SKIN

CONSENSUS STATEMENT

Expert Consensus on Sunscreen for the Primary Prevention of Skin Cancer: Results from the Skin Cancer Prevention Working Group Conference

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ABSTRACT

Background: Melanoma and non-melanoma skin cancers (NMSC) are the overall most common type of malignancy. Despite this fact, the use of sunscreen as a primary preventative measure for skin cancer is not ubiquitous.

Objective: To review the literature regarding efficacy and safety of sunscreens and to process and condense data into overarching principles to provide guidance to the public and improve outcomes for melanoma NMSC.

Methods: A systematic review of the literature pertaining to sunscreen efficacy in the primary prevention of melanoma and non-melanoma skin cancer, safety in humans and environmental impact was conducted. Following a thorough review of the literature, the Skin Cancer Prevention Working Group (SCPWG), an expert panel consisting of dermatologists with specialized training in melanoma and NMSC diagnosis and management, employed a modified Delphi technique to reach consensus over the development of statements regarding the current level of evidence for sunscreen efficacy and safety. Final statements were only adopted after achieving a supermajority vote >80%.

Results: 96 articles were identified for further review and discussion. The SCPWG developed 7 consensus statements regarding the efficacy and safety of sunscreens and their role in the prevention of melanoma and NMSC.

Conclusion: The proven benefits of primary skin cancer prevention outweigh the potential/hypothetical risks of sunscreen use, especially given insufficient real-world, prospective data for the discussed risks. As experts in skin health and skin cancer pathophysiology, the SCPWG believes dermatologists are uniquely qualified to lead future studies investigating sunscreen efficacy and safety and should counsel patients and the public on skin cancer primary prevention strategies.

INTRODUCTION

Skin cancer (including melanoma and non-melanoma skin cancer (NMSC)) accounts for the greatest incidence of new cancers in the US, with upwards of 200,000 cases of melanoma (~50% of which are invasive) and ~5.4 million cases of NMSC diagnosed annually.[1-6] Diagnosis and management of skin cancer accounts for $6 billion in yearly US healthcare expenditures.[7] Early diagnosis and treatment, especially for melanoma, is critical to improve patient outcomes.[8,9] However, despite significant improvement in understanding of cancer pathophysiology, diagnostic armament, and treatment efficacy and modalities, over 7000 individuals in the US die from advanced melanoma annually.[3,10] For this reason, one of the best forms of skin cancer management is primary prevention.

One of the primary drivers of skin cancer is exposure to ultraviolet radiation (UVR).[11] Studies attribute 90% of melanomas to deleterious UVR-induced genetic mutations, primarily from UVA radiation (320-400 nm wavelength) and UVB (280-320 nm).[11] Known methods to reduce harmful UVR exposure include decreasing time in direct sunlight, seeking shade, wearing dark-colored clothing, and regularly applying (and re-applying) sunscreen.[12,13]

The active ingredients in sunscreen are typically composed of mineral-based inorganic agents (e.g. Zinc Oxide (ZnO), Titanium Dioxide(TiO_2)) or organic compounds (e.g. oxybenzone, avobenzone, octinoxate, octisalate, homosalate, octocrylene).[14] Combinations of these filters are capable of broad-spectrum protection against UVA and UVB.[15] Despite data showing the ability of these agents to reduce UVR-induced erythema and decrease long-term incidence of melanoma and NMSC, questions have arisen regarding hypothetical systemic and environmental harms of sunscreen use, including concerns that misinformation may cause unwarranted harms to patients.[16-24]

The purpose of this expert consensus panel was to synthesize the most current available literature regarding sunscreen efficacy and safety into overarching principles, providing a framework with which dermatologists, physicians, and other non-physician providers may better counsel patients.

METHODS

Literature Search

A systematic review of the literature pertaining to the sunscreen efficacy in the primary prevention of melanoma and non-melanoma skin cancer and safety regarding human use and environmental impact was conducted. The MEDLINE database was queried for all relevant articles using exploded MeSH terms and keywords pertaining to the themes of efficacy (incidence, mortality, primary prevention, skin cancer, melanoma, non-melanoma skin cancer, basal cell carcinoma, cutaneous squamous cell carcinoma) and safety (organic sunscreen, mineral sunscreen, oxybenzone, avobenzone, octinoxate, octisalate, homosalate, octocrylene, titanium dioxide, zinc oxide, environment, patient education, and systemic absorption). The Boolean term “AND” was used to find the intersection of these themes with the term “sunscreen.” 96 articles were deemed relevant to the discussion of sunscreen safety and efficacy based on full-text review were selected for further review and analysis by members of the consensus panel.

Consensus Development Process

A 7-person consensus panel of dermatologists representing the Skin Cancer Prevention Working Group (SCPWG), physicians with specialized training in the diagnosis and management of melanoma and non-melanoma skin cancer, convened during May 2021. Panel members discussed issues regarding the efficacy of sunscreen in skin cancer prevention and potential systemic and environmental effects given the current findings and data in the literature. Statements were drafted based on review and analysis of the selected articles and relevant discussion.

Consensus among panel members was achieved using a modified Delphi technique, which has previously been used in developing dermatologic expert panel recommendations to reach consensus.[25-27] For consensus, a supermajority (>80%) agreement among participants was required. If a statement did not obtain supermajority approval, the proposal was returned to the group for modification in real-time followed by additional rounds of voting until supermajority approval was obtained.

RESULTS

The expert consensus panel developed 7 statements that all received supermajority approval using a modified Delphi technique (Table 1).

1. Skin cancer has a material impact on individual and public health.

Skin cancer (melanoma and NMSC) is the most common type of malignancy diagnosed annually, outnumbering all other cancer diagnoses ~3 to 1 with over 5.4 million new diagnoses per year and 1 in 5 Americans expected to be diagnosed with a type of skin cancer by the age of 70.[1-4] The incidence of skin cancer has continued to rise in the past several decades and only recently began to plateau as public outreach on sun-safety has increased.[3] However, timely diagnosis and adequate management and treatment of skin cancer still account for ~$6 billion in annual healthcare expenditures.[7] Furthermore, despite improvements in care and diagnostic techniques, there are expected to be 7180 deaths in 2021 due to invasive melanoma alone.[3,10]

Table 1. Consensus Statements

Statement	Panel in Agreement
1. Skin cancer has a material impact on individual and public health.	7/7
2. Ultraviolet radiation is a major modifiable risk factor for skin cancer.	7/7
3. Sun protective strategies, including the use of sunscreen, can reduce the risk of skin cancer.	7/7
4. Adherence among the public to recommended sun protective strategies are suboptimal, especially regarding sunscreen use.	7/7
5. To date, studies have not demonstrated that sunscreens cause harm in humans.	7/7
6. There is insufficient evidence to show that sunscreens cause harm to marine ecosystems, including coral reefs.	7/7
7. The proven benefits of sunscreen usage overwhelmingly outweigh the hypothetical risks.	7/7

2. Ultraviolet radiation is a major modifiable risk factor for skin cancer.

Up to 90% of melanomas can be directly attributed to ultraviolet radiation (UVR) exposure.[11] Increased frequency of sunbathing has also been found to positively correlate with a greater chance of being diagnosed with NMSC.[28] Artificial UVR from indoor tanning has been found to increase

melanoma risk by as much as 20%, especially in patients under 30 years old.[29]

While there are multiple risk factors for skin cancer (e.g., age, gender, family history, genetics, skin phototype), modifiable risk factors, such as degree of UVR exposure, can be mitigated during a patient's lifetime to prevent further increase in their individual risk for skin cancer.[28,30-35]

UVR exposure—specifically to UVA radiation (320-400nm wavelength) and UVB (290-320 nm)—is a modifiable risk factor that has a material impact on skin cancer incidence.[30,35] Studies have demonstrated chronic intermittent UVR may preferentially influence the risk of developing melanoma while chronic sustained UVR may be more related to the development of NMSC.[36,37]

3. Sun protective strategies, including the use of sunscreen, can reduce the risk of skin cancer.

There are several sun protective strategies that reduce UVR exposure including wearing sunglasses, dark-colored/long-sleeved clothing, and a hat, seeking shade, wearing sunscreen with a sun protection factor of at least 30 (SPF 30+) and potentially staying indoors between 10:00 AM and 4:00 PM (depending on UVR intensity).[38] Sunscreen remains one of the most common and effective methods of reducing UVR exposure.

Large scale, longitudinal randomized-control studies have found that daily application of SPF 15 sunscreen significantly reduced the number of clinically and histologically identified cutaneous squamous cell carcinomas (cSCC) within a 4.5 year period (Hazard ratio 0.61, 95% confidence interval 0.46-0.81) and even further specifically among histologically-confirmed cSCC (HR 0.48, 95%CI 0.35-0.64).[39] Additional follow-up over 8 years found a consistently significant decrease in incidence of cSCC as well as a trend towards decreasing the number of basal cell carcinomas (BCC) with daily SPF 15 sunscreen.[40] The authors noted that protection afforded by the SPF 15 sunscreen and relatively short follow-up period may have been insufficient for more thorough analysis regarding BCCs.[39,40] Additional subset analysis of the original study also found a significant decrease in new primary invasive melanomas over 14.5 years (HR 0.27, 95%CI 0.08-0.97).[41]

The sun protection factor (SPF) is a measure of a sunscreen's "strength", with higher SPF ratings indicating increased ability to block more UVB.[42,43] The American Academy of Dermatology (AAD) recommends everyone (regardless of age, gender, or race) use broad-spectrum, water-resistant sunscreens rated SPF 30+.[13] However data have shown higher SPF may yield additional benefits. For example, SPF 60 reduces the amount of UVR transmitted to the skin by an additional 50% compared to SPF 30, thereby reducing potential chance at mutational events, and reducing clinically significant sunburns.[43] Split-face trials, where SPF 100 was applied to half the face and SPF 50+ applied to the other half, demonstrated significantly reduced sunburns where SPF 100 sunscreen was applied.[44,45]

Of note, although concerns have also been raised that higher SPF sunscreens may provide a false sense of security and increase exposure to UVR,[46,47] a randomized-controlled trial demonstrated that higher SPF sunscreens did not alter sunbathing exposure but did significantly reduce incidence of sunburn[48].

4. Adherence among the public to recommended sun-protective strategies are suboptimal, especially regarding sunscreen use.

Despite solar radiation being classified as a carcinogen by the World Health Organization (WHO), up to 80.6% of individuals including up to 55.3% of patients with previously diagnosed NMSC self-report poor adherence to multi-modal sun protection guidelines.[49,50] Studies have found that even among patients with diagnosed melanoma, adherence to sun-protective strategies only improves transiently and then diminishes after a year, at which point it may even worsen compared to baseline.[51,52]

To achieve the optimal UVR protection, the US Food and Drug Administration (FDA) evaluates sunscreen applied at a density of 2 mg/cm^2.[14] Equal protection in actual-usage settings requires approximately 1 oz of sunscreen to be applied to the entire body.[13] However, under real-world conditions, patients may apply as little as 20-50% of this recommended amount.[53] These figures are further diminished when considering on average not allowing enough time is given for sunscreens to settle after application (~20 minutes) prior to exposure.[53] Furthermore, a majority of individuals do not re-apply sunscreen within the recommended timeframe (~2-3 hours) especially after activities that may remove sunscreen (e.g. swimming, excess friction from clothing or sand).[54-56] However, some of this loss of effectiveness may be offset through the usage of higher SPF sunscreens may partially compensate for poor application technique and adherence.[57,58]

Underutilization is often exacerbated by additional barriers including increased application challenges, poor comprehension of the risk of extensive UVR exposure, belief that tan skin appeared healthier, belief that sunscreen was harmful to the skin, or belief that sunscreens negatively impacts systemic vitamin D levels.[59]

5. To date, studies have not demonstrated that sunscreens cause harm in humans.

Two small-scale randomized control trials found that, under theoretical maximal-use conditions when several organic sunscreen components were applied in excess of 2-5 times real-world amounts (2 mg/cm^2) in a controlled indoor setting, serum concentrations exceeded the arbitrary "generally recognized as safe and effective" (GRASE) amount of 0.5 ng/mL proposed by the FDA.[21,22] Of note, the authors of this study reported no serious treatment-emergent adverse effects and also concluded that, while further studies are suggested, their findings should not deter from the use of sunscreens.[22]

Inconsistent findings from animal studies, including rodent models, have raised concerns organic sunscreen agents may potentially disrupt endocrine function.[23] One study found pregnant rats fed oral forms of oxybenzone in excess of 1605.5-7178.5 mg/Kg had significantly reduced body weight, increased liver and kidney weight and no statistical difference in sex ratio or weights of offspring.[60] A separate study found rats fed up to 1525 mg/Kg of oxybenzone for 4 days had increased uterine weight.[61] Importantly, a study determined the quantity of sunscreen required to reach equivalent body-weight standardized dose.[62] At the recommended 2mg/cm^2 applied over the entire body surface area of an average human adult, it would take 34.6 years of daily application to reach equivalent systemic concentrations.[62] However, when approximating real-world conditions in which only 50% of the

recommended amount of sunscreen (1 mg/cm^2) is applied to the face, neck, hands, and arms, it would take over 277 years to achieve similar doses orally administered to rats.[62]

A systematic review found only 1 randomized-control trial in humans investigating sunscreen use. This trial found no association between oxybenzone and follicle-stimulating hormone (FSH), luteinizing hormone (LH), steroid-hormone binding globulin (SHBG), testosterone, estradiol, or inhibin B after accounting for physiologic variations.[63] Of the additional 10 additional human studies that were reviewed, only 2 found potential statistically—but not clinically—significant associations with oxybenzone.[64,65] One study found that high maternal urine concentration of oxybenzone significantly correlated with 2.7-3.2 day decrease in gestation period during pregnancy, but did not affect birth weight nor body length.[64] A prospective cohort study found maternal oxybenzone urinary concentrations were significantly associated with increased birth weight in males and decreased birth weight in females but no association with birth length.[65] Importantly, neither study reported if subjects' oxybenzone exposure was from sunscreen usage.[64,65]

Studies have found that inorganic mineral agents (e.g., titanium dioxide (TiO_2), zinc oxide (ZnO)) poorly penetrate the stratum corneum with less than 0.03% of ZnO nanoparticles and no TiO_2 able to penetrate the upper stratum corneum, thereby limiting systemic absorption.[66-68] Further improvements in particle micronization have also improved cosmesis while also minimizing theoretical ability for mineral agents to induce the formation of free radicals.[69-71]

Finally, randomized-controlled trials have also found no evidence that real-world sunscreen usage negatively impacted physiologic vitamin D production.[73-75] For individuals who strictly adheres to ideal sun protective measures, studies have found oral vitamin D supplements provide adequate, affordable supplementation.[76]

Overall, there are no studies that definitively that show sunscreens including any of the 8 most common organic sunscreen agents (oxybenzone, avobenzone, octinoxate, octisalate, homosalate, octocrylene) cause systemic harms in humans.

6. There is insufficient evidence to show that sunscreens cause harm to marine ecosystems, including coral reefs.

As of January 2021, Hawaii has banned the sale of organic sunscreen agents oxybenzone and octinoxate and additional bills are being considered to ban avobenzone and octocrylene by 2023 (in the absence of a prescription).[24,77] These laws follow findings suggesting organic sunscreen agents were present in seawater around Hawaii, were difficult to remove/process in wastewater, and had the potential to bleach/ossify coral reefs in vitro.[78-80] Importantly, a study found that concentrations of organic sunscreen agents were materially higher in metropolitan water supplies (likely secondary to commercial/industrial run-off) than near recreational water sources.[20] Furthermore, studies found that actual oxybenzone concentrations in surrounding Hawaiian seawaters to be approximately 100-1000 times less concentrated than the in vitro concentrations toxic to species of microalgae, plankton, and zebrafish.[20,81-82]

Another important consideration is that potential environmental impacts of sunscreens may be confounded by other

factors, primarily climate change. Studies have demonstrated significant correlation between increasing global and ocean temperature that stress coral-algae symbiosis and stifle coral resiliency, inducing coral bleaching.[83-85] Additionally, while studies have found that oxybenzone had higher concentration in fish relative to seawater, there have not been any correlation with human health.[86] Finally, environmental-focused studies have found no evidence in real-world settings that inorganic mineral-based sunscreen agents could induce lasting damage to marine ecosystems.[24,66]

Overall, there are no direct in-vivo findings suggesting that mineral-based inorganic or any of the 8 most common organic sunscreen agents (oxybenzone, avobenzone, octinoxate, octisalate, homosalate, octocrylene) cause harm to marine ecosystems.

7. The proven benefits of sunscreen usage overwhelmingly outweigh the hypothetical risks.

Studies have consistently shown that regular sunscreen usage is capable of reducing the incidence of melanoma and NMSC.[39-41,44-46] Sunscreens can also prevent actinic damage and skin aging as well as ameliorate photodermatoses and photo-sensitive conditions.[87-89] In contrast, a majority of studies proposing hypothetical risks with sunscreen usage filters in controlled settings in concentrations far beyond what is commercially available to purposefully induce pathologic responses in animal models and the environment.[20,60-62,81,82] Under real-world conditions, these same pathologic responses have not been replicated. The panel also noted that real-world, prospective trials are simulated every weekend, on holidays, and even daily depending on local climate and season, as millions of individuals apply sunscreen without clinically appreciable adverse effects.

DISCUSSION

Sunscreens are an efficacious and integral component in the primary prevention of melanoma and NMSC. Studies have consistently shown that sunscreens are able to decrease incidence of NMSC and melanoma, with higher SPF-rated sunscreens being more capable of reducing sun burns and amount of UVR transmitted to the skin.

Unfortunately, due to a combination of inaccurate health and science literacy and misinformation campaigns, high-risk, vulnerable patients may be dissuaded from utilizing appropriate sun-protective measures, including sunscreen.[90,91] Sunburns continue to be prevalent beyond the non-Hispanic White population, also affecting younger adults, patients on chronic immunosuppressive therapy and 13% of Black and 30% of Hispanic Americans.[92,93] Even patients diagnosed with melanoma or NMSC have demonstrated poor long-term adherence to sun-protective measures.[50-52] Frequently reported barriers to using sunscreen and sun-protective strategies include increased application challenges, cosmetic acceptability (especially with thicker products), or poor understanding of the risks of extensive UVR exposure.[59] In the authors' opinion, these barriers are only exacerbated by third party evaluators that potentially have a financial interest in recommending specific sunscreen products.[90,94] For all of these reasons, the SCPWG believes that dermatologists are uniquely qualified to advocate for patients and educate the general public on the importance of sun-protective strategies.[95,96]

The SCPWG panel also noted inconsistencies and deficiencies in some of the sunscreen literature and supports further research to cultivate evidenced-based guidelines. Future studies should evaluate the longitudinal efficacy of higher SPF sunscreens in randomized-controlled trials, especially given improvements in broad-spectrum coverage and formulations since the prior studies that demonstrated skin cancer prevention efficacy.[39-41] Additionally, prospective studies in real-world settings regarding sunscreen agents and any impact they may have systemically in humans or on the environment could provide more definitive evidenced-based data to improve patient counseling.

CONCLUSION

With over 200,000 new cases melanoma and 5.4 million cases of NMSC in the US annually, accounting for over $6 billion in yearly healthcare expenditures, skin cancer poses a significant impact on both individual and public health. Primary prevention of skin cancer continues to be of utmost importance to reduce incidence, especially in melanoma prevention given over 7000 Americans continue to die annually from this cancer despite significant advancements in therapy.

As experts in the diagnosis and management of skin cancers, dermatologists are especially well-equipped to discuss with patients the risks of UVR exposure and skin cancer and benefits of multimodal sun-protective measures, including the regular and proper use of sunscreens. It is hoped that these consensus statements can serve as a basis for future health and public education initiatives. Dermatologists must continue to advocate for their patients by being involved in original investigations into the efficacy and safety of sunscreens and by educating the public on the nuances and merits of scientific findings in this space.

Conflict of Interest Disclosures: JWM, AF, AG, GHL, RS, and RRW have no relevant disclosures. DSR serves as a consultant for Beiersdorf and Proctor & Gamble.

Funding: None

Skin Cancer Prevention Working Group:
The Skin Cancer Prevention Working Group is a multi-center collaboration of experts dedicated to the prevention of skin cancer. The Working Group consists of clinical and research specialists that have spent years investigating and understanding the diagnosis and management of melanoma and non-melanoma skin cancer.

The mission of the Working Group is to cultivate and analyze evidence-based research to better understand skin cancer pathophysiology, treatment, and prevention to be leaders in skin health education.

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