EVIDENCE SYNOPSIS

Title: Benefits and Harms of Sunscreens to Decrease Ultraviolet Exposure from Sunlight

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Clinical question: What are the benefits and harms of sunscreens to decrease ultraviolet (UV) exposure from sunlight?

Author recommendations:

To prevent UV irradiation of the skin when exposed to sunlight, clinicians should recommend the use of broad-spectrum sunscreen with a minimum sun protection factor (SPF) rating of 15, applied in a dose of at least 2 mg/cm^2 every 2 hours during sun exposure.

Additional safeguards include limiting ultraviolet A (UVA) and ultraviolet B (UVB) radiation from 10 a.m. to 2 p.m. and wearing hats and sun-protective clothing.

Evidence and recommendations:

Quality of Evidence[a]	Strength of Recommendations[b]	Conclusion
Low	Strong	The potential preventive benefits of SPF 15 or higher sunscreen strongly outweigh the risks

[a]Quality of evidence scale (Grading of Recommendations Assessment, Development and Evaluation [GRADE]): high, moderate, low, and very low.
[b]Strength of recommendations scale (GRADE): strong, weak, or no recommendation. For more information on the GRADE rating system, see http://www.gradeworkinggroup.org/index.htm.

PICO:

Population	Healthy persons exposed to sunlight Time of day Duration and frequency of exposure
Intervention	Topical physical sunscreens (e.g., titanium dioxide, zinc oxide) Topical chemical sunscreens (e.g., para-aminobenzoic acid, avobenzone) Clothing with or without SPF With or without other sun avoidance and protective measures Dose, frequency, duration
Comparator	No sunscreen; other avoidance or protective measures only; sunscreen with beta-carotene; placebo Discretionary sunscreen use, active comparators
Primary outcome(s)	Long-term clinical effects of sunburn: solar keratosis counts, nevi counts Development of cancerous lesions; precancerous lesions; cancer rates: basal cell carcinoma, squamous cell carcinoma, cutaneous malignant melanoma, actinic neoplasia (keratosis) Safety outcomes: all harms

What are the parameters of our evidence search? Refer to the following tables (Tables 1 and 2)

TABLE 1 Outcome: Sunscreen for Prevention of Solar (Actinic) Keratosis: Standardized Mean Difference[a]

Study (Year) Design Study Duration	Comparator	Intervention	Standardized Mean Difference Estimate(95% CI) N	Quality of Evidence (GRADE)	Comment
Darlington (2003)[1] RCT 1992-1994 Sunscreen sites only	**Discretionary use of sunscreen**	**SPF 16 as directed**	**−0.13 (−0.25, −0.02) 1116**	**High risk**	**Solar keratosis counts were somewhat lower compared with 1992 in the intervention group**
Darlington (2003)[1] RCT 1992-1994 Full body	**Discretionary use of sunscreen**	**SPF 16 as directed**	**−0.14 (−0.26, −0.03) 1116**	**High risk**	**Solar keratosis counts were somewhat lower compared with 1992 in the intervention group**
Darlington (2003)[1] RCT 1994-1996 Sunscreen sites	Discretionary use of sunscreen	SPF 16 as directed	−0.03 (−0.15, 0.09) 1116	High risk	No statistically significant difference in solar keratosis counts during the second 2-year follow-up period
Darlington (2003)[1] RCT 1994-1996 Full body	Discretionary use of sunscreen	SPF 16 as directed	−0.03 (−0.15, 0.09) 1116	High risk	No statistically significant difference in solar keratosis counts during the second 2-year follow-up period
Thompson (1993)[2] RCT 1 year	**Placebo (base cream minus active ingredient)**	**SPF 17 cream on head, neck, forearms, and hands**	**−4.32 (−4.66, −3.97) 588**	**High risk**	**The sunscreen group had a reduction in lesions, while the comparator group's lesions increased in number 27% dropout rate**
Naylor (1995)[3] RCT 2-year follow-up	**Placebo (base cream minus active ingredient)**	**SPF 29 applied at least daily**	**−0.55 (−1.11, 0.02)[b] −0.77[c] (−1.36, −0.17) 50**	**High risk**	**Statistically significant difference in lesions in the intervention group, as reported and calculated using Glass's Delta 1 Small sample size**

[a]Statistically significant findings are in bold font.
[b]Cohen's d calculated with unequal variances.
[c]Glass's Delta 1 calculated with unequal variances.
CI, Confidence interval; *GRADE,* Grading of Recommendations Assessment, Development and Evaluation; *RCT,* randomized controlled trial; *SPF,* sun protection factor.

TABLE 2 Outcome: Sunscreen for Prevention of Skin Cancers

Study Description and Outcome Years	ILLUSTRATIVE COMPARATIVE RISKS (95% CI)		Rate Ratio (95% CI) NNTp (95% Ci)	Number of Participants	Quality of Evidence (GRADE)	Comment
	Assumed Risk Rate of Outcome in Control Groups	Corresponding Risk with Sunscreen Intervention				
Green (1999)[4] RCT, 4-year follow-up Basal-cell carcinoma SPF 16 as directed 1992-1996	25.09/1000 individuals	25.88/1000 individuals	1.03 (0.73, 1.46) NA	1383	High risk	Control group used discretionary sunscreen
Green (1999)[4] RCT Squamous cell carcinoma SPF 16 as directed 1992-1996	9.96/1000 individuals	8.76/1000 individuals	0.88 (0.50, 1.56) NA	1383	High risk	–
Van der Pols (2006)[5] RCT, 8-year follow-up 1993-2004 Basal cell carcinoma	12.70/1000 individuals	12.96/1000 individuals	1.02 (0.78, 1.35) NA	1484	High risk	–
Van der Pols (2006)[5] RCT, 8-year follow-up 1993-2004 Squamous cell carcinoma	**8.11/1000 individuals**	**5.45/1000 individuals**	**0.65 (0.45, 0.94) –14[a] (6, –4)**	**1484**	**–**	**–**
Green (2011)[6] RCT, 15-year follow-up 1992-2006 Invasive melanoma	**13.6/1000 individuals**	**3.7/1000 individuals**	**0.27 (0.08, 0.97) –4[a] (–42, –2)**	**1621**	**High risk**	**–**

[a]NNTp is the absolute value of 1/absolute risk reduction when the intervention is preventive. In all cases, the control group rate is greater than the intervention group rate, otherwise yielding a negative number (e.g., sunscreen use results in a lower invasive melanoma rate in the intervention group).
CI, Confidence interval; *GRADE*, Grading of Recommendations Assessment, Development and Evaluation; *NA*, not applicable; *NNTp*, absolute value of 1/absolute risk reduction when the intervention is preventive; *RCT*, randomized controlled trial; *SPF*, sun protection factor.

Guidelines: Ultraviolet Radiation and the INTERSUN Programme. World Health Organization[7] (AGREE II score: Not scored) No strength of recommendations or quality of evidence ratings.

- **Use sunscreen:** Apply a broad-spectrum sunscreen of SPF 15+ liberally, and reapply every 2 hours or after working, swimming, playing, or exercising outdoors. Sunscreen should never be used to prolong the duration of sun exposure.
- **Limit time in the midday sun:** The sun's UV rays are strongest between 10 a.m. and 4 p.m. To the extent possible, limit exposure to the sun during these hours.
- **Watch for the UV Index:** This important resource helps you plan your outdoor activities in ways that prevent overexposure to the sun's rays. While you should always take precautions against overexposure, take special care to adopt sun safety practices when the UV Index predicts exposure levels of moderate or above.
- **Use shade wisely:** Seek shade when UV rays are the most intense, but keep in mind that shade structures such as trees, umbrellas, or canopies do not offer complete sun protection. Remember the shadow rule: "Watch your shadow. Short shadow, seek shade!"
- **Wear protective clothing:** A hat with a wide brim offers good sun protection for your eyes, ears, face, and the back of your neck. Sunglasses that provide 99-100% UVA and UVB protection will greatly reduce eye damage from sun exposure. Tightly woven, loose-fitting clothes will provide additional protection from the sun.

Position Statement on Broad Spectrum Protection of Sunscreen Products. The American Academy of Dermatology. Revised 2009.[8] (AGREE II score: Not scored) No strength of recommendations or quality of evidence ratings.

- Use a broad-spectrum (UVA and UVB protection) sunscreen with SPF 30 or higher that meets the UVA protection criteria defined below.
  - Sunscreen UVB protection, as reflected by SPF, is an important initial consideration for sunscreen potency. UVA protection is an equally important consideration for sunscreen potency.
  - The UVA protection factor of a sunscreen should reflect at least a 10-fold increase in the UVA dose needed to induce a purified protein derivative (PPD) response, and it must be accompanied by a critical wavelength of 370-400 nm.
  - An increase in sunscreen SPF must be accompanied by a proportional increase in the UVA protection factor as measured by the PPD method. The ratio of UVA:UVB protection factors should be 1:3 at a minimum (e.g., an SPF 30 sunscreen will have at least a UVA protection factor of 10).
  - Only sunscreens that demonstrate both UVA and UVB protection may claim broad-spectrum coverage.
- Additional American Academy of Dermatology resources.

Behavioral Counseling to Prevent Skin Cancer: U.S. Preventive Services Task Force Recommendation Statement; 2012.[9] Moyer VA, on behalf of the U.S. Preventive Services Task Force (AGREE II Score: Score unavailable). Grade B recommendation: The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.

- Provide counseling about minimizing exposure to UV radiation to reduce the risk of skin cancer (for ages 10-24). (Grade B) For adults older than 24 years, there is insufficient evidence.
- Individuals with a fair skin type are at greatly increased risk for skin cancer.
- Behavioral change interventions are aimed at reducing UV radiation exposure. Sun-protective behaviors include the use of a broad-spectrum sunscreen with an SPF of ≥15, wearing hats or other shade-protective clothing, avoiding the outdoors during midday hours (10 a.m. to 3 p.m.), and avoiding the use of indoor tanning.

Sunscreen: The ABCs of Sun Protection. FDA; 2015.[10] (AGREE II Score: Not scored) No strength of recommendations or quality of evidence ratings.

- Use broad-spectrum sunscreens with SPF values of 15 or higher regularly and as directed.

- Reapply sunscreen at least every 2 hours; more often if you're sweating or jumping in and out of the water.
- Limit time in the sun, especially between the hours of 10 a.m. and 2 p.m., when the sun's rays are most intense.
- Wear clothing to cover skin exposed to the sun; for example, long-sleeved shirts, pants, sunglasses, and broad-brimmed hats.

Author commentary: We searched the literature on prevention of sunburn with sunscreen use. Though we found no studies that focused on acute sunburn, we included studies with precursor and intermediate clinical conditions that have been identified as skin cancer risk factors. Three of the included studies are based on the original work done in Queensland, Australia.[1,4–6] Because of the setting, these results may not be generalizable to more temperate climates. Nevertheless, the studies show a statistically significant protective effect of sunscreen in decreasing the development of solar keratosis, squamous cell carcinoma, and melanoma over the long term. For all outcomes and over a 10-year follow-up period, the results show no protective effects for beta carotene (30 mg/day). There are no reported harms associated with sunscreen use, although the effect of conscientious sunscreen use on vitamin D levels remains controversial, as the research findings are conflicting.[11] Overall, the evidence is rated low quality because of its high risk of bias and inconsistency across study results.

Despite its low quality, the evidence from the included RCTs supports the use of an effective broad-spectrum sunscreen with an SPF level of 15 or higher to cover sun-exposed skin, as the longer-term benefits may be far greater than the potential harms. There remain diverse opinions about whether higher SPF ratings provide greater risk reduction. Higher-rated sunscreens are more effective in blocking UV rays, and FDA regulations require a 2 mg/cm^2 application density for SPF testing. One argument is that higher SPF ratings (e.g., greater than 50) provide a greater margin of safety, as sunscreen is typically applied at 20-50% of the SPF-rated amount.[12]

Our recommendations are consistent with current clinical practice guidelines.

Update alerts: Important new citations relevant to this topic are added here as they become available.

Glossary: AGREE II, Appraisal of Guidelines for Research and Evaluation; CI, confidence interval; FDA, US Food and Drug Administration; GRADE, Grading of Recommendations Assessment, Development and Evaluation; NA, not applicable; NNT, number needed to treat; NNTp, absolute value of 1/absolute risk reduction when the intervention is preventive; PPD, purified protein derivative; RCT, randomized controlled trial; SPF, sun protection factor; UV, ultraviolet; UVA, ultraviolet A; UVB, ultraviolet B.

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