to close their eyes, try to relax, and visualize being at home in a comfortable, well-lit room. The nurse then systematically described the patient conducting SSE at home. The group randomized to SSE intervention with photobook (intervention A) received their personal whole-body photographs compiled in the form of a booklet. The nurse showed how to use the photobook as an adjunct to SSE. The group randomized to receive SSE intervention with no photobook (intervention B) received a written pamphlet on how to perform SSE and how to record moles in a diary format as an adjunct to SSE. The nurse showed in a systematic fashion how to look at all body parts and how to record current moles. After the 4-month assessment, intervention B participants received their own photobook with nurse instruction.

### **Proposed Mediational Model**

We proposed a set of psychosocial factors to explain the effect of provision of whole-body digital photography photobook as an intervention enhancement on increased use of SSE. First, we hypothesized that provision of the photobook would increase use of SSE through increased confidence in SSE performance (self-efficacy) and a stronger belief that SSE is an effective means of detecting early skin cancer (response efficacy). These constructs are derived from Social Cognitive Theory (23), which emphasizes the importance of beliefs about the efficacy of one's efforts in behavioral performance as an important mechanism of behavior change. Empirically, self-efficacy and response efficacy are related to increased use of SSE in high-risk individuals (8, 10-12). We hypothesized that the provision of the photobook, a personalized, concrete, take-home guide and point of comparison of the appearance of moles would further enhance efficacy beliefs, and thus adherence with SSE, over educational intervention alone. Second, we hypothesized that the effect of provision of whole-body digital photography on SSE adherence would be mediated by reductions in negative affect related to developing melanoma and performing SSE. Given the potential for negative affect related to SSE and melanoma in individuals with high numbers of dysplastic or atypical nevi, we anticipated that the provision of the photobook would aid in the management of negative affect over and above the educational intervention alone because providing more personalized, concrete guidance may provide these high-risk patients with an additional level of structure to help them manage their risk by conducting regular SSE. This is consistent with Leventhal's Self-Regulation Theory (24). Empirically, as well, there is evidence that those who anticipate that SSE will increase their anxiety about skin cancer prefer to rely on physician examination (11). We also hypothesized that skin cancer knowledge and heightened skin awareness would mediate the intervention effect because skin cancer knowledge is an outcome of SSE intervention (13), and both knowledge and awareness are key predictors of SSE performance.

### **Measurement Strategy**

In [Table 1](#), we describe the measurement strategy for each proposed psychosocial mediator, including for each one the number and wording of the items used in the scales, the response categories employed, the score ranges, and level of internal consistency of each psychosocial factor.

These psychosocial factors (see [Table 1](#)) were assessed by questionnaire at multiple time points, including baseline, before receipt of the intervention and follow-up, and after 4 months. At baseline, participants completed their questionnaire (demographics, medical and psychosocial factors, and SSE adherence) before their meeting with the dermatologist and nurse. Then, the dermatologic examination was conducted to collect information on the number of moles and dysplastic nevi. The nurse education module was also delivered at this appointment. All patients then underwent whole-body photography. Intervention A participants received their photobook immediately after the nurse-provided intervention, whereas intervention B participants received their photobook after follow-up 2, 4 months after their baseline visit. At 4-month follow-up, the questionnaires were either mailed directly to the patient for self-administration, or the nurse administered the questionnaire via telephone. Our primary dependent variable was adherence with SSE at 4 months, and we designated those who had completed three or more screenings during this time period as adherent, and those who had done fewer than three screenings as nonadherent. Most participants (95%) were retained through the 4-month assessment. We examined whether the five that dropped out differed from the 95 who were retained in demographic, medical history, or baseline psychosocial factors, and they differed significantly only on self-efficacy. The five who dropped out had significantly higher scores ( $m = 4.1$ ) than those who were retained ( $m = 3.4$ ,  $P = 0.04$ ).

**Table 1.**

**Proposed psychosocial mediators of a 4-month SSE intervention effect**

Psychosocial factor	No. items	Item wording	Response category for each item	Score ranges	Baseline, $M$ (SD)	Internal consistency*
Self-efficacy	3	How confident are you that you can: (1) perform SSE? (2) perform effective SSE? (3) I am not confident that I know what to look for when doing SSE <sup>‡</sup>	1 = Not at all, 2 = a little, 3 = somewhat confident, 4 = very, 5 = extremely confident	1-5	3.4 (0.7)	0.77
Response efficacy	1	How certain are you that SSE is an effective means of detecting early skin cancer?	1 = Not at all, 2 = a little, 3 = somewhat certain, 4 = very, 5 = extremely certain	1-5	4.0 (0.9)	NA
Melanoma worry ( <a href="#">30</a> )	4	During the past two weeks: (1) how often have you worried about developing melanoma? (2) How often has your mood been affected by concern that you might get melanoma someday? (3) How often have thoughts about getting melanoma affected your abilities to	Items 1-3: 1 = rarely or never, 2 = sometimes, 3 = often, 4 = all the time Item 4: 1 = not at all, 2 = somewhat concerned, 3 = moderately concerned, 4 =	4-16	7.5 (2.6)	0.84

Psychosocial factor	No. items	Item wording	Response category for each item	Score ranges	Baseline, Internal consistency*
		perform your daily activities? (4) How emotionally distressed or concerned have you been about the possibility of getting melanoma?	very concerned		
SSE anxiety	1	When I think about doing SSE I become anxious	1 = Strongly disagree, 2 = somewhat disagree, 3 = undecided, 4 = somewhat agree, 5 = strongly agree	1-5	2.3 (1.0) NA
Skin cancer knowledge	11	Knowledge concerning types of skin cancer, curability, prevention methods, performance of SSE, body parts in SSE, signs and appropriate follow-up of suspicious lesions, time interval for SSE, and appropriate reminders for SSE	0 = Incorrect, 1 = correct	0-11	7.1 (1.2) 0.65
Skin awareness (31)	1	Do you think you would notice changes on your skin if they occurred?	0 = No/DK, 1 = Yes	0-1	0.7 (0.4) NA

- Abbreviation: NA, not available.
- ↵\* Internal consistency calculated at 4-month assessment for each psychosocial factor.
- ↵† This variable was reverse coded.

## Analytic Approach

Descriptive statistics, including medians, means, and SDs, were calculated for all patient characteristics and psychosocial factors. We also examined whether any of the psychosocial factors significantly varied across intervention arm.

Simple mediation models were evaluated for all psychosocial factors. Mediation was assessed using the following individual regression model methodology as described by Baron and Kenny (18) and expanded on by MacKinnon et al. (25).  $M = \beta_{0(1)} + \alpha X + \varepsilon_{(1)}$   $Y = \beta_{0(2)} + \tau X + \varepsilon_{(2)}$   $Y = \beta_{0(3)} + \tau X + \beta M + \varepsilon_{(3)}$  In this analysis, the dependent variable ( $Y$ ) is adherence to SSE at 4 months after intervention; the independent variable ( $X$ ) is the intervention group to which the patient belonged (group A or B); and the possible mediator variables ( $M$ ) are the psychosocial measures collected at 4 months after baseline. Eq. A tests the effect of the independent variable ( $X$ ) on the mediator ( $M$ ). Eq. B depicts the effect of the independent variable ( $X$ ) on the dependent variable ( $Y$ ). Eq. C tests the effect of the mediator ( $M$ ) on the dependent variable ( $Y$ ), adjusting for the independent variable ( $X$ , see Fig. 1 ). Baron and Kenny (18) consider a variable to be a mediator if three conditions hold: first, the independent variable affects the mediator (Eq. A); second, the independent variable affects the dependent variable (Eq. B); and third, the mediator must affect the dependent variable after controlling for the independent variable (Eq. C).

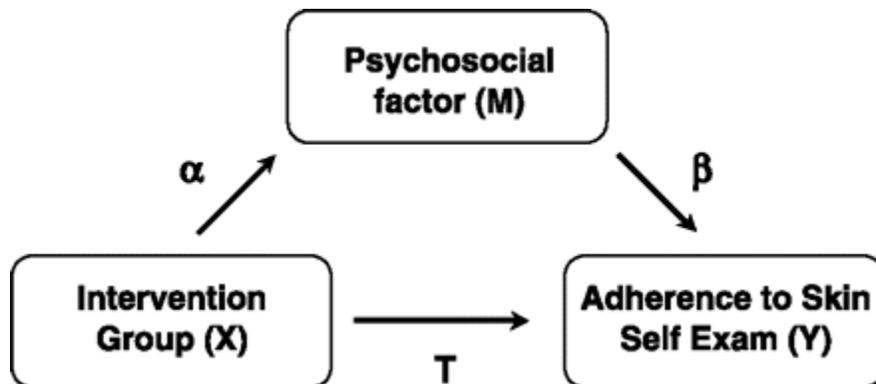


Figure 1.

Simple mediational model.

The mediation variable effect was assessed for each psychosocial measure individually using the product of the coefficients  $\alpha$  (representing the relation between the mediator and the independent variable) and  $\beta$  (representing the relationship between the mediator and the dependent variable, adjusting for the effect of the independent variable) as outlined in MacKinnon et al. (25). The Sobel (26) estimate of the SE was also calculated. The mediator variable effect was calculated as the product of the coefficients ( $\alpha\beta$ ) divided by the Sobel estimate of the SE. This procedure assumes that the error terms  $\varepsilon_1$  and  $\varepsilon_3$  are normally distributed, and that there was little measurement error. Because of the relatively limited sample size, bootstrap estimates of the product of the coefficients were also estimated along with 95% confidence intervals (27).

## Results

Participants were predominantly female (63%), White non-Hispanic (98%), married (61%), and with an average age of 40 (SD = 11.7). Almost half (40%) had education beyond college, and most (74%) saw a dermatologist regularly. Patients randomized to intervention A (photobook) versus intervention B (no photobook) did not differ significantly on any of the demographic or psychosocial factors (all  $P$ s > 0.05). Baseline descriptive statistics for all psychosocial factors are provided in Table 1.

Table 2 shows the results of mediation testing for each psychosocial factor measure. Eq. A was significant for self-efficacy alone, as delivery of the photobook was significantly related to increased self-efficacy at 4 months after intervention. None of the other psychosocial factors met this condition. Eq. B was significant such that delivery of the photobook was related to adherence to skin self-examination, as we reported previously (17). The condition for Eq. C was met by self-efficacy as well as skin cancer knowledge; these potential mediators were associated with adherence to SSE controlling for photobook delivery. The only psychosocial factor that met all three conditions of mediation effect was self-efficacy. The bootstrap estimate for the mediating variable effect for self-efficacy was 0.0808. The 95% confidence interval for the indirect effect of self-efficacy did not overlap zero (0.0172-0.1638), indicating statistical significance at alpha of 0.05. Self-efficacy accounted for ~8% of the total effect of photobook delivery on SSE adherence.

**Table 2.**

**Single mediator tests for each psychosocial factor ( $n = 95$ )**

Potential mediator variables	<u>Eq. A: <math>X \rightarrow M</math></u>		<u>Eq. C: <math>Y \rightarrow M.X</math></u>			Mediator variable effect	95% Confidence interval
	Estimate	$P$	Estimate	$P$			
Self-efficacy	0.5065	0.0030	0.1643	0.0076	0.0808	(0.0172, 0.1638)	
Response efficacy	-0.0594	0.7593	-0.0164	0.7626	-0.0002	(-0.0259, 0.0253)	
Melanoma worry	0.5045	0.2851	-0.0157	0.4856	-0.0085	(-0.0516, 0.0191)	
SSE anxiety	-0.0989	0.7259	-0.0605	0.1001	0.0046	(-0.0354, 0.0461)	
Skin cancer knowledge	1.5676	0.4758	0.0151	0.0086	0.0222	(-0.0473, 0.0998)	
Skin awareness	-0.0590	0.4734	0.2026	0.1141	-0.0119	(-0.0541, 0.0287)	

**Discussion**

This study examines psychosocial processes associated with an intervention to enhance the performance of SSE among patients at high risk for melanoma. We found that self-efficacy significantly mediated the relationship between provision of an SSE intervention enhancement, provision of digital photography photobook, and increased SSE adherence at 4 months over SSE intervention without provision of the photobook, with self-efficacy accounting for 8% of the total effect of the intervention enhancement on adherence to SSE.

This confirms our hypothesis that those patients who had an objective comparison on which to evaluate any new or changing lesions felt more confident in their SSE ability, and that this helped explain their increased use of SSE.

These findings confirm that this SSE intervention enhancement (provision of the photobook) met the process goals of increasing efficacy beliefs (23). As such, the study dictates that other methods aimed to increase and maintain SSE use should aim to address self-efficacy beliefs and could include methods for addressing any reductions in self-efficacy that could diminish adherence. We did not find evidence for mediation among the other psychosocial factors assessed, which could have been due to a lack of sensitivity in the proposed mediators and our small sample size. Despite this, it is also likely that there are other health behavior change processes at work driving increased SSE adherence in the presence of the photobook (28). There are opportunities to further explore and examine theory-based mechanisms of this and other novel SSE intervention components.

We note some limitations of the current study. The study comprised a relatively small number of participants and was conducted in a fairly ideal circumstance where high-risk patients were willing to be involved in a relatively time-consuming intervention strategy. Additionally, self-efficacy was assessed through direct questioning about level of confidence in performing SSE, which may not fully capture the self-efficacy construct. However, comprehensive and detailed information was obtained during this study, albeit on a small group of patients. Our sample size and potential measurement error in those psychosocial factors that were based on single items dictate the need for us to confirm our findings in a larger sample. Finally, our SSE end point was based on self-report rather than direct observation and thus is vulnerable to overestimation by participants. However, patients in this study were not privy to the underlying hypotheses, and any misclassification related to SSE self-report is not likely to have been differential between the two groups, thus not substantially biasing the study findings.

Additionally, a larger sample would allow for examination of potential moderators of the effect of the photobook on SSE adherence. In fact, photobook might be particularly useful in some subgroups of high-risk patients. We note that the five participants lost to 4-month follow-up had significantly higher levels of baseline self-efficacy than those retained; whereas this analysis is based on very few participants, it indicates interesting unanswered questions concerning psychosocial characteristics of those who might find the intervention strategy more or less relevant for themselves.

In sum, this study provides needed insight into the psychological mechanisms associated with a specific component of SSE intervention. Unique strengths of the study include focus on a cancer screening strategy that is equally applicable to men and women (unlike BSE), the prospective study design, and theory-driven nature of the photobook intervention. Additionally, this study examines these issues in a group of individuals where initiation and maintenance of SSE is highly recommended; thus, a greater understanding of the psychological mechanisms associated with adherence to SSE is of value. This study indicates the central importance of self-efficacy in driving increased SSE adherence rates after provision of advice, education, and personalized photobook. Finally, the study adds to our theoretical understanding of how cancer prevention behavior change takes place.

The development of new maintenance-focused theoretical models (29) and theory-driven empirical investigations will provide additional insight into the process and optimization of health behavior adherence, including SSE adherence, over time.

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## Skin Cancer Screening Exam

Select the *best* answer to each of the following items. Mark your responses on the Answer Form.

1. Skin cancer is the most commonly diagnosed cancer in the United States. The majority of skin cancer is nonmelanoma cancer, either basal cell cancer or squamous cell cancer. The incidence of both melanoma and nonmelanoma skin cancer has been increasing over the past \_\_\_\_\_.

- a. 5 years
- b. 12 years
- c. 2 decades
- d. 3 decades

2. In 2001, the U.S. Preventive Services Task Force (USPSTF) found \_\_\_\_\_ evidence to recommend for or against routine screening for skin cancer by using whole-body skin examination for early detection of skin cancer.

- a. no
- b. ample
- c. insufficient
- d. None of the above

3. Direct evidence linking skin cancer screening to improved health outcomes is \_\_\_\_\_. Information is limited on the accuracy of screening by physicians or patients using real patients and lesions.

- a. ample
- b. lacking
- c. non-existent
- d. None of the above

4. The authors report a significant association between "skin awareness" and death from melanoma (hazard ratio, 0.5 [CI, 0.3 to 0.9]) after controlling for other confounders. The authors defined skin awareness as a positive response to the question, "Did you ever think about your skin, how it looked, whether there were any changes, or whether there were any abnormal marks?"

- a. True
- b. False

5. Accuracy of screening is an important link in the chain of evidence connecting screening in asymptomatic persons with improved health outcomes. Evidence for the accuracy of screening with whole-body examination by physicians or by patients is limited and inconsistent. A recent systematic review using pictures of lesions reported a sensitivity that ranged from \_\_\_\_\_% to 100% and a specificity of 98%.

- a. 12
- b. 22
- c. 42
- d. 92

6. A more recent, community-based RCT of screening in Australia (15) involving 16 383 whole-body skin examinations reported the specificity and positive predictive value of screening by a primary care physician for melanoma as 86% and 2.5%, respectively. The overall positive predictive value for all types of skin cancer was \_\_\_\_\_%.

- a. 29
- b. 35
- c. 56
- d. 71

7. A study in Queensland, Australia, reviewed the characteristics of all histologically confirmed first melanomas in residents age 20 to 75 years. They found that the rate of thin lesions (<0.75 mm) detected by a physician (81%) was higher than the rate detected by nonphysicians (\_\_\_\_\_%).

- a. 22
- b. 32
- c. 51
- d. 62

8. There is evidence from retrospective studies of patients with diagnosed melanoma that, although most melanoma lesions are first noticed by someone other than a physician, lesions detected by a physician are thinner.

- a. True
- b. False

9. The direct evidence to support the benefits of a screening examination by a physician or patient in reducing morbidity and mortality is limited.

- a. True
- b. False

10. The evidence on accuracy of screening has limitations. Several different methods have been used to study the accuracy of screening for skin cancer by physicians and by patients. Many studies measure accuracy through the use of photographs of lesions of known histopathology. Other studies measure accuracy by following the referral patterns and ultimate histopathology of lesions from real patients. Both of these methods have obvious problems.

- a. True
- b. False

11. The literature on screening for skin cancer has several limitations. A major limitation is the lack of direct evidence linking skin cancer screening to improved health outcomes. An adequately powered, population-based RCT of screening demonstrating mortality outcomes would require approximately \_\_\_\_\_ participants because of the relatively low melanoma-related mortality rate in the United States.

- a. 250,000
- b. 480,000
- c. 650,000
- d. 800 000

12. Limitations of the literature include a lack of large studies on accuracy of screening in the general population and a lack of information on whether screening in the general population would result in the identification of lesions at an earlier stage than regular care.

- a. True
- b. False

13. In one study, skin self-examinations with and without access to the baseline photographs to identify the number of new and altered moles. The sensitivity and specificity of SSE for detection of both altered and new moles without photography were % and 96.2%, respectively. Skin self-examination with photography yielded a sensitivity and specificity of 72.4% and 98.4%, respectively.

- a. 40.5
- b. 50.2
- c. 60.2
- d. None of the above

14. One study showed that baseline digital photography in tandem with SSE may be effective in improving the diagnostic accuracy of patients performing SSE.

- a. True
- b. False

15. LESION THICKNESS (BRESLOW depth) has been identified as the most important prognostic factor for primary cutaneous melanoma, with survival inversely related to lesion thickness. There is a direct relationship between survival of patients with melanoma and early detection. The 5-year survival rate for patients with melanoma smaller than 1 mm thick is 94% compared with \_\_\_\_\_% for melanomas larger than 3 mm thick.

- a. 39
- b. 50
- c. 62
- d. 72

16. The American Academy of Dermatology has recommended that individuals practice skin self-examination (SSE) to detect new and/or changing lesions. Self-screening is important because self-detection by patients, spouses, and families is the most common way skin cancer is currently detected, even though SSE may not be performed routinely or thoroughly.

- a. True
- b. False

17. During the past decades, atypical nevi (dysplastic nevi) have been identified as the strongest indicators of melanoma risk. The presence of large numbers of clinically atypical nevi hinders self-examination and professional evaluation.

- a. True
- b. False

18. Providing patients with photographs offers a \_\_\_\_\_ and may encourage the patient to carefully watch lesions. It has been suggested that patients may be able to better detect changes in their lesions if they have an opportunity to repeatedly view the original lesion with photographs.

- a. mental image
- b. baseline measure
- c. guideline for viewing
- d. None of the above

19. Sex differences were apparent, with men performing better than women without the aid of photographs. However, women had a higher sensitivity and specificity of SSE with the use of photographs compared with men.

- a. True
- b. False

20. One studies's results suggest that baseline digital photography as an adjunct to SSE improves the diagnostic accuracy of patients performing SSE. Providing patients with photographs may encourage patients to more carefully monitor their lesions and may enable patients to better detect suspicious changes in their lesions.

- a. True
- b. False

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