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Downstream Consequences of Melanoma Screening in a Community Practice Setting: First Results

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Abstract

BACKGROUND—Population-based screening for the early detection of melanoma holds great promise for reducing melanoma mortality, but evidence is needed to determine whether benefits outweigh risks. Skin surgeries and dermatology visits after screening were assessed to indicate potential physical, psychological, and financial consequences.

METHODS—Targeted primary care providers (PCPs) at the University of Pittsburgh Medical Center were trained to detect early melanoma using the INFORMED (INternet course FOR Melanoma Early Detection) program. The authors analyzed aggregated administrative data describing 3 groups of patients aged ≥35 years who had received an annual physical examination by PCPs: group A1 included patients of PCPs from the group with the highest percentage of INFORMED-trained providers, group A2 included patients of PCPs from the group with a lower

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AUTHOR CONTRIBUTIONS

Martin A. Weinstock: Conceptualization, methodology, validation, formal analysis, investigation, resources, writing—original draft, writing—review and editing, visualization, supervision, project administration, and funding acquisition. **Laura K. Ferris:** Conceptualization, methodology, validation, formal analysis, investigation, resources, data curation, writing—original draft, writing—review and editing, visualization, supervision, project administration, and funding acquisition. **Melissa I. Saul:** Conceptualization, methodology, software, validation, formal analysis, investigation, resources, data curation, and writing—review and editing. **Alan C. Geller:** Conceptualization, methodology, and writing—review and editing. **Patricia M. Risica:** Conceptualization, investigation, writing—review and editing, and visualization. **Julia A. Siegel:** Validation, writing—review and editing, and visualization. **Francis X. Solano:** Conceptualization, methodology, investigation, resources, and writing—review and editing. **John M. Kirkwood:** Conceptualization, methodology, investigation, resources, writing—original draft, writing—review and editing, and supervision.

percentage of INFORMED-trained providers, and group B included patients of PCPs without INFORMED training.

RESULTS—INFORMED-trained PCPs screened 1572 of 16,472 patients in groups A1 or A2 and none of the 56,261 patients in group B. In group A1, there was a 79% increase (95% confidence interval, 15%–138%) in melanoma diagnoses noted; no increase was observed for the other groups, and no substantial increase in skin surgeries or dermatology visits occurred in any group.

CONCLUSIONS—A large-scale melanoma screening using the INFORMED program was conducted in Pennsylvania. To the best of the authors' knowledge, the current study is the first analysis of downstream results and the findings indicate increased melanoma diagnoses but little impact on skin surgeries or dermatology visits. This result provides some reassurance that such efforts can be conducted without major adverse consequences, at least as measured by these parameters, and therefore should be considered for more widespread use.

Keywords

dermatologic surgical procedures; mass screening; melanoma; mortality; office visits

INTRODUCTION

Widespread screening for the early detection of melanoma holds great promise for reducing melanoma mortality. However, to be implemented on a large scale, evidence is needed that the benefits of screening outweigh the potential harms. Work over the past decade has yielded evidence of benefits associated with screening, including reduced deaths due to melanoma,^{1–3} but to the best of our knowledge little has been published quantifying potential harms that may be associated with screening activities. Although there are some data regarding the number needed to screen or biopsy to diagnose a single melanoma,⁴ to our knowledge the downstream impacts of population-based screening have not been well quantified. We sought to address this gap by measuring the effects of a large-scale, population-based screening program that recently was initiated in western Pennsylvania.

Potential harms associated with melanoma screening include excess medical interventions that follow screening as well as the potential distress and anxiety that might be consequent to it. We chose to assess 2 events that are potentially associated with adverse consequences and are measureable with administrative data: surgeries on the skin and visits to dermatologists. The former is associated with potential morbidity (scarring, discomfort, and functional limitations as well as adverse cosmetic outcomes, which may affect social functioning), and both are associated with financial cost and potential patient distress or anxiety. Distress and anxiety associated with this screening will be reported in a subsequent publication.

The screening we evaluated was conducted by primary care providers (PCPs; ie, physicians and other clinicians) during the course of routine annual visits or other visits. These clinicians were offered online training using a modified version of the INFORMED (INternet course FOR Melanoma Early Detection) program, which was designed for PCPs with extensive input from PCPs.⁵ INFORMED has been previously shown to improve PCP

skills related to melanoma detection, including the ability to appropriately reassure patients who have benign lesions that may resemble melanoma, such as seborrheic keratoses.^{5,6} It was anticipated that the ability to appropriately reassure patients would reduce the risk of screening-induced harms.

MATERIALS AND METHODS

The University of Pittsburgh Medical Center (UPMC) melanoma screening program was initiated as a quality improvement effort of the UPMC Physician Services Division (UPMC-PSD) and the University of Pittsburgh Cancer Institute Melanoma Program. PCPs who were employed by UPMC were invited to take a modified version of the INFORMED training as a part of the Intranet uLearn educational program. This was offered as an online course designed to improve the early detection of melanoma and keratinocyte carcinomas (basal and squamous cell carcinomas of the skin) that has been described elsewhere.^{5,6} The program was first made available to these clinicians on January 1, 2014, after a trial comment period. The participation of these providers in the UPMC-PSD was encouraged through a series of town hall meetings, local hospital presentations, and electronic notices from the leadership of the UPMC-PSD and the University of Pittsburgh Cancer Institute. The electronic medical record used by these clinicians also included a health maintenance function to indicate screening for melanoma. Among the UPMC-PSD clinicians, those in the largest group of practices were a particular focus of outreach and were particularly receptive to this initiative. Three populations of patients, defined by their provider groups, were evaluated in this report. Group A1 included patients who were members of the UPMC Health Plan (UPMC-HP) aged ≥ 35 years who had an annual health maintenance physical examination visit with their PCP in the largest group of PCP practices. These PCPs were from the group with the highest percentage of INFORMED-trained providers. Group A2 included all UPMC-HP members aged ≥ 35 years who had an annual health maintenance visit with their UPMC-PSD-employed PCP but were not in group A1. These PCPs were from the group with a lower percentage of INFORMED-trained providers. Group A1 had a higher percentage of INFORMED-trained PCPs in part because the training was particularly encouraged by practice leadership and anecdotal communication of melanomas detected by virtue of screening among providers in this group. Group B comprised all UPMC-HP members aged ≥ 35 years who had an annual physical examination visit with a PCP who was not employed by UPMC-PSD and was not offered INFORMED training.

The current study describes the UPMC-HP summaries of the results of the UPMC melanoma screening quality initiative for the first 8 months of the effort for patients whose PCPs were employed by the UPMC-PSD, who received an annual physical examination (CPT codes 99385–99387 or 99395–99397), and who were aged ≥ 35 years. The quality initiative for melanoma screening did include patients who were not members of the UPMC-HP, but data regarding results among those individuals were not available. The data concerning the results used for the current analysis were provided by the UPMC-HP in aggregated form only. Screening numbers were available in aggregate form only, through a check-box in the electronic medical record for groups A1 and A2, and the INFORMED training status for all physicians was available from the online course records.

We assessed several events in these populations using data provided by the UPMC-HP from corresponding time periods in 2013 and 2014. Surgeries on the skin included procedures with Current Procedural Terminology (CPT) codes for excisions and other surgeries (CPT codes 11000, 11101, 11300, 11301, 11302, 11303, 11305, 11306, 11307, 11308, 11310, 11311, 11312, 11313, 11400, 11401, 11402, 11403, 11404, 11406, 11420, 11421, 11422, 11423, 11424, 11426, 11440, 11441, 11442, 11443, 11444, 11446, 11600, 11601, 11602, 11603, 11604, 11606, 11620, 11621, 11622, 11623, 11624, 11626, 11640, 11641, 11642, 11643, 11644, 11646, 17000, 17003, 17004, 17274, 17276, 17280, 17281, 17282, 17283, 17284, 17286, 40490, 54100, 56605, and 69100). UPMC-HP members with visits to dermatologists were those who had 1 Evaluation and Management CPT codes submitted during the relevant period. Melanoma diagnoses were defined as any claims with a primary diagnostic code of melanoma (*International Classification of Diseases, Ninth Revision* [ICD-9] codes 172.0–172.9). We only had access to aggregate statistics reported by the UPMC-HP, which extracted the above-mentioned parameters, but no individual-level data.

Statistical Analysis

Statistical analysis was performed with StatXact 4 For Windows (Cytel Software Corporation, Cambridge, Mass). Approvals were received by the UPMC Total Quality Council (for the quality initiative) and by the Institutional Review Boards of Rhode Island Hospital, Brown University, and the Providence VA Medical Center (for this data analysis and article preparation).

RESULTS

In total, 618 PCPs in groups A1 and A2 (including physicians, nurse practitioners, and physician assistants) saw patients during the study period. Of these PCPs, approximately 62% were in group A1 and 38% were in group A2; therefore, approximately 26% of the providers in group A1 (101 PCPs) and 9% of the providers in group A2 (21 PCPs) completed INFORMED training before the end of August 2014. None of the providers in group B underwent INFORMED training. Qualifications of INFORMED-trained PCPs in groups A1 and A2 are shown in Table 1. INFORMED-trained PCPs were followed for a median of 6.5 months (6.6 months in group A1 and 6.5 months in group A2) from the completion of training to the end of the study (August 31, 2014).

In this first report for groups A1, A2, and B, we focused on changes in the downstream consequences of melanoma screening between the prescreening period (January to August 2013) and the period immediately after the initiation of provider training and screening (January to August 2014).

A total of 16,472 unique UPMC-HP members aged ≥35 years were seen by UPMC-employed PCPs for an annual physical examination between January 1, 2014 and August 31, 2014 and thus would be considered eligible for screening (groups A1 and A2) according to the health plan administrative data. The numbers depended somewhat on how they were determined; electronic medical record data indicated 11% fewer visits. Screening occurred within other contexts as well. An additional 56,261 unique UPMC-HP members aged ≥35 years (group B) were seen by other PCPs for their annual physical examinations during this

period. In groups A1 and A2, the practices of INFORMED-trained PCPs screened 1572 unique individuals (11% of screen-eligible members) during this 8-month period, which represents 38% of members screened during that period by PCPs, dermatologists, or others in groups A1 and A2.

There was little difference noted between the numbers of UPMC-HP patients who underwent skin surgeries between the first 8 months of 2013 and the first 8 months of 2014. The increases in surgeries were 2% in group A1, 4% in group A2, and 0% in group B; none of these were significantly different from zero (Table 2). Similarly, the percentage of patients who had visits to dermatologists increased modestly in each of the groups (by 2.5%, 10.2%, and 4.4%, respectively, for groups A1, A2, and B). This increase was found to be statistically significantly different from zero only in group B, which was not a target for the melanoma screening effort (Table 2). The number of individuals with claims for a diagnosis of melanoma increased by 79% (95% confidence interval [95% CI], 15% to 138%) in group A1, whereas the changes in group A2 (−3%; 95% CI, −92% to +86%) and group B (7%; 95% CI, −20% to +34%) were much smaller, and were not statistically significantly different from zero. Group A1 had a total of 72 melanoma diagnoses in these 2 periods, whereas only 19 were coded in group A2, but 231 melanoma diagnoses were coded in the much larger group B.

DISCUSSION

The current study described certain key downstream consequences of screening for melanoma in a large primary care patient population. The screening was performed in a health system that launched this effort to screen its members who were aged ≥ 35 years. Targeted clinicians were trained through an Intranet educational system called uLearn that adopted a modification of the INFORMED online program that was developed to improve the early detection of melanoma by PCPs, and has previously been successfully tested and validated in primary care settings. INFORMED also was designed to improve decision making regarding referral and the management of basal and squamous cell carcinoma and benign skin lesions that may mimic the appearance of melanoma, such as seborrheic keratoses. In group A1, which had the highest percentage of INFORMED-trained providers, a marked increase in melanoma diagnoses was observed, which differed from what was observed in the other groups. There was little effect observed on either skin surgeries or visits to dermatologists. An increase in the number of visits to dermatologists was noted in group B, the group with no INFORMED-trained providers, but the absolute magnitude of this increase was small and only statistically significant because of the group's large sample size. In fact, the percentage increase in visits to dermatologists noted in group B was very similar to the percentage increase in visits to dermatologists observed in group A1 (0.43% and 0.49%, respectively), but this change was not statistically significant in group A1 because group A1 had fewer participants.

We are unaware of similar evaluations of large melanoma screenings in a general population sample. This is an important gap in the field, and for those currently evaluating the role of skin screening. We do have prior evidence from a randomized trial that skin self-examination training for the early detection of melanoma was associated with a transient

increase in the frequency of surgeries on the skin (during the first 6 months), but not afterward.⁷

For melanoma screening to gain more widespread acceptance and implementation, it is important to obtain endorsement by authoritative evidence-based groups that may motivate large health care entities to promote the appropriate conduct of screening. This in turn will require the publication of evidence that the benefits of screening outweigh the harms. The early evidence from this screening effort indicates that melanoma screening coupled with a modified INFORMED training program neither results in large numbers of skin surgeries nor a dramatic increase in visits to dermatologists, which are 2 potential adverse downstream consequences that have been of concern as a potential basis of morbidity, distress, and costs.

The weaknesses of the current study include that it was not a randomized trial, and therefore the comparisons may be susceptible to bias. We relied on the UPMC-HP compilation of administrative data to derive the outcomes reported from the 2 evaluation periods, and did not have access to individual patient or provider data. Therefore, a paired analysis to examine the changes in the practices of individual providers between the 2 evaluation periods was not possible. Coding may not have included all visits or procedures, but was unchanged between 2013 and 2014 apart from the advent of the offering of the training module and the implementation of the health maintenance module for an indication by the PCP of skin screening. The percentage of PCPs trained was modest. Although this may have reduced our power to detect potential consequences of that training, a substantial increase in melanoma diagnoses was associated with this effort. These diagnoses of melanoma also were based on administrative data (CPT and ICD coding), which are likely to be less accurate than data based on systematic central review of all specimens by expert pathologists. For example, an influence of INFORMED training on the fidelity of coding cannot be ruled out. Trained PCPs might have had a different level of awareness, which could have motivated the coding of patients with melanoma in a more consistent manner. In addition, the demographics of included patients were not available and statistical adjustment could not be made. We must consider the possibility of bias in the recording of melanoma diagnoses. It also must be recognized that accurate melanoma diagnoses may represent screen-detected melanomas, other melanomas detected due to the training of many PCPs, prior melanomas reported within the context of screening, or other effects of associated publicity. Nevertheless, it is striking that this bias or the real influence of the quality initiative on appropriate recognition of melanoma due to skin evaluation in primary care was not associated with major changes in skin surgeries or dermatology visits. It is interesting to note that although the INFORMED program included instructions on keratinocyte carcinoma screening, this was not its primary focus, and information regarding keratinocyte carcinoma was not provided by the UPMC-HP. The major strengths of the current study include the large population studied, the ability to ascertain the relevant parameters from routinely collected administrative data, and the fact that the current study addressed a major gap in the assessment of possible harms of melanoma screening.

In light of the recently published indications that melanoma screening may be associated with reduced melanoma mortality, and the absence of large increases in skin surgeries and dermatology visits associated with screening, the results of the current analysis of these

downstream consequences are reassuring and point to potential avenues to the reduction of melanoma mortality without substantial harm.

In December 2015, the US Preventive Services Task Force released a draft recommendation regarding melanoma screening and specifically noted the paucity of evidence pertaining to potential risks of melanoma screening.⁸ The US Preventive Services Task Force will soon publish an update of its recommendations regarding melanoma screening and this article may provide useful guidance.

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CONFLICT OF INTEREST DISCLOSURES

Martin A. Weinstock has received personal fees from University Dermatology for work performed outside of the current study. Laura K. Ferris was supported by a SPORE Grant in Skin Cancer (5P50CA121973-08) for work performed as part of the current study and personal fees and research support to her institution from DermTech and Castle Biosciences for work performed outside of the current study. John M. Kirkwood has received personal fees from Bristol-Myers Squibb, Merck, GlaxoSmithKline, Amgen, GreenPeptide, Roche, and Genentech for work performed outside of the current study.

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TABLE 1

Qualifications of INFORMED-Trained Primary Care Providers in Groups A1 and A2

Qualification of Provider	No. of Providers: Group A1	No. of Providers: Group A2
Physician	90	18
Nurse practitioner	8	3
Physician assistant	3	0

Abbreviation: INFORMED, INternet course FOR Melanoma Early Detection.

Other INFORMED trainees in group A1 (not providers) included 1 registered nurse and 4 medical assistants.

TABLE 2
Frequency of Consequences by Group Before and After Possible Melanoma Screening by INFORMED-Trained PCPs

		January to August 2013	January to August 2014	Increase From 2013 to 2014 (95% CI)	Proportion Increase From 2013 to 2014
Skin surgeries	Group A1	7.39% (831/11,238)	7.54% (947/12,560)	0.15% (−0.52 to 0.81)	0.020
	Group A2	6.21% (212/3414)	6.47% (253/3913)	0.26% (−0.86 to 1.37)	0.042
	Group B	5.84% (3088/52,908)	5.84% (3282/56,261)	0.00% (−0.28 to 0.28)	0
Dermatology visits	Group A1	17.31% (1945/11,238)	17.74% (2228/12,560)	0.43% (−0.54 to 1.40)	0.025
	Group A2	14.65% (500/3414)	16.15% (632/3913)	1.50% (−0.15 to 3.16)	0.102
	Group B	11.09% (5868/52,908)	11.58% (6515/56,261)	0.49% (0.11 to 0.87)	0.044
Melanoma diagnoses per 10,000	Group A1	21.36 (24/11,238)	38.22 (48/12,560)	16.86 (3.10 to 30.62)	0.789
	Group A2	26.36 (9/3414)	25.56 (10/3913)	−0.80 (−24.17 to 22.56)	−0.030
	Group B	20.41 (108/52,908)	21.86 (123/56,261)	1.45 (−4.00 to 6.90)	0.071

Abbreviations: 95% CI, 95% confidence interval; INFORMED, INternet course FOR Melanoma Early Detection; PCP, primary care provider.