

Effectiveness, compliance and application of sunscreen for solar ultraviolet radiation protection in Australia

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Key points

- Evidence shows that correctly applied sunscreen prevents acute sunburn
- More research is needed on the effectiveness of broad-spectrum high-SPF sunscreen in the prevention of skin cancers
- Sunscreen should be used in combination with other sun protection measures that include clothing, hats, sunglasses and seeking shade

Abstract

Objectives and importance of study: Sunscreens are widely used, not only to prevent acute sunburn, but also for skin cancer prevention and protection against photoaging and other skin conditions related to cumulative solar ultraviolet radiation (UVR) exposure. When correctly applied, sunscreens reduce the amount of UVR reaching the skin and therefore they can reduce harmful effects of such exposures. This paper examines the benefits and risks of sunscreens, compliance requirements and how sunscreen should be used for optimal effectiveness.

Study type: Narrative review.

Methods: We reviewed evidence relating to the benefits and risks of sunscreens, sunscreen manufacturing compliance, consumer usage of sunscreen and how sunscreen should be used to be most effective.

Results: There is strong evidence that sunscreen is safe to use and, when applied correctly, reduces the risk of skin cancer. There is a need to address questions about the impact of sunscreen on vitamin D and its risk to the environment, as well as a need to develop sun protection factor (SPF) sunscreen testing methods that are more reproducible and ethically based. The amount of sunscreen and the way it is applied varies considerably between individuals, and this in turn markedly affects the degree and duration of protection received. Sunscreen should be used in combination with other sun protection measures that include clothing, hats, sunglasses and seeking shade.

Conclusions: Regulation is essential to ensure high-quality, safe and effective sunscreen products are available to the Australian population. There is an important role for governments to put in place skin cancer prevention policies and long-term funding arrangements to build on our successful sunscreen programs so that future generations are afforded the highest level of topical protection against solar UVR.

Introduction

The effects of ultraviolet radiation (UVR) on the skin depend largely on the intensity of the source, the duration of the exposure, the UVR wavelength and the level of pigmentation of the skin. Sunlight contains a range of UVR wavelengths: approximately 95% of the solar UVR reaching Earth's surface is classified as UVA (wavelengths 315–400 nm) while the remaining 5% is within the UVB range (wavelengths 280–315 nm). UVB causes erythema (sunburn) far more effectively than UVA, while UVA is primarily responsible for skin photoaging, however this distinction is not absolute and both UVA and UVB have been implicated in skin cancer causation. Skin with lower levels of melanin pigment is more susceptible. Solar UVR is recognised as a Group 1 carcinogen by the International Agency for Research on Cancer (IARC).¹

Sunscreen products are designed to be applied topically to the skin in order to absorb or reflect UVR and thus provide some degree of protection to the skin of the wearer from sun damage. Broad-spectrum sunscreen provides protection against both UVA and UVB wavelengths of UVR. When properly applied, good-quality sunscreen can be effective in preventing or reducing adverse effects including erythema, skin aging and skin cancer.^{2,3} However, sunscreen alone should not be used to extend the duration of exposure, rather it should be considered the last element in a hierarchy of control measures for sun protection.

Sunscreen products come in many forms including a lotion, cream, spray or solid (stick). They can be broadly classified by the active ingredients they use as either physical blockers or chemical absorbers. Physical blockers contain mineral particulates, typically, titanium dioxide (TiO₂) or zinc oxide (ZnO), which reflect or scatter the incident UVR to prevent it reaching the skin. Chemical absorbers contain compounds which absorb energy from incident UVR and release it as lower energy photons (heat) when the molecule returns to its relaxed state. There are many UVR filter compounds used as chemical absorbers: common examples include avobenzone, octyl salicylate, oxybenzone (BP-3) and octinoxate (OMC) (see Serpone⁴ for more examples). Although it is possible to use only physical blockers or only chemical absorbers as the active ingredients, some formulations use a combination of both and it is common to have multiple active ingredients providing protection. A full list of the active ingredients permitted for use in sunscreens in Australia is maintained by the Therapeutic Goods Administration (TGA) and is published in the Australian regulatory guidelines for sunscreens.⁵

Whatever the formulation (active ingredients) and designation (primary or secondary/cosmetic sunscreen), all sunscreen products are tested to the Australian Standard (AS/NZS 2604) to determine the sun protection factor (SPF). To comply with the Australian Standard, all primary sunscreens must provide broad-spectrum protection.⁶ All products of equivalent SPF rating should

provide the same level of protection when applied at the appropriate thickness (2 mg/cm²) as required for testing. The Australian Standard includes test methods for both broad-spectrum and water-resistant sunscreen products.

Sunscreen is just one element of an effective sun protection strategy. Health protection agencies and nongovernment organisations tasked with delivering sun protection messages to the general public recommend using multiple defences against excessive sun exposure including the use of clothing, hats, sunglasses, seeking shade and minimising time spent outdoors when the UV Index is ≥ 3 . In situations when other sun protection measures are unsuitable (for a particular area of skin or a particular circumstance of exposure) sunscreen is a useful additional protection.

In Australia, public education campaigns and advice from government and nongovernment organisations on sunscreen use have shifted to recommending routine daily sunscreen application with a combination of additional sun protective measures.⁷ With an increased emphasis placed on sunscreen use, it is important for policy makers in public health-related sectors to maintain confidence in the safety and efficacy of sunscreens as part of a national approach to skin cancer prevention. This paper examines the benefits and risks of sunscreens, compliance requirements and how sunscreen should be used for optimal effectiveness.

Benefits and risks of sunscreens

There is coherent and compelling experimental evidence that sunscreens designed to prevent erythema also prevent DNA damage when applied to human skin before UVB exposure.⁸ A consensus statement from the peak bodies delivering sun protection advice in Australia and New Zealand concluded that the experimental studies and randomised trials provide strong evidence that daily sunscreen use reduces the risk of skin cancer. Furthermore, they concluded that the evidence that sunscreens are safe is both consistent and convincing, noting that adverse reactions are rare, usually temporary and almost always minor.⁷

It is conservatively estimated that sun exposure is the cause of virtually all keratinocyte cancers and around 63% of melanomas in Australia.⁹ Olsen et al.⁹ also estimated prevented fractions of 9.3% for squamous cell carcinoma and 14% for melanoma through regular use of sunscreen. Based on the few randomised controlled trials in humans that have been conducted to date^{2,3,10}, a review by Sander¹¹ concluded that sunscreen use does reduce the risk of squamous cell carcinoma and melanoma. These studies represent the highest-quality evidence to date. The evidence from observational epidemiological studies, while more abundant, is equivocal: several have reported conflicting results.^{12–15} However, since these studies are observational, their results are prone to bias and confounding, and the evidence they provide is

relatively weak. Several recent systematic reviews have also examined whether sunscreen use prevents skin cancer, again with mixed results, however this was largely driven by the bulk of observational evidence.¹⁶⁻¹⁸

Evidence is still needed on the long-term effectiveness of broad-spectrum sunscreen in preventing basal cell carcinoma and melanoma.¹⁹ Ideally, this would come from a randomised control trial, although ethical considerations make such a study unlikely. Future observational research should attempt to improve on methodological shortcomings, including bias and confounding. Exposure of the skin to sunlight is also beneficial for health since it generates vitamin D, which is essential for bone health. Therefore, a balance is required between achieving enough exposure to maintain adequate vitamin D levels and avoiding an increase in the risk of skin cancer by excessive sun exposure. Neale et al.²⁰ conducted a systematic review of the influence sunscreen use has on vitamin D levels. They found that while the experimental (laboratory) studies support the assertion that sunscreen use could theoretically reduce vitamin D levels, the evidence from observational studies and field trials indicates that the risk of this occurring in real life is very low. It was noted, however, that no field trials using high sun protection factor (SPF) sunscreens (SPF > 30) had been conducted.

Sensitivity to the ingredients found in sunscreen may cause irritant or allergic contact dermatitis or, more rarely, photocontact dermatitis in some individuals.²¹ Sunscreen-induced dermatitis generally does not have long-term consequences and may usually be alleviated by ceasing use of the product.⁷ Use of sunscreen is not recommended on children younger than 6 months since their skin is more sensitive and its use may result in irritation or rashes. A better approach to sun protection for babies is to avoid direct sunlight, use protective clothing and shade. There are many different sunscreen products with varying formulations available in Australia, so consumers will likely be able to find a well-tolerated sunscreen product for their skin.

Another safety concern that has been raised is the toxicity of nanoparticles found in some sunscreens. The TGA has published a series of reviews on this issue, most recently in August 2016.²² The majority of in vitro studies (using both animal and human skin) and in vivo studies have shown that both ZnO and TiO₂ nanoparticles either do not penetrate, or only minimally penetrate, the stratum corneum. This suggests that systemic absorption leading to a toxic response is highly unlikely. On current evidence, the TGA advise that neither TiO₂ nor ZnO nanoparticles are likely to cause harm when used as ingredients in sunscreens and when those sunscreens are used as directed.²²

Evidence of the measurable systemic absorption of sunscreen active ingredients following topical application has been presented²³, but the clinical significance of these results remains unclear. Sunscreen agents, including BP-3 and OMC, have been identified as having

the potential to cause endocrine disruption.⁴ However, a recent systematic review²⁴ concluded that there was insufficient evidence to support a causal relationship between elevated systemic levels of either BP-3 or OMC and adverse health outcomes. These authors cited the presence of contradictory findings among various studies and also noted that there are still insufficient numbers of studies to corroborate any observed association. Clearly, further studies using standardised exposure techniques and outcome measures that are clinically relevant will be required to help resolve this issue.

Another potential risk of sunscreen use is unintended environmental impacts, particularly in marine environments. A recent review²⁵ noted that while the US National Oceanic and Atmospheric Administration has identified 10 sunscreen ingredients as being toxic to coral and marine life, the in vitro studies demonstrating toxicity used concentrations of sunscreen ingredients in the range µg/l to mg/l, far higher than those actually found in marine environments (ng/l). Based on these limited laboratory data, two common sunscreen ingredients, BP-3 and OMC, have already been banned in parts of the US (Key West, Florida and the state of Hawaii). This highlights a need for both regulators and manufacturers to consider sunscreen product lifecycles to minimise environmental impact and adopt a more eco-sensitive approach to sunscreen formulation.

Sunscreen manufacturing compliance

In Australia, the TGA is responsible for regulation of primary sunscreens (products whose main purpose is to protect the skin from UVR) and some secondary sunscreens (products with a main purpose other than UVR protection, but which also contain sunscreens agents). Examples of TGA-regulated secondary sunscreens include skin care cosmetics or moisturisers containing sunscreens agents with SPF 15+ or greater. The regulatory requirements apply to the sunscreen products and their components, and enforce mandatory requirements for labelling, advertising, testing and ingredients. Only approved ingredients, each of which have been assessed for safety, can be included in sunscreen products. The TGA also requires the efficacy of each sunscreen product to be tested and for the resulting SPF to be printed on the label. Sunscreens must comply with the Australian and New Zealand Sunscreen Standard.⁶ This ensures that sunscreens available in Australia are safe, effective and of good quality.

The TGA continuously monitors the scientific literature on sunscreens and their ingredients to identify if any unacceptable risk of harm or toxicity emerges and ensure that appropriate regulatory action could be undertaken. In addition, the TGA conducts compliance reviews of the quality, safety and efficacy of sunscreens available on the Australian market. An example of this system in

practice is the recent product recall issued by the TGA for a particular aerosol sunscreen after some batches were found to contain a potentially harmful ingredient not listed for inclusion in the product.

In vivo testing in human subjects is currently the basis for testing sunscreen efficiency. The SPF is determined by comparing the time it takes for intense solar-simulated UVR to cause erythema in two regions of skin on human volunteers: one covered with a specific amount of sunscreen (2 mg/cm²) and the other with no sunscreen applied. The ethical status of such testing is highly questionable since it involves subjecting volunteers to carcinogenic UVR. The natural variability between human subjects and the difficulty in objectively classifying the onset of erythema leads to a lack of consistency in results between human test subjects of the same skin type and between test laboratories conducting in vivo testing.

The move towards in vitro testing, while desirable, is not without difficulties. The measured spectral transmission properties of sunscreen can be influenced by the properties of the testing slide and the topology of the sunscreen sample. Research into the development of reliable in vitro SPF methods is ongoing by multiple groups worldwide, but it is not yet clear when or even if such a method will be adopted into Australian or ISO Standards. The inherent variability of in vivo test results presents a problem for any transition to a new in vitro testing method as consistency between the different test methods is critical to establish confidence in the techniques.

Usage of sunscreens

The amount of sunscreen and the way it is applied varies considerably between individuals, and this in turn markedly affects the degree and duration of protection received. The labelled SPF of a sunscreen will not be achieved if the product is applied at less than 2 mg/cm². This equates to approximately 35 ml or seven teaspoons for full body application for an adult (one teaspoon per limb, one for the front of the body, one for the back and one for the head). It has long been reported that most consumers rarely use the recommended amount of sunscreen and so fail to achieve the desired SPF.²⁶ A pragmatic approach to ensure a thicker layer of sunscreen is applied in real-world settings is to recommend regular reapplication.²⁷ Primary sunscreens are superior to cosmetic sunscreens for several reasons: cosmetic products typically have a lower SPF rating, seldom offer broad-spectrum protection or water resistance, and are unlikely to be applied or reapplied in sufficient quantity to achieve the labelled SPF.

Advice from Cancer Council Australia recommends that sunscreen should be applied:

- Every day that the UV Index is forecast to be ≥ 3
- To clean and dry skin

- 20 minutes before exposure to UVR in order to create the intended protective barrier
- Liberally and evenly at a rate of 35 ml per full body coverage for an adult.

Furthermore, sunscreen should be reapplied:

- At least every 2 hours when outdoors
- After swimming, towel drying or when sweating.

The long-standing advice to apply sunscreen 20 minutes prior to sun exposure has been justified as the time required for the sunscreen to bond with skin and reduce the likelihood that it will be immediately compromised by sweat, water immersion or physical contact.²⁷ This advice is not meant to indicate that the sunscreen will not work for the first 20 minutes after application. It also ensures that no UVR exposure occurs prior to sunscreen being applied.

There are potential issues with application of aerosol spray-on sunscreen and these products are generally not recommended by Cancer Council Australia. Spray-on sunscreen can be difficult to apply evenly and at the recommended dosage, resulting in inadequate protection against UVR.²⁸ The effectiveness of applying aerosol sprays is strongly impacted by wind conditions. Recent research²⁹ has shown that as much as 93% of the sunscreen can be lost in moderate (20 kph) winds, conditions which occur 67–87% of the time between 9am and 4pm during summer at Australia's most popular beaches. Even in light wind conditions (10 kph), occurring 95% of the time, more than one-third of the sunscreen can be lost.

The choice between sunscreens using physical or chemical active ingredients (where they exist) is ultimately one of consumer preference. They are tested to the same standard and subject to the same regulatory regimen to ensure the formulations are safe to use. The best choice is a broad spectrum sunscreen with a SPF rating of 30 or more (the higher the SPF rating the better) regardless of the active ingredients.

It is also important to remember that sunscreen products have an expiry date and recommended storage conditions printed on the label. Most sunscreens last about 2–3 years and should always be stored at a temperature below 30°C to ensure they perform as intended.

Policies

Skin cancer prevention efforts in Australia are delivered by a wide range of government and nongovernment organisations operating at national, state, regional and local levels. Dating back to the 1970s, skin cancer prevention mainly focused on increasing awareness on reducing skin cancer risk and increasing early detection of skin cancer. Today, key sun protection messages have expanded to ensure a focus on individual and environmental strategies, targeting both the public and workers.³⁰

The most common cancers in Australia are skin cancers. Along with New Zealand, Australia consistently has the highest skin cancer incidence and mortality rates in the world. It is estimated that two in three Australians will be diagnosed with skin cancer by the age of 70. The costs to the health system of diagnosing and treating skin cancers are enormous. It was estimated that in 2017 the annual costs of treating melanoma in Australia was in excess of \$200 million³¹ while for keratinocyte cancers the figure was estimated to be \$700 million.³² A 2015 systematic review³³ found that successful prevention programs are highly cost effective since most skin cancers are preventable with easy to implement sun-protective behaviours. Analysis of the influence of the SunSmart program on sun protection behaviours on summer weekends in Melbourne has shown a nearly five-fold increase in the odds of sunscreen use over the 30 years of this cross-sectional survey (from 1987–88 to the 2010s).³⁴

In Australia, government funding in skin cancer prevention remains only a fraction of the substantial total spent on early detection of skin cancer, and treatments of skin cancer including drugs for the treatment of advanced melanoma. Only a strong and well-funded national approach to skin cancer prevention (through the promotion of sun protection using sunscreens, hats, clothing, shade and sunglasses) can provide the stimulus and guidance to governments, jurisdictions, nongovernment organisations and researchers to work to change UVR-protection behaviour across all age groups and targeted high-risk groups to reduce the burden of UVR-related skin disease in Australia.³⁵

Conclusion

There is strong evidence that sunscreen is safe to use and, when applied correctly, reduces the risk of skin cancer. But it also comes with its challenges. There is a need to address questions about the impact of sunscreen on vitamin D and its risk to the environment. Further research using methodologies that avoid the perils of bias and confounding should focus on newer formulations of broad-spectrum sunscreen with very high SPF. There is also a need to develop SPF sunscreen testing methods that are more reproducible and ethically based. Perhaps the biggest challenge however, is changing people's behaviour to use sunscreen and apply it correctly. Improving sun protection behaviour at the population level can best be attained by delivering comprehensive community-wide health promotion interventions.

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Peer review and provenance

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Competing interests

None declared.

Author contributions

SH was responsible for drafting, reviewing and editing the manuscript, and contributing to the design of the manuscript. KLK and KKK were responsible for providing analytical advice and reviewing the manuscript. RT was responsible for the design and review of the manuscript. AG was responsible for providing analytical advice, reviewing the manuscript and contributing to the design of the manuscript.

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