

## Chapter 10

# Recommendations

## Recommendations for research

A prerequisite for determining the role of sunscreens in the prevention of cancers of the skin is an understanding of the role of UVR in the causation of these diseases. In particular, it is important to understand the nature of the dose–response relationship, the influence of dose rate and pattern of dose delivery on risk and the action spectrum for each effect. Therefore, the Working Group recommends that:

- Studies should be conducted to determine whether there is a direct link between skin cancer and exposure to quantifiable doses of UVR in a defined spectrum. One example would be a prospective study of patients receiving phototherapy from TL01 UVB lamps. Such a study should be designed to evaluate fully the role of potential confounders of any association.
- Prospective studies should be conducted on the relationship between exposure to the sun and skin cancer and precursor lesions, in which the measurement techniques used are capable of differentiating between UVA, UVB and other wavelengths and show how solar radiation is distributed to skin cells.
- Randomized controlled trials, should be conducted among adults to evaluate whether a reduction in late-stage exposure to UVR can reduce the incidence of cutaneous melanoma and its precursor lesions, clinically atypical naevi, and among children to evaluate whether a reduction in early-stage exposure to UVR can reduce the prevalence of acquired naevi, which are precursors of cutaneous melanoma.
- Randomized controls trials should be conducted among adults to evaluate whether a reduction in late-stage exposure to UVR can reduce the incidence of basal-cell carcinoma. Randomized controlled trials should be conducted among adults to evaluate whether a reduction in late-stage exposure to UVR can reduce the incidence of squamous-cell carcinoma.
- To the extent possible, such randomized controlled trials should include quantitative assessment of solar exposure and evaluation of the various methods for reducing solar exposure, which include sunscreens, clothing and sun avoidance.

A better understanding will be gained of the mechanisms of skin cancer induction and the way in which sunscreens can effect them if intermediate end-points, such as naevi, or biochemical markers of carcinogenesis, such as DNA damage and *p53* mutations, are studied in relation to sunscreen use. To this end, the Working Group recommends that:

- Adequate controlled trials in humans and studies on appropriate animal models should be conducted to evaluate the relationship of intermediate biomarkers of sun exposure with the development particularly of cutaneous melanoma and the role of sunscreens in influencing such markers.
- The relationship between expression of such biomarkers and carcinogenic risk must be established, and the role of sunscreens in protecting against the appearance of biomarkers predictive of risk should be investigated.
- Studies should be conducted on the influence of photoinstability on the biomarkers.
- Studies should be conducted to determine whether there is a direct link between UVR-induced erythema (not necessarily from sunlight) and non-melanoma skin cancer.
- Studies should be conducted to establish the chromophore for erythema.
- Studies should be conducted to determine the importance of UVR-induced immunosuppression in the causation and progression of human skin cancers.
- Biomarkers of UVA-induced oxidative stress should be developed.

The mechanisms of carcinogenesis by UVR and the role of sunscreens in inhibiting the process are still not fully understood. The Working Group therefore recommends that:

- Studies should be conducted in animal models for various skin tumours to determine the carcinogenic protection factors based on ratios of the doses of UVR required to reach identical end-points. Squamous-cell carcinomas can be studied in existing models, but models are required for basal-cell carcinomas and cutaneous melanoma.
- Studies should be conducted on the effects of exposure to UVA in causing both photageing and skin cancer.

If it is assumed that sunscreens have some role in preventing skin cancer, the efficiency of sunscreen delivery should be increased and evaluated, and the effectiveness and safety of sunscreens should be increased. Therefore the Working Group recommends that:

- Sunscreens should be developed that by virtue of their content, consistency and ease of application achieve adequate protection against UVR when in common use.
- The most effect formulations of sunscreens should be determined by conducting research into optimal active ingredients, their distribution on the skin and the best spectral profile in terms of spectra and wavelength interactions.
- Studies should be conducted to determine whether sunscreens that provide much greater protection against UVR are required.
- Methods should be developed to discriminate between phototoxicity and photoprotection when these occur simultaneously with sunscreen use, for example, by use of a carrier that prevents skin contact, to assess the effect of UVR absorption alone.
- Studies should be conducted (or published if already conducted) to determine the carcinogenic risk of inorganic sunscreen ingredients.
- Studies should be conducted not only of single UVR filters but also of combinations of active ingredients in complete formulations. Such studies should include relevant controls, such as exposure to UVR through the vehicle.
- Studies should be conducted to define the role of free radicals and active oxygen intermediates in solar UVR-induced damage, mutation, photoageing and carcinogenesis, and the usefulness of adding free-radical scavengers to sunscreens should be assessed.
- Studies should be conducted to investigate the nature of endogenous antioxidant defence systems relevant to exposure to solar radiation, including genetic determinants, to provide a rationale for selection of sunscreen components.

The theoretical potential of sunscreens against skin cancer is probably reduced by failure to use them effectively. Further evaluation of the behavioural aspects of sunscreen use is therefore desirable. The Working Group recommends that:

- The place of sunscreens in the context of overall protection against the sun should be defined, and studies should be conducted to define the best ways of conveying this understanding to the public.
- Educational strategies should be devised to train people who expose themselves intentionally to the sun to use sunscreens as only one part of a sun protection strategy.
- Studies should be conducted to evaluate whether qualitative rating of the potential protective function of sunscreens against UVR, such as low, medium, high and ultra-high, rather than SPF, would improve use of sunscreens.

Many of the studies recommended above cannot be conducted effectively unless qualitative and quantitative methods are developed for measuring sunscreen use and the major variables confounded with it, namely sun sensitivity and sun exposure. Therefore, the Working Group recommends that:

- Methods should be developed to increase the accuracy of measures of use of sunscreens and of individual cutaneous sun sensitivity and sun exposure.
- Portable instrumentation should be developed to measure, in the field, how much protection is provided by sunscreens at various sites on the skin.

## Recommendations for public health action

- Protection of the skin from solar damage ideally involves a number of actions which include wearing tightly woven protective clothing that adequately covers the arms, trunk and legs, a hat that provides adequate shade to the whole of the head, seeking shade whenever possible, avoiding outdoor activities during periods of peak insolation and use of sunscreens. Sunscreens should not be the first choice for skin cancer prevention and should not be used as the sole agent for protection against the sun.
- Sunscreens should not be used as a means of extending the duration of solar exposure, such as prolonging sunbathing, and should not be used as a substitute for clothing on usually unexposed sites, such as the trunk and buttocks.
- Daily use of a sunscreen with a high SPF (greater than 15) on usually exposed skin is recommended for residents of areas of high insolation who work outdoors or enjoy regular outdoor recreation. Daily use of a sunscreen can reduce the cumulative solar exposure that causes actinic keratoses and squamous-cell carcinoma.
- Adequate solar protection is more important during childhood than at any other time in life, and the first two recommendations should be assiduously applied by parents and school managers.
- In view of the widespread use of sunscreens, even on children, stringent evaluation of their safety is necessary, particularly with regard to long-term effects. Data on the safety evaluation of sunscreens must be in the public domain so that they are available for independent scientific evaluation.
- Sunscreens should be subject to the same regulatory safety requirements as medicines.
- Once the optimal method for specifying protection against broad-spectrum UVA has been agreed, a labelling method should be introduced that is internationally congruent and understandable to the public.
- Advertising for sunscreens should promote a global sun protection strategy (see first recommendation). Advertising should avoid promoting sunscreen use for intentional exposure to the sun (e.g. acquisition of a tan), and avoid messages likely to provide a false sense of security for people using sunscreens.
- Health promotion interventions should be designed to increase the appropriate and effective use of sunscreens by the general public and subgroups at particular risk for skin cancer because of their phenotype or a predisposition to intentional solar exposure.
- A warning should be displayed on bottles of sunscreens informing consumers of the second recommendation.