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State of the Science on Prevention and Screening to Reduce Melanoma Incidence and Mortality: The Time is Now

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Abstract

Although overall cancer incidence rates are decreasing, melanoma incidence rates continue to increase about 3% annually. Melanoma is a significant public health problem that exacts a substantial financial burden. Years of potential life lost from melanoma deaths contribute to the social, economic and human toll of this disease. However, most cases are potentially preventable. Research has clearly established that exposure to ultraviolet (UV) radiation increases melanoma risk. Unprecedented anti-tumor activity and evolving survival benefit from novel targeted therapies and immunotherapies are now available for patients with unresectable and/or metastatic melanoma. Still, prevention (minimizing sun exposure that may result in tanned or sunburned skin and avoiding indoor tanning) and early detection (identifying lesions before they become invasive,

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or at an earlier stage) have significant potential to reduce melanoma incidence and melanoma-associated deaths. This paper reviews the state of the science on prevention and early detection of melanoma, and current areas of scientific uncertainty and ongoing debate. The US Surgeon General's Call to Action to Prevent Skin Cancer and US Preventive Services Task Force reviews on skin cancer have propelled a national discussion on melanoma prevention and screening that makes this an extraordinary and exciting time for diverse disciplines in multiple sectors – health care, government, education, business, advocacy and community – to coordinate efforts and leverage existing knowledge to make major strides in reducing the public health burden of melanoma in the US.

Keywords

Melanoma; Skin cancer; Melanoma/prevention & control*; Melanoma/epidemiology; Sunbathing; Suntan; Ultraviolet rays/adverse effects*; Indoor tanning; Legislation as Topic; Early Detection of Cancer; United States Food and Drug Administration; United States Preventive Services Task Force; Public health

INTRODUCTION

The incidence of melanoma has been increasing for more than forty years in the US, since population-based cancer statistics have been collected.¹ Although the incidence rate for all cancer sites combined is decreasing, the melanoma incidence rate has continued to increase.² Melanoma is the only cancer which is not projected to meet federal objectives for reductions in death rates.³ Melanoma is a significant public health problem that exacts a substantial financial and social burden; however, most cases are potentially preventable.¹ Research has clearly established that exposure to ultraviolet (UV) radiation increases melanoma risk.^{4, 5}

Melanoma prevention recommendations include minimizing overexposure^a to the sun and avoiding indoor tanning, yet studies show that US adults, adolescents and children are not adequately protected from the sun, and indoor tanning remains prevalent in older adolescents and young adults.^{6–9} These alarming data, along with the availability of best practices and evidence-based interventions to reduce UV exposure, inspired the US Surgeon General to publish a “Call to Action to Prevent Skin Cancer” in 2014.¹ Key goals of this effort are to increase opportunities for sun protection in outdoor settings, provide individuals with information to make informed, healthy choices about UV exposure, promote policies that advance the national goal of preventing skin cancer, reduce harms from indoor tanning, and strengthen research, surveillance, monitoring, and evaluation related to skin cancer prevention. Along with this Call to Action, recent state legislation to support sun protection in schools and restrict minors' access to indoor tanning, and actions by the US Food and Drug Administration (FDA) to reclassify tanning devices¹⁰ and propose a new federal rule restricting minors' access to tanning beds,¹¹ have heralded a national focus on melanoma prevention that is unparalleled in US history. Together these changes present a significant

^aFor the purposes of this document, overexposure is defined as sun exposure that may result in tanned or sunburned skin, or that may increase a person's risk of skin cancer.¹

opportunity for the US to change norms and policies to increase sun protection and reduce tanning behaviors.

Unprecedented anti-tumor activity and evolving survival benefit from novel targeted therapies and immunotherapies that are now available have ushered in a new era for patients with unresectable and/or metastatic melanoma.^{12–18} Still, prevention (through minimizing overexposure to the sun and avoiding indoor tanning) and early detection (identifying lesions at earlier stages of development) have significant potential to reduce melanoma incidence and melanoma-associated deaths. Earlier detection of thinner melanomas is linked to higher survival rates, although no randomized, controlled trials have been conducted to assess the impact of clinician screening on melanoma mortality. The lack of clear evidence regarding effectiveness of population-based screening to reduce melanoma mortality resulted in a US Preventive Services Task Force (USPSTF) recommendation in 2009, and an updated draft recommendation statement proposed in 2015, that current evidence for skin screening of the general population is, “insufficient to reliably conclude that early detection of skin cancer through visual examination by a clinician reduces morbidity or mortality.”^{19, 20} The USPSTF’s 2015 draft recommendation statement highlights research needs and gaps, and this critical guidance can be utilized to further develop the scientific evidence base for screening.

The national discussion on melanoma prevention and screening makes this an extraordinary and exciting time for clinicians and researchers to impact melanoma incidence and mortality. The time is now for diverse disciplines in multiple sectors – health care, government, education, business, advocacy and community – to coordinate efforts and leverage existing knowledge to make major strides in reducing the public health burden of melanoma in the US. Examples of how clinicians and researchers are collaborating to embrace approaches with broad reach and maximal impact include The University of Texas MD Anderson Cancer Center’s Melanoma Moon Shot, which as a component of this broad effort emphasizes a program of innovative behavioral research and dissemination of evidence-based prevention strategies and public policy initiatives alongside a research focus on personalized melanoma treatment strategies (<http://www.cancermoonshots.org/cancer-types/melanoma>),^{21–23} and Oregon Health and Science University’s War on Melanoma, which prioritizes research, public education and early detection (<https://www.ohsu.edu/xd/health/services/dermatology/war-on-melanoma/>).

Epidemiology of melanoma and nonmelanoma skin cancer

Nearly 5 million patients receive treatment for melanoma or nonmelanoma skin cancer (NMSC) in the US each year.²⁴ These cases are primarily keratinocyte carcinomas (i.e., basal cell [BCC] and squamous cell carcinomas [SCC]), which are the most common cancers in the US but are not tracked in central cancer registry systems. Although melanoma is less common, it causes nearly 75% of skin cancer deaths.²⁵ Melanoma is the fifth and sixth most common cancer in males and females, respectively,²⁵ and is one of the most common cancers among adolescents and young adults.²⁶ In 2012, the most recent year for which national data are available, 67,753 people in the US were diagnosed with invasive melanomas of the skin,²⁵ and the American Cancer Society estimates that 76,380 cases of

invasive melanoma and 68,480 cases of melanoma *in situ* will be diagnosed in 2016.²⁷ From 1975 to 2012, incidence increased steadily at an annual average rate of 3.2% in males and 2.4% in females (Figure 1).²⁸ Unlike most other cancers for which the incidence rate is either stable or decreasing,² the incidence rate for melanoma is expected to continue to rise. Indeed, a recent estimate projected that 112,000 new invasive melanomas (i.e., exclusive of melanoma *in situ*) will be diagnosed in the US in 2030 in the absence of new public health interventions.²⁹

Melanoma incidence is more common overall among some groups: non-Hispanic whites, males, and older individuals (Tables 1 and 2). However, among individuals younger than age 50, melanoma is more common among females than males.²⁵ Some have attributed higher rates and recent increases among young females to intentional tanning behaviors, especially indoor tanning.³⁰ After age 50, melanoma incidence rates stabilize for females while increasing steeply among males.²⁵ These patterns by age and gender likely reflect different sun protection and exposure patterns over a lifetime among women compared to men.⁹

The scientific community has debated the reasons for trends in melanoma incidence over time.³¹ Mortality has remained relatively stable, and early-stage melanomas make up much of the increase in incidence, leading some to suggest that increased incidence may be due solely to screening and overdiagnosis of potentially indolent lesions.^{32, 33} Screening for skin cancer has become increasingly common.³⁴ However, recent analyses have described incidence increases among melanomas of all thicknesses,^{35, 36} and melanoma mortality among males has been gradually increasing about 1% a year (Figure 2). Increasing melanoma incidence also has been observed across all socioeconomic status (SES) groups in the California subset of the Surveillance, Epidemiology, and End Results (SEER) Program.³⁷ Among the lowest SES group, who may have limited access to screening, the highest increases were observed for 2.01 to 4.00 mm and 4.01 mm tumors. Overall, findings suggest that melanoma incidence increases are not solely a result of increased screening.

In 2012, 9,251 persons died from melanoma in the US: 6,013 males and 3,238 females (rate of 4.0 and 1.7 per 100,000, respectively),³⁸ with an estimated 10,130 deaths expected to occur in 2016.²⁷ Deaths due to melanoma are most common among those with the highest incidence: non-Hispanic whites, males and individuals over age 50.³⁸ Melanoma survival is strongly associated with stage at diagnosis;³⁹ individuals diagnosed at a later stage have poorer survival.^{35, 40} Five-year survival has been higher in females than males, even when stratified by stage at diagnosis.⁴⁰ Although black and Hispanic patients are generally diagnosed with melanoma at later stages and have poorer survival compared to non-Hispanic whites, differences were not statistically significant when controlled for stage at diagnosis.⁴⁰ Overall, melanoma survival has been improving over the past two decades, with 92% of people diagnosed during 2001–2003 surviving 5 years after diagnosis compared to 88% of those diagnosed during 1989–1991.³⁵ Based on a SEER Cancer Statistics Review, the overall 5-year relative survival rate for those diagnosed 2005–2011 was 92%.⁴¹ Ninety-eight percent of patients diagnosed with local disease survived for five years, compared to 63% diagnosed with regional nodal disease and only 17% diagnosed with distant metastasis. These wide variations highlight not only the tremendous heterogeneity of prognosis across all stages of disease, but also the significant opportunity to reduce the public health burden

of melanoma with successful prevention and early detection efforts in the US. Remarkably, only since 2011 have new treatment options become available – including both checkpoint inhibitor-based immunotherapy and targeted therapy for patients with BRAF mutations – that together are beginning to provide great promise for patients with advanced melanoma.
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Financial and Social Costs

The average annual cost of melanoma treatment increased by 288%, compared to 25% for all other cancers combined, between 2002–2006 and 2007–2011.²⁴ Overall, skin cancer treatment costs \$8.1 billion in the US each year, with \$3.3 billion attributable to melanoma.²⁴ Indirect costs such as lost productivity attributable to melanoma are estimated to be \$39.2 million for morbidity and \$3.3 billion for mortality each year.⁴² Beyond treatment, each potentially preventable melanoma death causes about 15 additional years of potential life lost, which contribute to the social, economic, and human toll of this disease. Prevention interventions aimed at reducing melanoma incidence have the potential to substantially decrease melanoma-related costs by an estimated \$250 million per year (Figure 3).²⁹

MELANOMA PREVENTION AND EARLY DETECTION

The following sections elaborate on the state of the science pertaining to prevention strategies (sun protection and avoidance of indoor tanning) and evidence-based interventions and best practices for early detection and screening. USPSTF recommendations concerning skin cancer counseling and screening are discussed along with current areas of ongoing debate.

Melanoma Prevention: Reducing UV Exposure

The vast majority of skin cancers are caused by UV exposure from the sun and/or indoor tanning devices.^{4, 43} Melanoma prevention strategies include sun protection (i.e., using sunscreen regularly; wearing protective clothing, wide-brimmed hats and sunglasses; seeking shade and limiting time outdoors during midday hours when UV radiation from the sun is most intense) and avoidance of indoor tanning.^{27, 44} Although it is clear that UV exposure plays a key role in the development of most skin cancers, the importance of age at overexposure is unclear, with some research showing that sunburns in childhood are particularly harmful and other studies showing that sunburn during any life period raises risk.^{45, 46} Scientific evidence links indoor tanning to an increased risk of developing melanoma, BCC and SCC.^{47–50} Moreover, genetic sequencing data support the role of UV exposure in increasing risk for melanoma; recent studies, including the melanoma effort of The Cancer Genome Atlas Program, demonstrated that melanoma has the highest mutation rate among all solid tumors studied and that the majority of somatic mutations in melanomas are associated with a “UV signature.”^{51–53}

Occupational exposure to UV may play a role in the development of melanoma. Some ecological studies have shown that outdoor workers were at increased risk of SCC and BCC, but not melanoma.^{54, 55} However, studies on the relationship between occupational UV exposure and melanoma are often limited by lack of information on other related factors.

^{56, 57} A large meta-analysis stratifying studies by latitude found that workers in UV-intense areas were at increased risk of melanoma.⁵⁸ An Australian analysis of melanoma by body site found that occupational exposure was associated with melanomas of the head and neck, whereas recreational exposures were associated with melanomas of the trunk.⁵⁹

Sun Protection

Prevalence of Sunburn and Sun Protection Behavior: In 2010, 38% of US adults reported being sunburned in the past year.⁹ Although most (70%) US adults reported usually or always protecting their skin from the sun when outdoors for more than an hour on a sunny day,⁹ individual methods of protection were less common. For example, only 31% of adults (21% of men and 41% of women) reported use of sunscreen with a sun protection factor (SPF) of 15 or higher on exposed skin. Non-Hispanic whites had the highest prevalence of sunscreen use (37%), followed by Hispanics (22%) and non-Hispanic blacks (10%). Sunscreen use was less common in younger adults ages 18 to 24 (23%) compared to individuals 25 or older (32%). More males (46%) than females (34%) wore protective clothing, while more females (44%) than males (31%) sought shade; adults 25 and older were more likely to use protective clothing and shade.⁹ Research shows that some melanoma survivors sunbathe, experience sunburns or do not use adequate protection despite their diagnosis.⁶⁰

A 2004 population-based survey of adolescents ages 11 to 18 showed that 69% reported at least one sunburn during the previous summer; 5% routinely wore wide-brimmed hats, 23% wore protective clothing and 22% sought shade.⁶¹ According to the 2013 Youth Risk Behavior Survey (YRBS), a nationally representative sample of high school students in grades 9 through 12, only 10% of high school students (13% of females and 7% of males) reported using sunscreen with SPF 15 or higher always or most of the time when outside for more than one hour on a sunny day.⁸ Sunscreen use was highest in Asian students (16%; 24% of females and 8% of males) followed by non-Hispanic white students (12%; 15% of females and 8% of males). US population-based estimates of parent sun protection practices for children are lacking. In a population-based study of fifth-grade children from Framingham, Massachusetts, 55% of children reported experiencing one or more sunburns during the previous summer, and only 25% reported routinely using sunscreen.⁶²

Evidence on Effectiveness of Community-wide Programs: The Community Preventive Services Task Force conducted systematic reviews on the effectiveness of community-based interventions to prevent skin cancer. Recommendations based on these reviews are published in The Guide to Community Preventive Services (aka The Community Guide). Currently, The Community Guide states that there is sufficient evidence to recommend education and policy approaches to increase preventive behaviors in the following settings: child care centers, primary and middle schools, outdoor recreational and tourism areas, and occupational settings.⁶³

The Community Guide also states that multicomponent community-wide interventions are effective at increasing preventive behaviors. These interventions are defined as having at least two distinct components (such as strategies directed toward individuals, mass media

campaigns or environmental and policy changes) implemented in multiple settings or the entire community in a defined geographic area.⁶³ Although mass media campaigns, specifically, were found to be effective when used as one component in a multicomponent community-wide intervention, the small number of studies regarding mass media campaigns in the absence of other initiatives, as well as methodological issues, led to a finding of insufficient evidence for mass media campaigns alone.

Much of The Community Guide's review of multicomponent community-wide interventions was based on research conducted in Australia,⁶³ which has one of the highest skin cancer incidence rates in the world.⁶⁴ In 1988, a sun protection program called SunSmart began in the state of Victoria, and has since been implemented in all Australian states and territories.⁶⁵ After decades of prevention efforts in Australia, skin cancer incidence rates are beginning to stabilize or decline among adolescents and young adults.^{66, 67} A recent study estimated that regular sunscreen use in Australia has likely reduced skin cancer incidence by 10–15%, potentially preventing 14,190 people from developing SCCs and 1,730 people from developing melanomas.⁶⁸ An economic evaluation of Australia's SunSmart program demonstrated that the program saved an estimated \$AU2.30 in health care costs for each \$AU1 invested in the program.⁶⁹

Policies and Environmental Interventions to Support Sun Protection in Schools, Occupational, and Recreational Settings: In 2002, the CDC published guidelines for school programs to prevent skin cancer.⁷⁰ This document underscores the importance of policies in schools to support skin cancer prevention through strategies such as allowing or encouraging students to wear hats and protective clothing, and to carry and apply sunscreen in schools. Addressing the physical environment is also a priority of the school guidelines, especially by increasing shade in outdoor areas. As a follow-up to the publication of the guidelines, the CDC produced a document, "Shade Planning for America's Schools," to provide specific guidance on how to evaluate and increase the availability of shade on school grounds.⁷¹

According to the 2012 School Health Policies and Practices Study (SHPPS), which examined state and school district policies, 31% of states reported developing, revising or assisting in developing model policies related to sun safety for schools or districts, and 32% reported distributing such policies to districts or schools.⁷² Less than 2% of school districts required that schools allow students to apply sunscreen while at school, and most districts had no policy either requiring or recommending that schools allow students to apply sunscreen. School district guidance regarding other sun protection strategies, such as avoiding outdoor activities during peak hours of UV exposure intensity or encouraging students to wear sun protective clothing and hats, was not required or recommended in over 50% of school districts.⁷²

The 2014 SHPPS, which examined individual school policies, reported that 15% of schools surveyed reported scheduling outdoor activities to avoid times when the sun was at peak UV intensity, 48% of schools reported that teachers allowed time for students to apply sunscreen at school and 28% stated that teachers reminded students to apply sunscreen before going outside.⁷³ Additionally, 30% of schools reported encouraging students to wear protective

clothing, while 8% prohibited students from wearing hats or visors when in the sun during the school day. SHPPS did not directly report on schools allowing or prohibiting use of sunscreen while on school grounds. California, Oregon and Texas have passed state laws allowing children to carry and apply sunscreen while on school property.^{74–76}

Municipal and recreational policies and environmental interventions are also critical to support sun protection. The city of Phoenix, Arizona, adopted a Master Shade Plan, led by the city's Parks and Recreation department, to increase shade and tree cover in the city.⁷⁷ The city of Toronto, Canada, also has implemented a municipal shade policy since 2010, intended to increase shade in that city.⁷⁸ Several municipalities and organizations have increased availability of sunscreen for the public. The city of Miami Beach has partnered with Mount Sinai Medical Center and a sunscreen manufacturer to offer sunscreen at 50 dispensers in public pools, parks and beaches.⁷⁹ The city of Boston has distributed 30 sunscreen dispensers in city parks, in partnership with the Melanoma Foundation of New England and Make Big Change.⁸⁰ Additionally, some sports venues have made free sunscreen available.^{81–84} Likewise, colleges and universities can support skin cancer prevention by making sunscreen available in outdoor recreation and sports venues and implementing policies to promote sun protection and the avoidance of indoor tanning.⁸⁵ Although these particular efforts have not been evaluated, The Community Guide recommends environmental approaches to sun protection in outdoor and tourism settings.⁶³

Sun protection interventions in outdoor occupational settings are also recommended by The Community Guide.⁶³ Educational, environmental and policy approaches increased uptake of sun protection among outdoor workers. Policy approaches, such as requiring or providing sun protective clothing or rotating workers out of UV-intense tasks, may be particularly important for outdoor workers because they may have little individual control over their environment and UV exposure levels while at work.

Indoor Tanning—Indoor tanning is the practice of using tanning beds (also called “sunbeds”), booths or lamps to tan the skin for cosmetic purposes. Most tanning devices emit primarily UVA radiation and small amounts of UVB, though amounts vary widely.^{86, 87} Although UVB radiation is much more potent than UVA radiation in causing sunburn, high doses of UVA can lead to erythema, burning and tanning; both UVA and UVB radiation have been shown to cause skin cancer.^{88, 89} Almost 2,000 indoor tanning-related injuries were treated in emergency departments in 2012; most of these injuries were skin burns.⁹⁰ Studies show that, depending on the type of tanning device used, the amount of UVA exposure may be 4 to 13 times the amount typically received from summer noontime sun in the District of Columbia.^{86, 87} Frequent indoor tanners may receive 1.2 to 4.7 times the yearly dose of UVA they receive from sunlight, in addition to doses received by sun exposure.⁸⁷

Carcinogenicity of indoor tanning: The first expert review of tanning bed use and skin cancer was published in 2006 by the World Health Organization's (WHO) International Agency for Research on Cancer (IARC).⁹¹ In that review, IARC released results of its meta-analysis of 19 studies of associations between tanning bed use and skin cancer risk. The IARC meta-analysis showed a 15% increase in melanoma risk (summary relative risk [RR],

1.15; 95% confidence interval [CI], 1.00, 1.31) for those who had ever used a sunbed compared to those who never had. Based on those data, in 2009 IARC added UV-emitting tanning devices to its list of group 1 carcinogens – meaning that tanning lamps are “carcinogenic to humans.”⁵ Recent evidence shows that the tanning response is mediated in large part by signals emanating directly from damage to DNA and that tanning does not occur without DNA damage.⁹²

Early life exposure and melanoma risk: The IARC meta-analysis showed that melanoma risk was greater with first exposure to an indoor tanning device before age 35 (summary RR, 1.75; 95% CI, 1.35, 2.26).⁹¹ Although some challenged these findings because the association was weak, a dose-response relationship could not be confirmed, and studies did not examine exposures to specific tanning devices, more recent research has strengthened the evidence of an association between tanning bed exposure and melanoma risk. A Minnesota case-control study of indoor tanning and melanoma risk revealed that risk increased with the number of years, hours, and sessions of indoor tanning, and risk increased independent of outdoor exposure.⁹³ An Australian population-based case-control study of early onset melanoma showed that ever using a sunbed (i.e., indoor tanning device), compared to never using one, was associated with a greater risk of developing melanoma (odds ratio [OR], 1.41; 95% CI, 1.01, 1.96).⁹⁴ This association was stronger for earlier age at first use ($p_{\text{trend}} = 0.02$). There was a doubling of risk for > 10 lifetime sunbed sessions (OR, 2.01; 95% CI, 1.22, 3.31). This association was stronger for melanoma diagnosed between ages 18 and 29 (OR for > 10 lifetime sessions, 6.57; 95% CI, 1.41–30.49) than for melanoma diagnosed between ages 30 and 39 (OR, 1.60; 95% CI, 0.92–2.77; $p_{\text{interaction}} = .01$). Among those who ever used a sunbed and were diagnosed with melanoma between ages 18 and 29, 76% of melanomas were estimated to be attributable to sunbed use.⁹⁴ A recent case-control study from Minnesota found that 97% of women in the study who were diagnosed with melanoma younger than age 30, and 94% of women who were diagnosed from age 30 to 39, had engaged in indoor tanning; the median age of initiation of indoor tanning was 16 years, and the median number of sessions was over 100, in both age groups.⁹⁵ In a study in Norway and Sweden, authors concluded that the risk of melanoma appeared to increase with accumulating solarium exposure during early adulthood.⁹⁶ More recent meta-analyses have continued to document increased risk of melanoma for indoor tanners, especially those who start at younger ages or tan more frequently.^{48, 49, 97} It is estimated that for each additional session of tanning bed use per year, there is a 1.8% increase in melanoma risk.^{48, 49}

Prevalence of Use: Indoor tanning’s popularity surged in the US in the 1980s.⁹⁸ Approximately 18,000 to 19,000 indoor tanning salons and 15,000 to 20,000 other commercial facilities (e.g., health clubs, gyms and spas) offer tanning services in the US.¹¹ A report of data from 116 US cities showed that the average number of tanning salons exceeded the average number of Starbucks or McDonald’s in those cities.⁹⁹ Tanning services are sometimes offered as amenities in gyms and residential settings such as apartment buildings.¹⁰⁰ In an observational study of 125 US colleges and universities, researchers found that indoor tanning was available on campus in 12% of colleges and in off-campus

housing in 42% of colleges. More than 14% of colleges allowed campus cash cards to be used to pay for indoor tanning at off-campus facilities.¹⁰¹

An estimated 1 million people visit a US tanning facility each day,¹⁰² and 11.3 million people engage in indoor tanning each year.^{6, 7} According to the 2013 National Health Interview Survey, a representative sample of the US civilian noninstitutionalized population age 18 or older, 4.2% of all adults (6.5% of females and 1.7% of males) reported using an indoor tanning device in the past 12 months.⁷ Use was most common among young adults ages 18 to 29 (11%; 19% of females and 4% of males). Although all percentages represent significant reductions in prevalence compared to 2010,⁷ these data suggest that about 7.8 million US adult females and 1.9 million males engaged in indoor tanning in 2013. Research shows that about 25% of female indoor tanners ages 18 to 25 practiced indoor tanning in locations other than tanning salons, mostly in gyms, private homes or apartments, and year-round tanning was more common in this group.¹⁰⁰ Adult males who self-reported as gay, homosexual or bisexual (sexual minority males) were more likely to report engaging in indoor tanning than males who self-reported as heterosexual. Sexual minority females were less likely to report indoor tanning than heterosexual females.¹⁰³ Remarkably, some melanoma survivors continue to engage in indoor tanning despite known risks.⁶⁰

According to the 2013 YRBS, 5% of US high school student males and 20% of females reported using an indoor tanning device one or more times during the 12 months before the survey (not including spray tanning).⁶ Indoor tanning was most common among non-Hispanic white females in higher grades: 35% of 11th graders and 40% of 12th graders.⁸ Among students who reported using devices within the past year, more than one-half (51%) were “frequent tanners,” doing so 10 times within the past year. Among non-Hispanic white female high school students, 31% reported using a tanning device in 2013, representing a decrease from 37% in 2009.⁶ Despite reductions in indoor tanning prevalence, about 1.5 million female and 400,000 male students are still estimated to use indoor tanning devices; most (1.6 million) of these students are younger than 18.

Association with other Risk Behaviors: Frequent tanning bed use was associated with smoking cigarettes, binge-drinking, having high concern about weight and other risk behaviors in female teens.¹⁰⁴ According to the 2009 YRBS, male high school students who tanned indoors were more likely to have ever taken steroids without a doctor’s prescription, used unhealthy weight control practices, engaged in binge drinking and attempted suicide.¹⁰⁵ In a survey of Colorado high school students, use of steroids, alcohol, marijuana and illicit drugs was positively associated with indoor tanning.¹⁰⁶ In young women, indoor tanning was associated with substance and alcohol use.^{107, 108}

Motivations for Tanning: Some people continue to intentionally tan even if they are aware that UV exposure raises skin cancer risk,¹⁰⁹ often believing that having a tan is attractive and appears healthy.⁶¹ Some have promoted sunless tanning (such as “spray tanning”) as an alternative to indoor tanning.¹¹⁰ However, a significant majority of tan seekers continue to sunbathe or indoor tan despite also using sunless tanning products.^{111, 112} Sunless tanning has preceded initiation of indoor tanning in teens.¹¹³ Exposure to chemicals through inhalation is another concern with sunless tanning.¹¹⁴

About 5 to 10% of indoor tanners have met criteria for tanning dependence,^{115–117} similar to prevalence rates for substance dependence. Assessments of tanning dependence have been adapted from Diagnostic and Statistical Manual of Mental Disorders criteria^{118, 119} or the CAGE, a brief screening instrument for problematic alcohol use.¹²⁰ Other studies in humans and mice add evidence to the possibility of tanning addiction.^{121–124} Exposure to UV light triggers damage to DNA in the nucleus of keratinocytes, resulting in activation of the p53 tumor suppressor gene. This then transcriptionally up-regulates the expression of the gene encoding proopiomelanocortin (POMC) that is processed to melanocyte-stimulating hormone, inducing tanning. At the same time, another POMC-derived peptide, β -endorphin, is synthesized in skin, elevating plasma levels.⁹² Endogenous β -endorphin has analgesic effects and promotes relaxation and feelings of well-being in humans, similar to opiates.

Recommendations of Organizations: In addition to individual statements from numerous professional and other organizations (WHO, American Academy of Pediatrics [AAP], American Academy of Dermatology, American Medical Association, Canadian Pediatric Society, National Council on Skin Cancer Prevention and Society for Behavioral Medicine), leading cancer-focused and other concerned organizations signed a “Joint Position Statement on Indoor Tanning” in July 2015, citing high usage of tanning beds by teens and young women and the carcinogenicity of this exposure. The statement strongly supported state and federal legislation to prohibit the use of indoor tanning by minors under 18, educational efforts to effectively communicate risks of indoor tanning to teens and their parents, and counter-advertising to de-normalize the perceived beauty of tanned skin.¹²⁵ To date, 22 organizations have endorsed this joint position statement on indoor tanning.

Regulation of Tanning Devices

Federal Regulation: The FDA is responsible for regulating UV tanning devices. Until 2014, the FDA categorized tanning devices as Class 1 medical devices, in the same category as tongue depressors and Band-Aids®. On March 25, 2010, the General and Plastic Surgery Devices Panel of the FDA Center for Devices and Radiologic Health Medical Devices Advisory Committee convened a public meeting to discuss tanning devices whereby experts discussed evidence that tanning bed exposure increases skin cancer risk; counter-arguments were provided by representatives of the indoor tanning industry.¹²⁶ On May 27, 2014, the FDA issued a final order announcing the reclassification of UV sunlamp products from ‘low-risk’ Class I devices to ‘moderate-risk’ Class II devices that require stricter controls for design and safety and carry a visible boxed warning: “Attention: This sunlamp product should not be used on persons under the age of 18 years.”¹⁰

On December 18, 2015, the FDA announced a proposed rule to restrict the use of sunlamp products to people ages 18 and older.¹¹ If finalized, this rule will become law in the US, superseding state laws. The rule also will require users over age 18 to sign a risk acknowledgement certification before use, and then every 6 months, stating that they have been informed about health risks.

The Tanning Accountability and Notification (“TAN Act”) (HR 945) of 2007 requires the FDA to conduct consumer testing to determine if warning labels on commercial tanning

beds are positioned correctly and provide sufficient information pertaining to skin cancer risk.¹²⁷ The Affordable Care Act (ACA) mandated in 2010 that indoor tanning services be levied with a 10% excise tax (the “tanning tax” or “tan tax”) to provide revenue for the ACA.^{128, 129} Tanning salons must receive a payment for indoor UV tanning services, report the tax each quarter and remit the tax to the Internal Revenue Service. The tan tax was expected to raise 2.7 billion dollars over 10 years, but initially the number of taxpayers filing tanning services excise tax returns was lower than expected.¹³⁰ Research suggests that most salons are collecting the tax from clients, and that younger clients do not appear to mind paying the tax.¹³¹

State and Local Regulations: In 2009, Howard County, MD, became the first US jurisdiction to ban tanning for children under age 18. In October 2011, Governor Brown of California signed the first state law banning under-18 salon tanning, effective January 2012. As of April 2016, 13 other states (Delaware, Hawaii, Illinois, Louisiana, Massachusetts, Minnesota, Nevada, New Hampshire, North Carolina, Oregon, Texas, Vermont and Washington), the District of Columbia and other jurisdictions have passed under-18 bans. Now 42 states have at least some kind of legislation regarding minors’ use of indoor tanning.^{132, 133}

Are State Indoor Tanning Laws Effective?: Studies examining parental permission laws found that tanning facilities had poor compliance with these laws,^{134–136} and these laws were not effective in reducing indoor tanning among teens.^{137, 138} More recently, researchers have evaluated tanning bed laws including age restrictions using data from the YRBS.¹³⁹ Tanning laws were classified into “systems access” (e.g., requirements for indoor tanning device operators to obtain signed statements from patrons and post a warning sign); and “youth access” (parental permission [laws prohibiting minors under a certain age from using indoor tanning devices without parental consent or parental accompaniment] and age restrictions [laws prohibiting minors under a certain age from using indoor tanning devices]). The presence of any law was associated with a significant reduction in indoor tanning by 30% among female students. Systems access, parental permission and age restriction laws were associated with a larger reduction, 42%, in indoor tanning by female students. Of all forms of legislation, age restrictions appeared to be most effective at reducing rates of indoor tanning.¹³⁹ Given the small number of states with these laws, states were not categorized by type of age restriction law and thus the study was unable to assess effects of different age restrictions on tanning rates. Associations between indoor tanning laws and reported indoor tanning among male students were not statistically significant, possibly due to their lower prevalence of indoor tanning and older age of tanning initiation.¹³⁹

Enforcement provisions for tanning legislation vary across states, and there is a need for future research to examine the enforcement of stated provisions and the impact on indoor tanning behavior and skin cancer incidence.¹⁴⁰ To realize the public health benefits intended by legislation to restrict minors’ access to tanning beds, facilities must comply. Research on California’s age restriction law showed that 77% of facilities were compliant.¹⁴¹ Data were collected by telephone by an individual posing as a 17 year-old, which is a common

methodology in studies that evaluate large numbers of tanning facilities where it may be resource-prohibitive to conduct in-person visits to collect compliance data. Research suggests that telephone assessment of compliance with tanning laws is comparable to face-to-face assessment,¹⁴² but additional study of intermethod reliability would advance this research. While a majority of California facilities appeared compliant with the under-18 ban, statewide education or other interventions may be indicated to enhance compliance, especially considering that most facilities in this study denied that UV tanning posed any dangers and made specific unlawful claims about health benefits. Direct sales to the public can present problems for enforcement; WHO recommends prohibiting direct sales and unsupervised use of tanning equipment as a complement to age restrictions.¹⁴³

Tanning Restrictions in other Nations: Austria, Belgium, Finland, France, Germany, Iceland, Italy, Norway, Portugal, Spain, the United Kingdom and several Canadian provinces ban tanning salon access for minors under age 18 years. Brazil and all states and territories in Australia have banned indoor tanning beds for everyone, regardless of age.^{144–146}

Targeting the Tanning Industry's False and Deceptive Practices: The US Federal Trade Commission (FTC) issued a complaint against the Indoor Tanning Association (ITA) alleging that its 2008 advertising campaign included false statements portraying indoor tanning as safe and beneficial and sanctioned by the government (thus misrepresenting the nature of FDA approval). In January 2010, a settlement was reached barring the ITA and related entities from making the misrepresentations or providing deceptive advertisements.¹⁴⁷ In 2016, the FTC reached a settlement with Mercola indoor tanning systems; the company will pay refunds to consumers and will be permanently banned from marketing or selling indoor tanning systems.¹⁴⁸

In 2012, a minority investigative report commissioned by representatives of the US House of Representatives Committee on Energy and Commerce revealed findings of false and misleading health information given to adolescents by the vast majority of tanning salons contacted by investigators.¹⁴⁹ Salons minimized the dangerous effects of indoor tanning; 51% of salons specifically denied that indoor tanning would increase skin cancer risk.

Two state attorneys general have filed suits against several tanning chains or franchises in their states; suits were related to false health claims, unlawful concealment of indoor tanning risks and the offer of unlimited tanning by salons. These suits have generally been resolved through the payment of fines or agreements resulting in salons changing their messaging, including ceasing to make claims regarding the health or safety of indoor tanning.^{150–153}

Melanoma Prevention Recommendations for Clinicians—Clinicians have an important role to play in addressing prevention of skin cancer, yet studies show that only about one-third of primary care physicians counsel patients on sun protection and one-half counsel on the avoidance of indoor tanning.¹⁵⁴ In a population-based survey of adolescents and their parents, 44% reported receiving sun protection counseling from a physician.¹⁵⁵ Counseling rates may be higher in pediatricians^{156, 157} or for patients who are at higher risk of skin cancer.¹⁵⁴

A review of clinical preventive services conducted by the USPSTF in 2012 recommended that health care providers counsel fair-complexioned children, adolescents and young adults ages 10 to 24 to minimize UV exposure to reduce skin cancer risk, assigning this service a “B” grade.^{158, 159} The implications of the rating are significant, as an “A” or “B” grade means that the USPSTF recommends that providers offer or provide the service. The USPSTF ratings mean that there is high certainty that the net benefit is substantial (“A” grade) or moderate, or there is moderate certainty that the net benefit is moderate to substantial (“B” grade). Effective counseling used cancer prevention or appearance-focused messages to promote the use of broad-spectrum sunscreen with a minimum SPF of 15, protective clothing including hats, shade, avoidance of the outdoors during midday hours and avoidance of indoor tanning. The USPSTF identified effective low-intensity counseling strategies that could be conducted during the primary care session, including self-guided booklets, a video, peer counseling, clinician counseling with computer-assisted feedback and UV photography which shows the patient the extent of UV-induced facial skin damage.^{160–164} Through the Affordable Care Act, recommended preventive services with an A or B rating from the USPSTF are reimbursable to providers under most insurance plans, and must be provided with no cost sharing to patients. However, specific details regarding coverage vary by insurers, and providers and patients may be unaware of requirements.¹⁶⁵ There is no specific billing code for skin cancer prevention counseling (though there is an existing code for “other specified counseling”).

The AAP recognizes that skin cancer prevention is a life-long effort. Beginning in infancy, pediatricians are advised to incorporate skin cancer prevention advice into at least one well child visit per year, and during “teachable moments” as when a child or teen presents with a sunburn. AAP also advises pediatricians to encourage children and teens to engage in outdoor physical activities, but to do so in a sun-safe manner.¹⁶⁶ As pediatricians often have relationships with families over years and decades, they are well positioned to discuss with pre-teens, teens and their families the importance of avoiding indoor tanning.¹⁶⁷ Discussions about indoor tanning could be included in the confidential part of the teen interview that requests information such as the teen’s tobacco and electronic cigarette use, alcohol and substance use, and sexual activity.

Early Detection: Skin Examination and Screening

Early detection of melanomas is important, as those diagnosed at later stages are associated with a greater risk of death from melanoma and are overall less treatable. However, the evidence on the best way to reduce melanoma mortality through early detection is currently a subject of ongoing debate. The following sections present information about three approaches that could potentially detect melanomas earlier: skin self-examination, clinician skin examination, and population-based screening.

Skin Self-Examination (SSE)—In a population-based, case-control study of 1,199 Connecticut residents, Berwick et al.¹⁶⁸ reported a 63% reduction in fatal or advanced melanoma associated with SSE. While only 13% of patients performed SSE, the mean thickness of melanomas on the back was significantly lower in those who performed SSE (1.09 mm) compared to those who did not (1.65 mm) ($p = 0.014$). Subsequent analysis of the

data at a median of 5.4 years demonstrated a lower risk of death from melanoma in patients with increased skin awareness; SSE was not associated with reduced melanoma mortality.^{169, 170} A 2003 study found that regular SSE performance was significantly associated with a reduced likelihood of being diagnosed with a melanoma > 1 mm (OR, 0.65; 95% CI, 0.45–0.93), although details regarding the thoroughness and frequency of SSE were not reported.¹⁷¹ Swetter et al. assessed SSE in 566 newly-diagnosed melanoma patients, and routine SSE of some/all of the body compared with none was associated with nearly twice the likelihood of a < 1 mm melanoma at diagnosis (OR, 1.98; 95% CI, 1.24–3.18), with the greatest benefits observed in individuals older than 60 years and in men who used a melanoma picture to aid in SSE.¹⁷² Thoroughness of SSE, as measured by the number of body sites examined and use of a picture aid illustrating a melanoma, has been shown to be the best predictor of reduced melanoma thickness.^{172, 173} However, variable study definitions of SSE, including the number or percent of body sites examined, frequency and method of examination,^{174, 175} and the small number of studies examining supplemental techniques such as the use of photographs,¹⁷⁶ impede the understanding of the potential effect of SSE on melanoma thickness at diagnosis.

The USPSTF evaluated SSE in their 2009 statement, which designated the evidence as insufficient to recommend SSE for the general population.¹⁹ Despite the potential benefit of SSE for early melanoma detection, SSE prevalence in the general population is low, with less than 20% of individuals in the US estimated to practice regular, thorough SSE.^{174, 177} Rates of SSE in middle-aged and older men also appear to be low. In a population-based telephone survey in Queensland, Australia, 20% of men 50 years or older reported conducting whole-body SSE one or more times in the past year.¹⁷⁸ Various educational and interventional programs, including dual patient and partner skin examination training, workbooks, videos and postcard reminders, and mole-mapping diagrams,^{179–182} have successfully increased SSE performance in higher risk populations.

Clinician Skin Examination—Melanomas detected by clinicians through directed skin examinations or during the course of routine physical examinations (i.e., “opportunistic screening”) are thinner than those found by patients or their significant others.^{172, 183–187} In an analysis of 3 international studies of more than 2,400 patients, tumor thickness was reduced by a mean of 0.55 mm when comparing melanomas initially detected by physicians versus by patients or family members.¹⁸⁸ A population-based, case-control study was conducted by Aitken et al.¹⁸⁴ of more than 3,700 Queensland residents with histologically-confirmed first primary invasive melanoma diagnosed between January 2000 and December 2003, and a similar number of eligible controls. Whole-body physician skin examination (PSE) in cases in the three years before diagnosis was inversely associated with melanoma thickness (χ^2 test for trend, 44.37; $p < .001$), ranging from a 14% lower risk of being diagnosed with a melanoma > 0.75 mm (OR, 0.86; 95% CI, 0.75–0.98) to a 40% lower risk for melanomas \geq 3 mm (OR, 0.60; 95% CI, 0.43–0.83). Skin screening was associated with a 38% increased likelihood of being diagnosed with melanoma \leq 0.75 mm and a 32% higher likelihood of melanoma \leq 1 mm (OR, 1.32; 95% CI, 1.18–1.47), resulting in a projected (though not proven) 26% fewer melanoma deaths in screened cases versus unscreened cases within 5 years.

Similar benefit of PSE within the year prior to diagnosis was noted in an observational cohort study of 566 newly-diagnosed adults with cutaneous melanoma referred to 2 geographically-distinct US academic institutions.¹⁷² Tumors (≥ 1 mm) were significantly associated with physician discovery ($p = .0001$), which was reported by only 19% of patients. However, patients who had a whole-body skin examination by a physician in the year prior to diagnosis were more than twice as likely to have a ≥ 1 mm tumor (OR, 2.51; 95% CI, 1.62–3.87), largely due to the effect of physician skin examination in men > 60 years, who had over 4 times the odds of a ≥ 1 mm melanoma (OR, 4.09; 95% CI, 1.88–8.89) and thus, appeared to benefit most from PSE.

Worldwide Data on Melanoma Population-Based Screening, Incidence, and Mortality

Population-based melanoma screening studies include a community-based clinical trial in Queensland, Australia,¹⁸⁹ a screening program conducted at Lawrence Livermore National Laboratory (LLNL),¹⁹⁰ and a pilot study of general population screening in the German state of Schleswig-Holstein beginning in 2003,^{191, 192} which was followed by a nationwide screening program initiated in Germany in 2008.^{193, 194}

Queensland, Australia: Forty-four eligible Queensland communities (estimated population of 560,000 adults who were 30 years or older) were randomized into intervention or control groups to compare the effects of a three-year community-based melanoma screening intervention and usual medical care.¹⁸⁹ The Queensland trial was designed to detect a 20% reduction in mortality from melanoma during the 15 years following the start of the screening intervention. Due to financial constraints, the trial was not completed, although some observations were made from 18 communities enrolled and randomized in the study.¹⁹⁵ Within intervention communities, the overall rate of skin cancer detected per patient screened increased, and men and attendees 50 years or older were more frequently referred and diagnosed with melanoma,¹⁹⁶ again supporting the value of targeted screening to older individuals, and men in particular.¹⁹⁷ Melanomas detected by the screening intervention tended to be less advanced than melanomas detected in the general population of Queensland: 39% were in situ lesions, 55% were < 1 mm, and 6% were ≥ 1 mm,¹⁹⁶ in contrast to the general population of Queensland from 1999 through 2002, in which 36% were in situ lesions, 48% were < 1 mm, and 16% were ≥ 1 mm.¹⁹⁸ Furthermore, the specificity (86%) for detection of melanoma through whole-body skin examination was deemed comparable to that of other screening tests, including mammography for breast cancer.¹⁹⁶

Lawrence Livermore National Laboratory (LLNL): A long term employee program conducted at the LLNL included melanoma education, SSE, and the opportunity for skin screening by a physician.¹⁹⁰ The incidence of melanomas > 0.75 mm was reduced by 69% in the screening program period (1984 to 1996) compared to the preceding early awareness period (1976 to 1984, during which time employees learned about their melanoma risk). This program also showed a crude reduction in melanoma mortality in the LLNL workforce compared with California during this timeframe, based on observed mortality in five San Francisco-Oakland-Bay Area counties as reported to the SEER program from 1984 to 1996: 0 deaths at LLNL compared to an expected number of 3.39 deaths ($p = .034$).¹⁹⁰

Schleswig-Holstein, Germany: The most compelling population-based data regarding potential screening effectiveness were collected from the “Skin Cancer Research to Provide Evidence for Effectiveness of Screening in Northern Germany” (SCREEN) pilot project conducted in the northern state of Schleswig-Holstein, Germany.^{191, 192} General practitioners and dermatologists completed an 8-hour skin cancer training program. Sixty-four percent (1,673) of Schleswig-Holstein’s general practitioners participated in the screening, along with 98% (116) of dermatologists. Whole-body skin examination by a general practitioner was followed by referral to a dermatologist for further evaluation of suspicious skin findings and biopsy if necessary. It was possible for patients to initially visit a dermatologist based on skin cancer risk factors alone, but most patients opted to visit a general practitioner first.

Following a two-year pre-screening period of intensive public education regarding melanoma clinical warning signs and the screening initiative, almost 20% of the adult population aged 20 years or older (360,288 participants with a mean age of 49.7 [SD = 16.2] years¹⁹²) was screened over a one-year period from 2003 to 2004. The majority of initial screening examinations (77%) were performed by general practitioners; dermatologists performed 23% of the initial examinations.^{191, 192} Although 73,710 individuals (26%) were referred to dermatologists following initial general practitioner screening, nearly 37% of those referred did not undergo consult by a dermatologist and were lost to follow-up.¹⁹² In 2009 (5 years after the screening program), age- and sex-adjusted melanoma mortality rates declined by 48% (a 47% decline in men and 49% decline in women), compared to historical mortality rates in Schleswig-Holstein and prior and 2009 mortality rates in surrounding states and Denmark, where no screening intervention took place.¹⁹¹

To what degree extensive pre-SCREEN public awareness campaigns themselves contributed to the mortality reduction remains unclear, as it is difficult to separate the potential mortality benefit of this education on early detection from the visual skin inspections by clinicians during the one-year screening period. Additionally, the demonstration of improved survival is insufficient evidence of the benefit of screening, as this may simply reflect lead-time, length bias, or overdiagnosis. Some have hypothesized that differences in coding of death data could have been responsible for temporal declines in melanoma mortality.^{194, 199}

An increased incidence of melanoma and NMSC occurred during the screening intervention and early follow-up period; an initial increase was expected given the detection of existing skin cancer in the population.¹⁹² The proportion of individuals diagnosed with early stage tumors increased from 52% in the pre-SCREEN period (2001 to 2003) to 64% in the one-year screening period (2003 to 2004).¹⁹² In July 2008, the German Federal Joint Committee included skin cancer screening as part of nationwide services provided by the Health Insurance Funds.^{192, 193, 200} Whole-body screenings have been offered free of charge once every 2 years for an estimated 45 million German residents who are 35 years of age or older, with the 8-hour physician training course and dual screening process used in the pilot study in Schleswig-Holstein.^{192, 193, 200}

The first analyses of this nationwide effort showed that melanoma mortality in Schleswig-Holstein increased to its pre-SCREEN rate for both sexes and all ages, thus demonstrating

only a transient decline in mortality in Schleswig-Holstein five years after the SCREEN pilot project.^{193, 194} No decrease in mortality has been observed five years after screening began in Germany overall; a slight increase was actually noted, likely due to population changes per census data in men and individuals 64 years of age or older.^{193, 194} Potential reasons for the lack of a measurable reduction in mortality rates in Germany or Schleswig-Holstein after the nationwide screening effort include: less intensive or thorough screening (e.g., poorer quality, less consistently performed skin exams and suboptimal referral patterns from primary care providers [PCP] to dermatologists); higher age of eligibility for the nationwide screening program (35 years of age) compared to the pilot SCREEN program (20 years of age); inability to accurately track participation rates by physicians or patients; nonreferral of individuals by general practitioners to dermatologists based on melanoma risk factors alone (as was permissible in the Schleswig-Holstein pilot); and lack of intensive nationwide mass-media publicity as was used in SCREEN.^{193, 194} It is possible that reduced mortality will be observed with longer follow-up, although no such trend has yet been observed in preliminary analyses. The economic impact of this ambitious nationwide skin cancer screening endeavor, and how the German health care system has managed the various screening-related outcomes, have not been reported.

USPSTF Recommendations for Screening by Primary Care Providers (PCP)—

Given the lack of a prospective, randomized controlled trial assessing the impact of screening on melanoma mortality, the USPSTF in 2009 recommended neither for nor against routine skin cancer screening of the general population by PCPs, assigning a rating of “I” for “insufficient” evidence to support this practice.¹⁹ The USPSTF further noted that the potential harms of screening had not been adequately addressed, including both physical and psychological effects related to misdiagnosis and unnecessary biopsies.

In preparing the 2015 draft recommendation, the USPSTF evaluated an AHRQ evidence-based systematic review of literature published from January 1, 1995 through June 1, 2015, which yielded 13 relevant studies. Studies focused primarily on the SCREEN program, which was assessed to be of “fair-quality.”¹⁹¹ However, the recent analyses of melanoma incidence and mortality in Schleswig-Holstein and Germany following the nationwide screening initiated in 2008^{193, 194} were not included in the systematic review, given the date of publication. The updated 2015 Task Force review differed from that which led to the 2009 recommendation in that NMSC was excluded as an outcome of interest due to its low mortality rates and lack of “substantial morbidity.” The USPSTF Draft Recommendation Statement was released on November 30, 2015, followed by a four-week period for public comment (closed December 28, 2015) before the final statement will be issued.²⁰ The USPSTF concluded that, “current evidence is insufficient to assess the balance of benefits and harms of visual skin cancer screening in adults,” and has once again tentatively assigned this practice an “I” grade, pending a final recommendation.

The USPSTF noted limitations of the SCREEN pilot, including the high proportion of “lower-risk” women screened compared to higher-risk men, the 37% of general practitioner-referred patients who did not follow up with dermatologists for their suspicious skin lesions, and the inability to assess the impact of the pre-SCREEN public education program apart from the visual skin cancer screening. Furthermore, the population-based changes in

mortality in the SCREEN program could not be interpreted as causal because individual-level data on outcomes for screened individuals were not available. The USPSTF Evidence Synthesis concluded that the absolute mortality reduction of 0.8 deaths per 100,000 individuals screened suggested a modest benefit overall.²⁰¹ Additional analyses have raised concerns about the design of the SCREEN study, including potential underreporting of melanoma deaths by physicians and self-referral of high-risk participants, and thus the data that demonstrated the initial reductions are a subject of ongoing debate.^{194, 199} The lack of available data regarding thickness-specific incidence or potential benefit of screening in certain subgroups (e.g., older men) makes firm conclusions regarding the German nationwide screening effort premature. Nonetheless, Germany's national screening program provides a valuable opportunity to collect effectiveness data on population-based screening.

Importantly, the USPSTF noted that their latest screening recommendation does not apply to patients with a history of premalignant skin lesions or skin cancer, who present with a suspicious skin lesion, or are already followed for increased risk of skin cancer based on abnormal mole phenotype or family history of melanoma. Potential harms of screening related to overdiagnosis and overtreatment were noted, though precise assessment of these harms was not possible from data included in the Evidence Synthesis.²⁰¹ Further research regarding screening high risk groups, and case-control studies of screened versus unscreened individuals – without potential confounding from an educational campaign or other intervention – was deemed necessary to fully evaluate the benefit of skin screening.

Potential Impact of Screening on NMSC Morbidity and Cost: Detection of (highly curable) NMSC was not a directive of the latest USPSTF review and in fact, was considered a potential harm of screening for “lesions that may have little potential for malignant spread and mortality.”¹⁹ Concern for overtreatment of both indolent pigmented lesions mimicking melanoma (i.e., “false-positives” detected through screening) as well as nonfatal NMSCs was raised in the 2009 USPSTF recommendation statement. However, SCC results in the second highest rate of skin cancer-associated mortality after melanoma; up to 5.2% of patients with cutaneous SCC will develop nodal metastasis and up to 2.1% will die from distant disease.²⁰² The economic burden of treating NMSC cannot be ignored, in addition to patient-related factors including optimizing surgical and cosmetic outcome and reducing lost work-time. The annual cost of treating NMSC in the U.S. has been estimated at \$4.8 billion.²⁴ Earlier detection of NMSC is likely to result in fewer surgeries with more rapid patient recovery, improved cosmetic outcome for these UV-related tumors on the head and neck, and lower cost of treatment.

Feasibility of Skin Cancer Screening Implementation in the US—Recent evidence from the screening studies in Germany and the latest USPSTF recommendation raise questions regarding where screening is headed for PCPs in the US. A nationwide screening program as was conducted in Germany is not likely to be feasible, and findings of population-based skin screening studies in other countries may not generalize to the US depending on the comparability of skin cancer risk factor distributions across populations. PCPs may not be adequately trained to identify early skin cancer.^{203, 204} A survey of more than 1,600 randomly-selected physicians found that time constraints, competing

comorbidities, and patient embarrassment were the top three barriers to performing whole-body skin examinations.²⁰⁵ Factors that facilitated examination by physicians included having more patients at high risk for skin cancer, patient demand for a complete examination or mole check, and appropriate training.

It is unclear what implementation techniques will overcome these barriers in clinical practice, though various training strategies are being tested. A 1.5 hour, web-based curriculum entitled INFORMED (INternet-based program FOR Melanoma Early Detection, available at www.skinsight.com/info/for_professionals/skin-cancer-detection-informed/skin-cancer-education) was designed to provide clinical guidance for early detection of melanoma (as well as other common skin cancers) by PCPs.²⁰⁶ A study evaluating the effect of INFORMED on 54 PCPs in two integrated health care delivery systems suggested that it decreased dermatology referrals, particularly for benign skin lesion assessment.²⁰⁷ The INFORMED training improved appropriate PCP diagnosis and management from 36% pre-training to 47% post-training, and dermatology utilization decreased without any change in biopsies performed or skin cancers diagnosed.

A population-based study in France evaluated the effect of a PCP awareness and training campaign on stage-specific melanoma incidence.²⁰⁸ All (1,241) general practitioners in the region of Champagne-Ardenne received repeated postal mailings to raise melanoma awareness, and 398 (32%) attended a 2.5-hour, dermatologist-led, skin cancer training session. From pre- (2005–2007) to post-intervention (2009–2011), Champagne-Ardenne showed a 34% reduction in the incidence of melanomas ≥ 3 mm in tumor thickness, from 1.07 to 0.71/100,000 habitants per year (standardized for age) ($p = .01$). This reduction was most pronounced in men compared with women (44% vs 11 %, respectively). Likewise, the proportion of in situ and < 1 mm melanomas increased from 20 to 28% ($p = .001$) and from 51% to 57% ($p = .05$), respectively. There were no significant changes in incidence in the control area that comprised regions without the PCP educational campaign.

Since Americans make an average of 1.7 visits to PCPs each year,²⁰⁹ PCPs can serve as an important source of skin cancer diagnosis and triage. Although the USPSTF did not recommend skin cancer screening, they advised clinicians that biopsy of suspicious skin lesions noted during physical examinations is warranted.¹⁵⁹ Implementation of skin screening requires a paradigm shift in the way primary care is delivered, necessitating evaluation of feasibility including adequate time to conduct the exam, and possible harms, such as cost and utilization of scarce resources, along with further study of the potential benefits of early melanoma detection.

SUMMARY AND CONCLUSIONS

US adults, adolescents and children are not adequately protected from excessive UV exposure, despite expert guidance and the existence of evidence-based, melanoma prevention interventions recommended by The Community Guide and USPSTF. The Surgeon General's Call to Action highlights youth as a critical population to reach with intervention to promote sun protection and discourage indoor tanning, and invites multiple

sectors across the US to coordinate efforts and leverage existing knowledge to reduce the nation's skin cancer burden.

There is a lack of national, population-based data or estimates of parent sun protection practices for children in the US, and estimates of behaviors other than indoor tanning and sunscreen use across age groups. Furthermore, physician counseling for sun protection and assessments of provider knowledge of skin cancer prevention are understudied areas. These gaps in research minimize our ability to spot trends, target interventions and evaluate progress.

As increasing numbers of states prohibit indoor tanning among minors, researchers will need to evaluate compliance with and enforcement of such laws. The proposed FDA rule to ban minors' access to tanning is significant, but finalization of this age restriction rule may not occur for months or years after the public comment period. Despite the expansive effects of legislation and FDA regulations, it is necessary to continue to develop and disseminate evidence-based interventions to reduce positive tanning attitudes and tanning behaviors, starting in childhood, given the current availability of indoor tanning devices at home through direct purchase as well as the alternative to sunbathe for individuals seeking a tan.

While multiple studies support the value of early detection of melanoma through clinician skin examination,¹⁸⁸ evidence that this translates into reduced population-based melanoma mortality has been insufficient, in both 2009 and 2015, for the USPSTF to recommend skin screening as part of primary care practice.^{19, 20} An observational study of a population-based screening program in one state in Germany showed promising results, with large reductions in mortality rates not observed in surrounding states without screening programs.¹⁹¹ Based on these early results, the screening program was expanded to the rest of the country, but mortality rates have remained stable nationally and mortality reductions in the state initially piloting the screening program were not sustained.¹⁹³ There is a critical need to augment evidence regarding the potential benefits of skin screening; PCP and other providers' education regarding skin cancer awareness, SSE and screening; and appropriate triage to dermatologists, as PCPs account for the majority of physician-detected melanoma. The proliferation of new technologies may hold promise for future prevention and early detection of melanoma. For example, smart phone applications (or "apps") are available to give users real-time information regarding their UV exposure based on their location, methods of protection, and skin type, and may be effective at improving sun protection.²¹⁰ The growing popularity of wearable health monitoring devices has incorporated sun protection, and some devices include wearable UV sensors.²¹¹ Mole mapping apps can assist high-risk patients with many nevi keep track of any changes, and tele-dermatology may expand access for some who have questionable lesions but do not live close to a dermatologist.^{212, 213} Though these new approaches are exciting, evaluation of their effectiveness in the real world will be important; one study from 2008 found that users of personal UV sensors were likely to use *less* sun protection when wearing the sensor.²¹⁴

Increased attention to the problems of melanoma resulting in high-level government support such as the Surgeon General's Call to Action and continuing FDA actions to address the harms of indoor tanning have the potential to reduce their future health burden if

implemented and supported. New tools for early detection may result in earlier diagnoses. Moreover, improved understanding of the molecular and immunological underpinnings of melanoma have ushered in a new era of transformative treatment options for patients with advanced melanoma over the past five years that have already begun to improve survival outcomes. In conclusion, we are at a uniquely exciting time in the area of melanoma prevention and treatment – the time to act is now to continue to reduce the burden of melanoma in the US and beyond.

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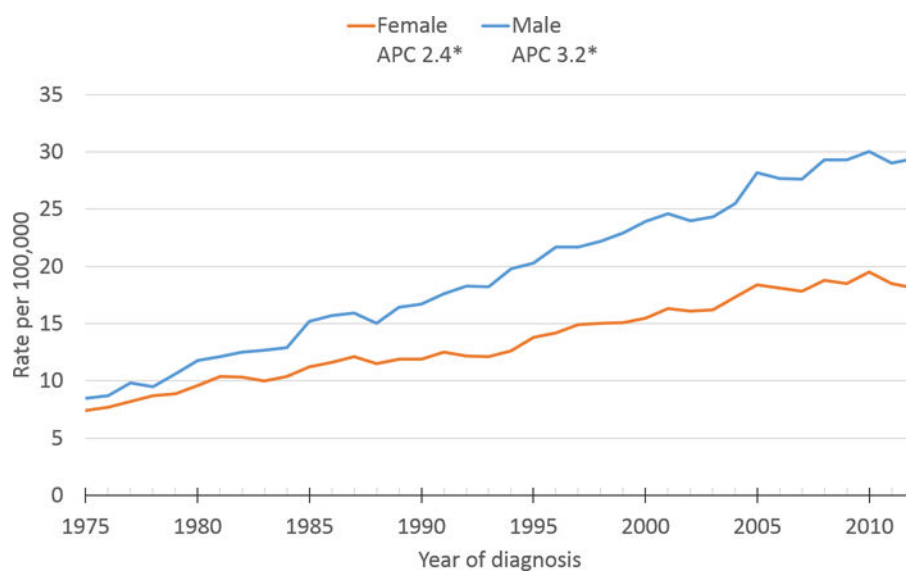


Figure 1.

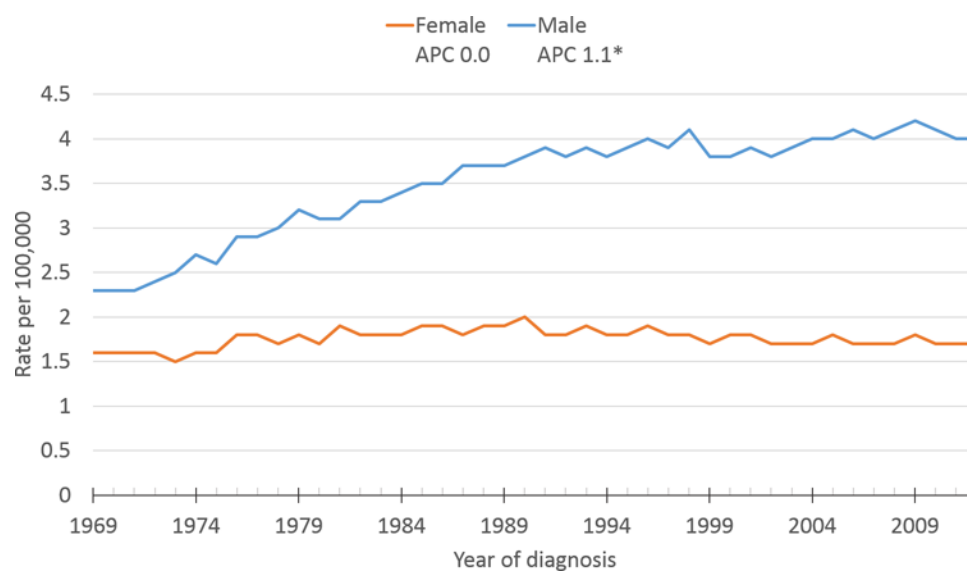


Figure 2.

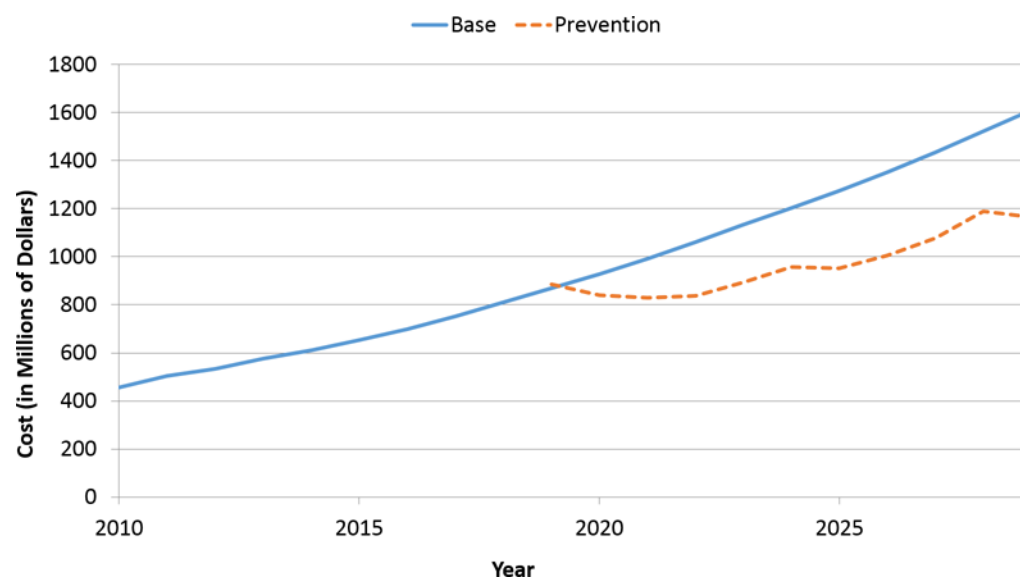


Figure 3.

Table 1

Melanoma Incidence and Mortality Rates by Age and Sex, United States, 2008–2012

Sex	Age (years)	Rate per 100,000	95% CI	Average annual count
Incidence				
Male	0–19	0.3	(0.3–0.4)	143
	20–49	9.9	(9.8–10.0)	6087
	50–64	41.4	(41.0–41.7)	12011
	65+	117.4	(116.7–118.1)	19872
Female	0–19	0.5	(0.5–0.5)	213
	20–49	13.9	(13.8–14.1)	8650
	50–64	27.6	(27.3–27.8)	8379
	65+	44.2	(43.8–44.6)	10223
Mortality				
Male	0–19	0.0	(0.0, 0.0)	3
	20–49	1.1	(1.0, 1.1)	658
	50–64	5.7	(5.6, 5.8)	1661
	65+	21.7	(21.4, 22.1)	3613
Female	0–19	0.0	(0.0, 0.0)	4
	20–49	0.7	(0.7, 0.7)	439
	50–64	2.7	(2.6, 2.8)	840
	65+	7.7	(7.6, 7.9)	1852

Source for 2008–2012 incidence rates:

United States Cancer Statistics: 1999 – 2012 Incidence, WONDER Online Database. United States Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; 2015. Data are from population areas that meet United States Cancer Statistics publication criteria (www.cdc.gov/cancer/npcr/uscs/technical_notes/criteria.htm) for 2008–2012 and were reported to the National Program of Cancer Registries (CDC) and the Surveillance, Epidemiology and End Results (SEER) program (NCI). They cover about 99.1% of the U.S. population.

Source for 2008–2012 mortality data: Surveillance, Epidemiology, and End Results (SEER) Program (www.seer.cancer.gov) SEER*Stat Database: Mortality – All COD, Aggregated With State, Total U.S. (1969–2012) <Katrina/Rita Population Adjustment>, National Cancer Institute, DCCPS, Surveillance Research Program, Surveillance Systems Branch, released April 2015. Underlying mortality data provided by NCHS (www.cdc.gov/nchs).

Table 2

Melanoma Incidence and Mortality Rates by Sex and Race/Ethnicity, United States, 2008–2012

	Both Sexes			Male			Female		
	Rate per 100,000	95% CI	Average annual count	Rate per 100,000	95% CI	Average annual count	Rate per 100,000	95% CI	Average annual count
Incidence									
All races	19.9	(19.9–20.0)	65,557	25.5	(25.3–25.6)	38,112	15.0	(15.9–16.0)	27,465
White	22.6	(22.5–22.6)	62,009	28.4	(28.3–28.5)	36,256	18.3	(18.2–18.4)	25,753
White, Hispanic	4.3	(4.2–4.4)	1,264	4.8	(4.6–5.0)	577	4.2	(4.0–4.3)	687
White, non-Hispanic	25.1	(25.0–25.2)	60,744	31.2	(31.0–31.3)	35,678	20.7	(20.5–20.8)	25,066
Black	1.0	(1.0–1.1)	342	1.1	(1.0–1.2)	156	1.0	(0.9–1.0)	186
American Indian/Alaska Native	4.6	(4.3–5.0)	135	5.8	(5.1–6.5)	71	3.9	(3.5–4.4)	64
Asian/Pacific Islander	1.3	(1.2–1.4)	191	1.5	(1.4–1.7)	94	1.2	(1.1–1.3)	97
Hispanic *	4.2	(4.1–4.4)	1,354	4.7	(4.5–4.9)	618	4.1	(3.9–4.2)	736
Mortality									
All races	2.7	(2.7, 2.7)	9,071	4.1	(4, 4.1)	5,936	1.7	(1.7, 1.7)	3,135
White	3.1	(3.1, 3.2)	8,872	4.6	(4.6, 4.7)	5,838	2	(1.9, 2)	3,033
White, Hispanic	0.8	(0.8, 0.9)	210	1.1	(1, 1.2)	123	0.6	(0.6, 0.7)	87
White, non-Hispanic	3.4	(3.4, 3.4)	8,651	5	(4.9, 5.1)	5,709	2.1	(2.1, 2.2)	2,942
Black	0.4	(0.4, 0.4)	132	0.5	(0.4, 0.5)	63	0.4	(0.3, 0.4)	70
American Indian/Alaska Native	0.7	(0.6, 0.9)	19	1	(0.7, 1.3)	11	0.6	(0.4, 0.8)	8
Asian/Pacific Islander	0.4	(0.3, 0.4)	48	0.4	(0.3, 0.5)	24	0.3	(0.3, 0.4)	24
Hispanic *	0.8	(0.7, 0.8)	214	1	(1, 1.1)	125	0.6	(0.5, 0.6)	88

* Hispanic ethnicity includes persons of all races.

Source for 2008–2012 incidence rates: United States Cancer Statistics: 1999 – 2012 Incidence, WONDER Online Database. United States Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute, 2015. Data are from population areas that meet United States Cancer Statistics publication criteria (www.cdc.gov/cancer/hpctr/uscs/technical_notes/criteria.htm) for 2008–2012 and were reported to the National Program of Cancer Registries (CDC) and the Surveillance, Epidemiology and End Results (SEER) program (NCI). They cover about 99.1% of the U.S. population.

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