

The health effects of using solarium and potential cost-effectiveness of enforcing solarium regulations in Australia

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Acronyms

AIHW	Australian Institute of Health and Welfare
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
BCC	Basal cell carcinoma
CFR	Case-fatality rate
CI	Confidence interval
CIE	Commission Internationale de l'Éclairage
GP	General practitioner
IARC	International Agency for Research on Cancer
ICNIRP	International Commission on Non-Ionising Radiation Protection
MED	Minimum erythemat dose
NMSC	Non-melanocytic skin cancer
PBS	Pharmaceutical Benefits Scheme
QIMR	Queensland Institute of Medical Research
RR	Relative risk
SCC	Squamous cell carcinoma
SED	Standard erythemat dose
SPF	Sun protection factor
UK	United Kingdom
US	United States
USFDA	United States Food and Drug Administration
USFTC	United States Federal Trade Commission
UVA	Ultraviolet radiation in the A wavelength band (315-400 nm)
UVB	Ultraviolet radiation in the B wavelength band (280-315 nm)
UVC	Ultraviolet radiation in the C wavelength band (100-280 nm)
UVR	Ultraviolet radiation
WHO	World Health Organisation

Executive Summary

In line with several leading international organisations, there is growing concern about the Australian solarium industry among the state Cancer Councils and other health agencies, due to increased patronage of solaria and the associated risk of skin cancer. Following a recent intense period of media attention on this issue in Australia, this report has been generated to investigate the health effects of solaria use and to estimate the costs and benefits to the Commonwealth Government should they decide to fortify existing regulatory controls of the industry.

The actual size of the solaria industry is unknown and difficult to quantify though recent audits have shown that solarium businesses have at least quadrupled since 1992 and that Victoria has seen the largest growth. Compared to the situation outside Australia, the prevalence and frequency of the general population's usage of solaria is fairly low (approximately 0.6-3.0%). However, the prevalence of use among adolescents and females is higher with one study showing 12% of NSW school children had used solaria. At this time, we know little about the change of solarium usage over time, or of consumer patterns and predictors of use. However, the increased supply of these services is partly reflected in their increased demand. Studies indicate that the level of compliance with the Australian/New Zealand Standard on Solaria for Cosmetic Purposes (AS/NZS 2635:2002) within the market is poor to many behavioural elements of the Standard, including prohibiting individuals with skin type I, obtaining parental consent for youths under 18 years and obtaining consent from every consumer prior in regard to use. Compliance with the technical elements of the Standard is unknown (i.e., sunlamp emission intensity, replacement of ageing lamps, operator training levels). Based on overseas trends, the level of ultraviolet (UV) emissions in the UVB waveband from sunbeds is likely to be in the range of 4-6% of the total UV emissions from the sunbed, or similar to that of solar UVB.

Ultraviolet radiation (UVR) is the principal causative factor of malignant melanoma and keratinocytic skin cancers. Both UVB and UVA wavelengths are classified as carcinogenic to humans by world health authorities. Australia has among the highest ambient UVR levels in the world with most States having more intense UVR in winter than in a European summer. Australia also has the highest rates of skin cancer in the world with over 9,500 new cases of melanoma diagnosed in 2003. Melanoma incidence has increased rapidly by approximately 40% from 1993-2003, the highest increase of any cancer in Australia. The change in the incidence of keratinocytic skin cancers since 2002 is unknown, but is also likely to have increased. Skin cancer is the most expensive cancer to treat in Australia and costs are continuing to rise rapidly in real terms. The known treatment costs to the Government are likely to be a fraction of all costs for the treatment of sun-damaged skin through Medicare Australia.

It is of particular concern that the additive effect of Australians using artificial UVR against already intense levels of solar UVR (i.e., 'photoaddition') will mean that the existing high burden of skin cancer will increase. There is compelling evidence that individuals who use artificial indoor tanning devices will increase their risk of skin cancer. Results from a meta-analysis of 21 studies investigating the association between solarium use and risk of skin cancer show an increased

risk for developing melanoma (by 22%) and squamous cell carcinoma (by 78%), an increased risk of melanoma for first users under 35 years (by 98%) and for women (by 71%). The risk also appears to be increased for basal cell carcinomas (18%), although these latter findings were inconclusive.

Using a crude mathematical model combining data parameters for solar and artificial UVR doses, population prevalence of indoor and outdoor tanning, and melanoma mortality and incidence figures, we estimated that currently the number of new cases of melanoma attributable to indoor tanning devices is in the range of 12-62 per year. In terms of mortality, less than 1% of all UVR-caused melanoma deaths would be attributable to solarium use (or approximately 1-7 melanoma deaths) each year.

A decision-analytic model was created to project the future cost and health effects comparing current solaria practice with enforcing solarium regulations, based on the current Standard, thereby effectively restricting youths under 15 years and prohibiting persons with skin type I. The health effects were measured in terms of new cases of melanomas and squamous cell carcinomas (SCCs), life years gained and life years lost due to premature melanoma mortality. The costs were limited to those incurred by Medicare Australia for the diagnosis, treatment and care of individuals with skin cancers.

If the Government were to regulate the industry, we estimate that around 20-35 melanomas and 240-320 SCCs would be avoided and 35 life years gained per 100,000 persons. The corresponding cost-savings generated from avoided health care costs are expected to be approximately \$300,000 per 100,000 persons. For all young Australians, we could expect that over their lifetime, over 1,000 melanomas and 12,000 SCCs would be avoided and at least \$12.2 million would be saved. These estimations are sensitive to the relative risk estimates for skin cancers and solarium use and discount rates.

In summary, there are strong arguments for government intervention in the solarium market to ensure that health risks are minimised and solaria practices are monitored. There is clear evidence that solarium users are increasing their risk of skin cancer. Reports indicate that there is market failure in this industry as operators are unaware of and/or failing to comply with the voluntary code of practice which aims to minimize these increased health risks. Given the huge burden imposed by skin cancer in Australia now, growth in the solaria industry will inflate this human and economic burden in years to come. Results from a cost-effectiveness analysis suggest that by enforcing solaria regulations the government can expect favourable cost and health benefits.

1. Introduction and Objectives

1.1 Introduction

The largest source of ultraviolet radiation (UVR) to which we are exposed is the sun, but there are individuals who further expose themselves to UVR for cosmetic purposes through the use of artificial indoor tanning devices, also known as sunbeds, sunlamps or solaria. These tanning devices may be purchased by individuals for home use or commercial businesses may offer indoor tanning services such as sole-operating solaria, hairdressing and beauty salons and fitness clubs.

The recent and highly publicised death of a young Victorian woman and solarium consumer, Clare Oliver, has drawn attention to the solaria industry in Australia and the increased risks of skin cancers as a result of exposure to artificial UVR. Cancer Councils and other health agencies around Australia have called for tighter controls within the industry to ensure that consumers are fully aware of the risk they take when using a solarium and that solaria operators comply with the current voluntary Australian/New Zealand Standard (AS/NZS 2635:2002) on Solaria for Cosmetic Purposes¹.

The increased skin cancer risk among users of solaria has been an international concern for a number of years. In 1994, the World Health Organisation (WHO) released findings from a review stating that there are adverse health effects associated with sunbed use². The findings from the WHO have been supported by other key authorities, including the Commission on Non-Ionizing Radiation Protection³, the National Toxicology Program of the US Department of Health and Human Services⁴, the UK National Radiological Protection Board⁵, the National Health and Medical Research Council of Australia⁶ and EUROSkin⁷. This was followed by further guidance from the WHO in 2003⁸ reinforcing the dangers of sunbeds and the need for government regulation of the industry. In 2006, the Scientific Committee on Consumer Products, a branch of the European Commission, adopted the position that *'the use of UVR tanning devices to achieve or maintain cosmetic tanning, whether by UVB and/or UVA, is likely to increase the risk of malignant melanoma of the skin and possibly ocular melanoma'*⁹. In the US there has been a gradual tightening of restrictions on the solarium industry across the states¹⁰ as policy makers become aware of the potential risks of sunbed use and the characteristics of those seeking a tan.

1.2 Aim and Objectives

The overall aim of this report is to answer the following question:

What are the expected costs and benefits to the Federal Government for regulating the solarium industry in Australia?

The specific objectives were:

1. To assess the level of compliance with the current Australian Standard (AS/NZS 2635:2002) by solarium operators within Australia.
2. To assess the health effects of solarium use with a focus on the main health risk of skin cancer.
3. To undertake quantitative assessments using computer modelling to answer the two questions:
 - What is the estimated annual number of deaths from melanoma attributable to indoor tanning in Australia?
 - What is the potential cost-effectiveness in the long-term of regulating solarium in Australia?

1.3 Structure of report

Chapter 2 of this report addresses Objective 1, provides an overview of the solarium industry in Australia and report on the popularity of solarium use within Australia and internationally. The current Australian Standard (AS/NZS 2635:2002) on Solarium for Cosmetic Purposes (hereafter called 'the Standard') is discussed along with the reasons for government intervention and finally, the evidence for compliance of the Standard by solarium operators. The health effects of UVR are presented in Chapter 3 and incorporate both the beneficial and harmful effects of UVR. The adverse health effect of skin cancer is a focus of this report and the chapter closes with an outline of the burden of skin cancers in Australia and their known risk factors. Chapter 4 addresses Objective 2 and the evidence on health effects from solarium use is presented. A systematic review of solarium use and the risk of developing skin cancer comprise the bulk of this chapter with results from a quantitative meta-analysis reported and discussed. Chapter 5 addresses the first question of Objective 3, and covers the methods, results and conclusions drawn from a mathematical model that estimates the number of melanoma deaths per year that is attributable to solarium use. Chapter 6 follows with a second modelling exercise that assesses the potential costs and consequences of choosing to regulate solarium use in Australia in the longer term. Methods involved in deriving the data parameters used for the analysis are presented and justified. Chapter 7 provides the report conclusions and recommendations for consideration.

1.4 Definitions of key terms

'Basal cell carcinomas' (BCC) are the most common form of skin cancer which develops on the sun-exposed areas of the body. It is rare for these cancers to spread beyond the affected site (e.g., lymph nodes or distant parts of the body).

‘Cost-effectiveness analysis’ in health care is an assessment of the resources and health effects of a particular health intervention compared with another option (or many options).

‘Erythema’ is the medical term for reddening of the skin or sunburn.

‘Erythemally effective UVR’ is the level of emission in each wavelength weighted by the biological action spectrum¹¹ and are used to determine the biologically effective UV dose (given in W cm^{-2}) per hour.

‘Keratinocytic skin cancers’ refer to squamous cell carcinomas and basal cell carcinomas. Keratinocytes are the main types of cells in the skin’s epidermis from which squamous and basal cell cancers arise. Although squamous and basal cell carcinomas have traditionally been called non-melanoma skin cancers, this latter term is non-specific and strictly encompasses other more rare skin cancers (e.g., Kaposi sarcoma, Merkel cell carcinoma) in addition to squamous and basal cell carcinomas.

‘Minimal Erythmal Dose’ refers to the minimum dose of UVR required to elicit erythema (sunburn) in a person of a specific skin type.

‘Squamous cell carcinomas’ (SCC) are the second most common form of skin cancer. SCCs commonly appear on the sun-exposed areas of the body such as the face, ear, neck, lip and back of the hands. These cancers are more aggressive than basal cell carcinomas and can metastasize to lymph nodes or distant parts of the body.

‘Solaria’ refers to all forms of artificial tanning devices that are used for cosmetic tanning purposes and includes, among others, sunbeds, sunlamps and stand-up tanning booths.

‘Sun Protection Factor’ (SPF) is a laboratory-derived rating system of protection from erythema by sunscreen. The SPF number is the multiple by which a dose of UVB causes minimal erythema in human skin.

‘Ultraviolet radiation’ (UVR) is a non-visible high energy component of the electromagnetic spectrum and is emitted primarily from the sun.

‘UVA, UVB, UVC’ are the three common categories of UVR defined by their relative wavelength band; UVA (315-400 nm), UVB (280-315 nm) and UVC (100-280 nm). UVC is the most dangerous UVR type and is filtered out through the earth’s atmosphere. UVB is received in small proportions (4-6%) while UVA comprises the majority of solar UVR.

‘the Standard’ is used throughout this report and refers to the current Australian/New Zealand Standard on Solaria for Cosmetic Purposes (AS/NZS 2635:2002). This is a voluntary code of practice for operators and users of solaria in Australia and New Zealand.

2. Solaria in Australia

2.1 Introduction

Sunbeds or tanning lamps are devices that emit artificial ultraviolet radiation. Individuals expose their skin to the radiation for the purpose of inducing a tan while indoors for cosmetic reasons. These devices are most commonly found in solarium businesses, but also in a variety of other settings such as fitness centres and beauty salons, and even video shops and supermarkets¹². Tanning devices are generally sunbeds (coffin design), stand-up tanning booths, or lamps (similar to an over-sized desk lamp). These can either be purchased for home use or accessed at a solarium or other tanning device provider. Modern devices can include features such as surround sound audio and aromatherapy.

The first use of artificial UVR was at the beginning of the 20th Century as a means to treat tuberculosis and other infectious diseases¹³. Exposure to the sun as beneficial to children was encouraged by the medical profession in 1930s and 1940s. It was around this time that a suntan for cosmetic purposes was popularised by the French fashion designer Coco Chanel¹⁴.

The first indoor tanning beds emitted primarily UVB with some UVC radiation, and had numerous safety problems¹⁵. The development of high intensity artificial UVA radiation for medical purposes quickly spawned UVA tanning beds in commercial salons. These were (and often still are) advertised as 'safe tanning' devices because they contained none of the 'burning' UVB radiation¹⁴. However, no tanning device has ever emitted pure UVA; some UVB has always been present¹⁴. In 2007 a study from the UK found an uptake of new 'fast-tan' sunlamps that contain a higher proportion of emissions from UVB, above that set by the European Standard¹². The carcinogenicity of these lamps was found to be 1.15 times that of the southern European sun¹².

A literature review has been undertaken firstly to determine the prevalence of indoor tanning in Australia compared to international rates, and the level of compliance among solarium businesses to the recommendations in each country. This chapter presents the available data on the size of the solarium industry in Australia, followed by the prevalence of solarium use internationally and in Australia. An outline of the Australian/New Zealand Standard on Solaria for Cosmetic Purposes is provided followed by the case for government intervention in the solarium industry. The results from the literature review on compliance in Australia and internationally are then discussed.

2.2 How many solarium businesses are there in Australia?

The true size of the solarium industry in Australia is unknown. In a 2006 audit of the scale of the industry in urban Australia, the number of telephone listings

for solaria in Australian capital cities was 406 (excluding Hobart) and had increased nearly four-fold since 1992, with the highest growth of over 600% seen in Melbourne¹⁶. However, it was suggested that that number of solaria listed in the telephone directory is a gross underestimate of the actual numbers of solarium operators in Australia because this is likely to represent sole-operators only¹⁷. In addition to this, the audit also excluded establishments such as beauty salons and fitness centres that do not have a listing under Solarium/Tanning Centres. A sample of these establishments found that 8% of beauty salons and 11% of fitness centres had sunbed facilities available¹⁶. As part of a regulatory framework, it would be important to monitor the size of the industry as this reflects the level of demand for indoor tanning.

2.3 International popularity of solaria

More research on the popularity of solarium use is available for Europe and the US than for Australia, hence it is useful to understand the extent and consumer characteristics of solarium users reported within the global literature (see Appendix A). Tanning practices differ between countries with estimates of artificial UVR exposure for cosmetic purposes varying significantly. Sweden has the highest prevalence of use with up to 28% of people aged 13-50¹⁸ being current users and this rate is even higher among women. In 2005, a systematic review by Lazovich and Forster¹⁹ identified nine studies from the US²⁰⁻²⁸ and six from Europe^{18,29-33} and found between 24-30% of youth aged between 13-19 years had ever used artificial UVR for cosmetic purposes and 8-12% were frequent users. The review found that girls were two to three times more likely than boys to use artificial UVR.

Cultural attitudes towards tanning, such as tans being attractive or healthy have been associated with use of artificial UVR²³⁻²⁵. Studies have found that the individuals using solaria are more likely to have a limited decision-making ability²², be more depressed²⁵, have lower perceived attractiveness²⁹ and less satisfaction with oneself³¹ or appearance²⁵ compared with non-users. Other social factors have also been found to be associated with the use of artificial UVR. Having a high proportion of friends who use indoor tanning devices or having parents that allow indoor tanning or do so themselves have been strongly correlated with artificial UVR tanning among adolescents²³⁻²⁶ even after adjusting for individual attitudes and psychosocial factors in multivariate models. Prevalence of artificial UVR tanning among adolescents with none of the risk factors just mentioned was 9%, whereas it was 78% among those adolescents with all the risk factors. Other studies in the US and Europe have also found an increased prevalence of use (either 'ever use' or 'recent use') among older adolescents and young adults than in other age groups³⁴⁻⁴⁰.

2.4 Prevalence of solarium use in Australia

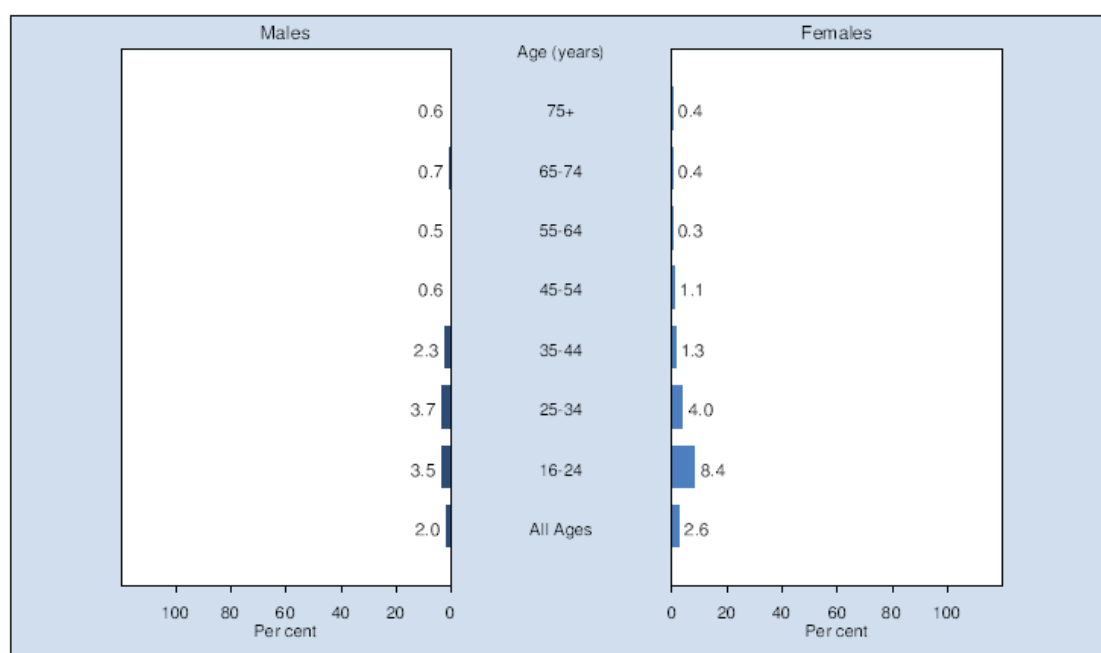
The prevalence of artificial UVR in Australia has been studied less thoroughly than the US or Europe, but existing results show a far lower rate of artificial UVR exposure than in other countries⁴¹⁻⁴⁵. A media release from the WA

Cancer Council in 2004 claimed that over 290,000 Australians have been exposed to UVR from solariums⁴⁶. In an earlier study, a representative household survey of 601 Victorians in 1999⁴⁴ found that 9% of people aged 14-29 had used a solarium in the past 12 months. This fell to 2% in the 30-49 age group. Overall, 3% of Victorians surveyed had used a solarium in the past 12 months. In a similar survey of 1,426 Victorians several years later⁴², it was again found that 3% of survey respondents in Victoria had attended a solarium in the past 12 months, suggesting that usage rates were keeping pace with population growth. Of those who had attended a solarium, 57% had attended more than five times during the last 12 month period. There also appeared to be a higher prevalence among females, although the low prevalence of use weakened statistical analysis.

A 2006 study of solarium use in 9,298 Queenslanders⁴⁷ found that less than 1% of respondents had used a solarium in the past 12 months, although around 9% had ever used a solarium. Again, the results indicated that people exposing themselves to artificial UVR were more likely to be female and younger than 40. The study also found that more than one third of solarium users attended tanning sessions at least once per week.

In the *2005 NSW Health Survey Program*, of 11,241 survey respondents it was found that around 2% of the population had attended a solarium in the past 12 months, the largest group being those aged 16-24 (6%). Figure 1 shows the concentration of artificial UVR exposure in younger age groups and higher prevalence of use among females. The survey also found that among solarium users (n=170) around 60% had attended between 1-5 times during the past year, about 19% of female users had attended between 6-10 times per year, with 12% of male users and 6% of female users attending more than 25 times per year.

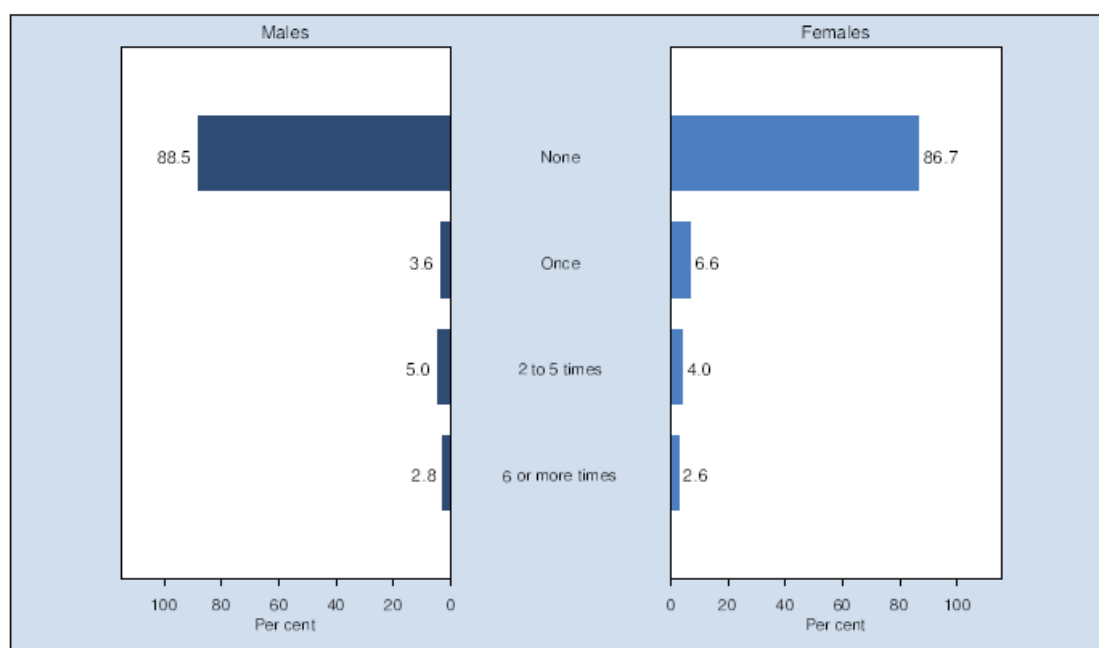
Figure 1. Proportion of NSW population having attended a solarium in the past 12 months (2005)⁴¹



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Another part of the *NSW Health Survey Program* was the *NSW School Students Health Behaviours Study*. In 2005 the survey included 120 schools with more than 100 students: 61% of these were State Schools, 23% Catholic and 19% independent. The ratio of males to females in the study closely matched the population ratio. English speakers at home made up 82% of the sample and 15% spoke English and another language at home. Aboriginal and Torres Strait Islander backgrounds were reported in 3% of the sample. The survey included a wide range of health and lifestyle related questions, including the use of indoor tanning devices in the past 12 months. The survey found that among 2,618 school children, use of solaria in the past 12 months was alarmingly high at 12%. The biggest users were females aged 12, with a prevalence of use of over 20%⁴⁵. Again, while the prevalence of use among females was higher, the frequency exposures were higher among males as Figure 2 shows.

Figure 2. Frequency of solarium or sunbed use in the past 12 months among NSW school students aged 12-17 (2005)⁴⁵



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2.5 The Australian/New Zealand Standard on Solaria for Cosmetic Purposes (AS/NZS 2635:2002)

Australian Standards are developed in collaboration with committees of experts from industry, governments, consumers and other sectors. The general intent of the Standard on Solaria for Cosmetic Purposes is to provide a guide for setting up and operating artificial tanning equipment primarily in commercial facilities. The over-riding purpose of the Standard is to provide operators with procedures that will minimize the health risk associated with indoor tanning. The Standard assumes that all tanning units are performing

according to their respective manufacturers' specifications and it does not cover coin-operated sun-tanning equipment. It may also be used as a guide for operation of sun-tanning equipment for home use. The key components of the Standard may be viewed in terms of either behavioural and technical elements, though these are intertwined throughout the Standard.

Behavioural elements of the Standard:

- prohibit the use of solaria by persons under the age of 15;
- require parental consent for persons under the age of 18;
- exclude people with fair skin (skin type I¹) from using solaria;
- require a signed and dated client consent form for all eligible users (a template is provided in the Standard);
- require at least 48 hours between repeat exposures and such exposures can not exceed 3 Minimum Erythematol Doses per week;
- require the provision and use of protective goggles at all times;
- impose maximum exposure times according to skin type (formulas to calculate these are provided);
- require operators to be trained in the: 1) requirements of the Standard, 2) assessment of skin types and exposure times, 3) screening of exposure limiting conditions, 4) emergency procedures in case of over exposure to UVR, 5) types and wavelength of UV light and 6) hygiene protocols;
- require operators to supervise users at all times;
- require operators to be able to terminate the tanning session at any time at a central control station;
- require users to be able to terminate the session at any time through means within easy reach of the unit;
- do not allow claims of non-cosmetic health benefits of solaria to be used in their promotion;
- require all surfaces of a sun-tanning unit subject to body contact must be disinfected;
- require warning notices with certain specifications to be clearly displayed; and
- limit one person in the unit or immediate enclosure at any time.

Technical elements of the Standard require:

- installation and use timing devices;
- protective screening, mechanical (to prevent knocking and/or breaking of the UV lamp) and UVR (to ensure all direct UVR is contained within the space occupied by the user);
- lamp emission restrictions to a maximum intensity of 1.5 W/m² of erythemally effective UVR;
- lamps must be replaced at the end of their useful life;
- each tanning unit to be on a separate circuit breaker;
- at least one hand grip or other support mechanism to be installed for upright (standing) tanning units and;
- no detectable radiation with wavelengths below 290nm (approximately the UVC upper limit).

1. The skin phototypes referred to in the Standard (and broader literature) are summarised in Table 1

Table 1. Skin phototypes⁴⁸

Phototype	Reaction to sun exposure ^a
I	Always burn, never tan
II	Burn slightly, then tan slightly
III	Rarely burn, tan moderately
IV	Never burn, tan darkly
V	Oriental or Hispanic skin
VI	Black skin

^a specifically, a 30 minute direct exposure after a long period of no sun exposure (eg. First exposure to sun in spring)

In 2004, the Australian Government Radiation Health Committee issued a position statement that encouraged compliance with the Standard (http://www.arpana.gov.au/pubs/rhc/sol_rhc_04.pdf), however, at the present time, the Standard is undergoing review. In comparison with similar recommendations made by the WHO and the International Commission on Non-Ionizing Radiation Protection, the Australian Standard is less stringent because it allows individuals under 18 years to use solaria; it allows individuals with skin type II to use solaria; and requires no maximum level of sessions per year⁴⁹. Furthermore, confusingly, the Standard states there should be no detectable radiation at wavelengths below 290 nm (i.e., the UVC wavelength category of 100-280 nm) but also states that UVC is permitted (though in a very small dose) in Section 2.1.2: '*The erythema effective irradiance of ultraviolet lamps in the wavelength range 200 nm to 290 nm shall be not greater than $1.0 \times 10^{-5} \text{ W/m}^2/\text{nm}$* '.

2.6 Market failure and government intervention

Conventionally, governments intervene in an industry when it is deemed that market failure is occurring. There are various sources of market failure, including excessive transaction costs, externalities, asymmetric information and the provision of public goods. An externality occurs when a decision causes costs or benefits to third party stakeholders. In other words, the participants in the transaction do not bear all of the costs or reap all of the benefits of the transaction. In a competitive market, this means too much or too little of the goods may be produced and consumed in terms of overall cost or benefit to society. Information asymmetry is present when one party to a transaction has more information than the other party. By definition, public goods are goods that are non-rivalrous and non-excludable by nature. In other words, the consumption by one person does not reduce or prevent the consumption of the good by another person. This feature makes the provision of public goods a government domain due to the impossibility of efficient markets forming for the good.

The promotion of solaria as sources of non-cosmetic health benefits and the lack of awareness of health risks posed by UVR and solaria are both possible cases of information asymmetry, since the provision of information on the health effects of UVR are a public good. In this context, intervention by government may be required⁵⁰. A summary of the key components of information asymmetry between the solarium industry and health interest groups are compiled in Table 2. This information has been derived from recent media reports and internet information.

Table 2. Summary of the key controversies on health effects from solarium use

Claims from the solarium industry	Responses from the health industry
Indoor tanning is safer than outdoor tanning because sunbeds contain only UVA which does not cause skin cancer.	There is growing evidence UVA is implicated in the development of skin cancers. UVB is still emitted from sunbeds to produce a more lasting tan.
Indoor tanning is safer than outdoor tanning because it is 'controlled' and 'responsible' tanning which avoids sunburn.	Sunburn still occurs in solarium users. Solarium users can sunbathe outdoors before and after indoor tanning or attend multiple solarium businesses. There is no way of knowing or controlling an individual's cumulative UVR exposure over a set time period.
Pre-holiday tans are a good idea to get your skin protected from subsequent outdoor UVR while on holiday.	Tans can be induced by UVA and UVB. A UVB induced tan gives a SPF of 2-3 while UVA tans SPF of 0. There is very little protection from a pre-holiday tan.
Not all UVR is bad for you, there are positive effects too like obtaining vitamin D.	No tanning is safe – all UVR causes damage at a cellular-level. Active individuals should obtain sufficient UVR levels for vitamin D synthesis in their everyday activities without needing to use a sunbed.
For every study that says solarium use contributes to skin cancer, another one can be found that refutes this.	UVA and UVB are listed carcinogens by WHO. Solaria are a source of UVA and UVB and therefore it is likely to contribute in the development of skin cancers.

In 2005, Canada's largest sunbed provider achieved an agreement that allows providers to advertise the vitamin D benefits from sunbed use if the tanning equipment emits UVB irradiance⁵¹. It is possible that this agreement may set a precedent for allowing solaria in other countries to promote health benefits from using artificial UVR.

Studies have shown that younger people are particularly price-sensitive to tobacco products (for first use) and it is possible that the same could be true for indoor tanning¹⁹ however solarium use differs from smoking in that it is not an addictive substance. Also, due to their providing a luxury good, solaria are more likely to be used by individuals of higher socio-economic status. There are arguments for imposing an excise or product-specific tax on solaria for the dual purpose of consumption restriction and revenue generation, whereby revenue can be used to fund skin cancer awareness campaigns^{19,52}.

However there are economic arguments against such taxes. Administrative costs of imposing taxation in relation to the size of the industry in Australia would be excessive. Furthermore, tying taxation revenue to specific spending programs also incurs further administrative costs that should be avoided. Any education campaigns or expenditure more generally should be evaluated and funded appropriately from general revenue. Economic theory also suggests that deadweight losses occur where taxes are used, that is, that a portion of the benefits from trade are lost. It is also argued that restricting consumption and generating revenue from taxation are incompatible goals, where the success of one implies the failure of the other. It is also often the case that taxation may result in an inequitable distribution of resources depending on the demographic profile of consumers. However, the burden of taxation on solarium use, a luxury good, would fall most heavily on the older and wealthier age groups who are less price-sensitive. Despite the arguments for taxation, it is not recommended that taxation be used as part of any mandatory regulations.

2.7 Evidence of solarium industry compliance with the Standard

The degree to which solarium operators comply with the Standard has been the focus of five studies in Australia^{46,47,49,53,54}. A NSW study by Paul *et al.* (2005) found that the number of solariums complying with specific regulations ranged from 12% (informing the client of the supervision procedure) to 76% (recommending non-use by skin type I)⁴⁹. Dobbinson *et al.* (2006) in Victoria found only 10% of solariums prohibiting use by people with skin type I, 48% required a parental consent form to be signed for youths aged under 18 years and 87% required the use of protective eyewear⁵⁴. Lawler *et al.* (2006) found that only 43% people using a solarium in Queensland had signed a consent form⁴⁷. Of 22 tanning device websites, Team and Markovic⁵³ found that half made claims of non-cosmetic health benefits from artificial UVR, and 59% had no warning or precautionary information, with the remaining 41% offering incomplete or partial information.

Perhaps the most comprehensive study of solarium compliance with the Standard was undertaken by the Western Australian Department of Health in 2006⁴⁶. Two surveys of 50 metropolitan and rural tanning device operators were undertaken, one before and one after the target businesses were provided with educational information outlining the current Standard. The surveys revealed a significant lack of awareness and education about the Standard, and failure to comply with many elements of the Standard. Awareness of the Standard increased from 62% to 84% of solariums after educational material had been distributed. The largest improvement (from 22% to 68%) was the number of solariums displaying warning notices. Skin type monitoring fell from 98% in the first survey to 18% in the second, suggesting that one or both of these results was an anomaly. The requirement to wear goggles and the supervision of clients was either 100% or nearly 100% in both surveys. In the second survey, more premises had a copy of the Standard and had an increased awareness of the cancer risk from artificial UVR. Most

other elements of the standard had either a small increase or decrease in compliance (see Appendix B)

With only five published reports of compliance levels to the Australian Standard, it is inevitable that there are still considerable gaps in our knowledge about industry practice. For example, most of the studies address the key behavioural elements of the Standard (i.e., age restrictions, skin type restrictions, warning notices, wearing goggles) but we know little about the technical elements such as sunbed emission, intensity restrictions or replacement of ageing lamps. In addition, with regards to requiring the operators to be trained, there is little information available on the source or content of this training. Any proposed regulatory model which aims to monitor all elements of the Standard thoroughly, will need to address these issues.

2.8 International compliance studies

In relation to the few reports in Australia on solarium industry practices, it is useful to review the international situation. Numerous studies in the US, UK and Europe^{10,19,43,46,47,49,53-60} have investigated the level to which solarium operators comply with state or national laws. Dellavalle *et al.*⁵² found that in 2003 France was the only nation with a minimum legal age for tanning, while many other countries have adopted controls or considered regulating certain aspects of exposure to artificial UVR^{8,61}. In the US, the National Food and Drug Administration (USFDA) and the Federal Trade Commission (USFTC) both have policies that target the solarium industry. The USFDA regulations contain equipment standards and performance, instructions for users and warning signs and compulsory availability of protective eyewear. The USFTC prohibits advertising claims of health benefits and other deceptive advertisements¹⁹. In general, the overseas trend suggests that compliance with the relevant recommendations in these countries is comparable to that seen in Australia. For example, around 40% adhered to age restrictions^{10,55,56,59}, and 90-100% of solarium users wore protective goggles⁵⁵ (except in Poland, with around 40% requiring protective goggle use⁶⁰). It is also interesting to note that in a large UK study, roughly equal proportions of people with skin types I, II and III were using solarium⁶².

Solarium use in Australia - Key points

- The true size of the solarium industry is unknown but an audit in 2006 showed a four-fold growth in businesses across Australia since 1992 with the highest growth (600%) seen in Melbourne.
- Population-based studies suggest that the prevalence of solarium use in the previous 12 months is around 0.6% (Queensland) and 3% (Victoria) among persons of all ages.
- The prevalence of using solariums in the last 12 months among adolescents is higher than the rest of the population and in one study was 12% among 2,618 NSW school children (2005)⁴⁵.
- Adolescents and females are more likely to use solariums than other population groups.
- Industry compliance with the Australian/New Zealand Standard on Solariums for Cosmetic Purposes (AS/NZS 2635:2002) appears to be poor for many behavioural elements of the Standard including prohibiting individuals with skin type I, obtaining parental consent for youths under 18 years and obtaining consent from every consumer prior to use.
- Compliance with the technical elements of the Standard is unknown (i.e., sunlamp emission intensity, replacement of ageing lamps, operator training levels).

3. Health effects of ultraviolet radiation

3.1 Types of UVR

Ultraviolet radiation is a non-visible high energy component of the electromagnetic spectrum and is emitted primarily by the sun. Categories of UVR are classified by three common bands of wavelength, UVA (315-400 nm), UVB (280-315 nm) and UVC (100-280 nm)⁶³. In 1992, UVA and UVB were categorised as 'probably carcinogenic to humans' (Group 2A of the International Agency of Research on Cancer (IARC) classification of carcinogenic agents)⁶⁴. Prior to 1990, it was believed that only UVB was implicated in the development of skin cancers.

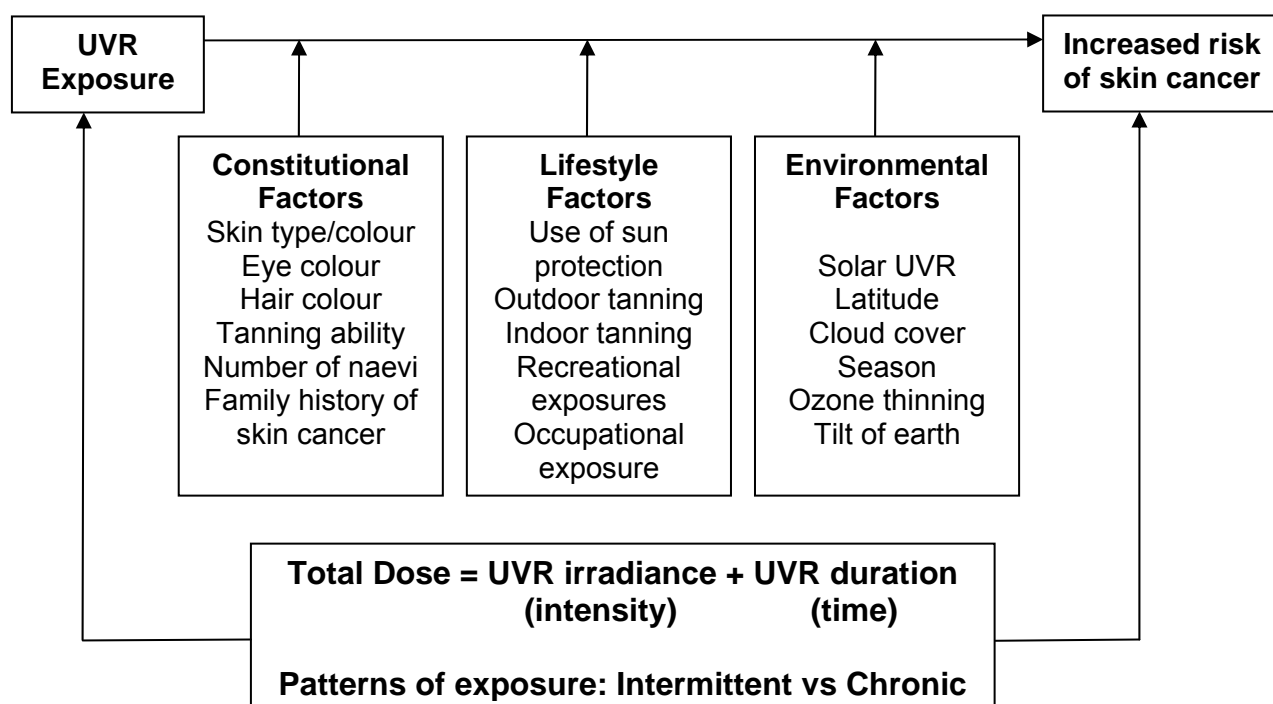
3.2 Ambient UVR levels in Australia

The earth's atmosphere filters out all of the very harmful UVC and a small amount of the UVA/B. However, Australia receives some of the highest levels of solar UVR in the world as a result of its proximity to the equator, the ozone depletion over Antarctica, the relatively clear atmospheric conditions and the earth's elliptical orbit of the sun bringing the southern hemisphere closer to the sun in January. These factors, combined with a predominantly fair-skinned population that evolved in high latitudes in the northern hemisphere, results in the highest incidence of skin cancers in the world⁶³. UVR levels in most Australian states are more intense in our winter than in the European summer⁶⁵. More information about UVR and protective measures is available from the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)⁶³ who closely monitor UVR levels around Australia.

3.3 Total personal UVR exposure

The relationship between a person's UVR exposure and risk of developing skin cancer, particularly BCC and melanoma, is very complex and difficult to quantify. This is due to the many possible known factors involved. These may be classified into personal, environmental and constitutional factors as illustrated in Figure 3. Solaria UVR exposure falls into recreational exposure and this is said to account for most personal exposure¹⁴. A person's total UVR exposure is a product of UVR irradiance and time, therefore, short bursts of intense UVR exposure could be equivalent in total dose to moderate UVR over a longer duration. The role of these patterns of UVR exposure per se play in causing skin cancers is still being studied.

Figure 3. The complex relationship between UVR exposure and risk of skin cancer



UVB is considered to be the major cause of skin cancers although UVA, which was previously thought to contribute primarily to premature ageing and wrinkling of the skin, has recently also been implicated in the development of skin cancers^{63,66}. Studies have shown that UVB is more effective than UVA at causing erythema^{11,67,68}, delayed pigmentation⁶⁹, cellular photodamage⁶⁷, and cis-urocanic acid production⁷⁰. The action spectra for immunosuppression in human skin are not available; while UVB is a known immunosuppressant, the role of UVA is not clear⁹. However, recent research suggests that UVA by itself and in conjunction with UVB has many powerful biologic effects on the skin¹⁴. The penetration of the skin of UVA is deeper than UVB and reaches the dermis, where the majority of histologic change occurs following a UVA burn. Burns from UVB are primarily epidermal⁷¹.

3.4 Maximum safe exposure

Clinical effects of UVR are either deterministic or stochastic. A deterministic effect such as erythema is related to the total dose and has a threshold at which erythema will occur. Therefore, it could be said that, theoretically, there is a 'safe' level at which tanning can occur without erythema. However, effects which are stochastic or cumulative and unrelated to a threshold value, cannot provide a maximal 'safe' dose as cellular damage is occurring at every exposure. Cancers such as SCC are an example of effects that are stochastic⁹, they develop from the cumulative effect of UVR exposure. In light of the data available, the risk of developing skin cancer from artificial UVR

exposure is high in comparison to the 'acceptable' risk level from other consumer products⁷².

3.5 Beneficial health effects of UVR

Infrared radiation from the sun is responsible for the heat felt on the skin, while visible light appears to have a positive effect on mood⁷³, seasonal affective disorder and depressive disorder⁷⁴. Artificial UVR in medical settings is also used to treat neonatal jaundice and dermatologic conditions such as psoriasis, eczema, and acne^{75,76}. The use of UVR for medical purposes generally uses UVB lamps or UVA plus psoralen.

3.5.1 Vitamin D

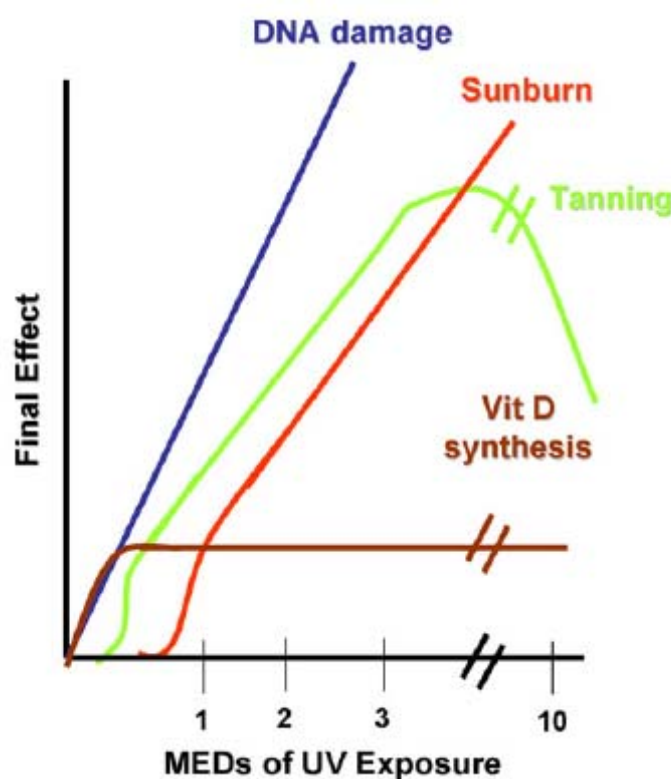
Vitamin D plays an important role in the maintenance of bone health, preventing the onset of rickets, osteoporosis and osteomalacia. The photosynthesis of 7-dehydrocholesterol with UVB in the skin produces pre-vitamin D₃ and the gradual thermal isomerisation of this compound yields vitamin D which slowly filters into the circulatory system. This is the mechanism whereby over 90% of our vitamin D is produced⁷⁷.

There is still considerable uncertainty in the published literature on many issues relating to vitamin D deficiency. This includes the precise measurement and thresholds of 'vitamin D deficiency', the photobiology of vitamin D formation in the skin, the precise effect of vitamin D synthesis in certain high-risk population subgroups, and the minimum amount of sunlight required for maintaining healthy bones⁷⁸. Until these fundamental issues are resolved, caution should be used when interpreting the growing body of published research into the alleged health effects from low levels of vitamin D.

Low levels of vitamin D are believed by some to play a role in the aetiology of certain cancers^{79,80}, schizophrenia⁸¹, and some immune disorders⁸². While the incidence of breast and colon cancer has been found to be associated with ambient UVR levels^{79,80}, socioeconomic status in some regions has been found to have a stronger association with breast cancer than ambient UVR⁸³. Some prominent media attention was given to studies finding a relationship between low vitamin D levels and colorectal cancer or other closely related diseases, despite other studies of similar size finding either the opposite or no relationship⁴⁸. In addition, a recently published prospective randomised placebo-controlled trial of vitamin D supplementation for 7 years or longer in 36,000 post-menopausal women found no relationship between colorectal cancer and vitamin D supplementation, total vitamin D intake, or amount of sun exposure⁸⁴. An Australian study in 2001⁸⁵ found between 37-67% in healthy populations had insufficient levels of vitamin D (≤ 50 nmol/L) in areas of moderate levels of ambient UVR. Despite the occurrence of vitamin D deficiencies in unlikely populations there still exists a wide gap between the sufficient UVR dose to synthesise vitamin D and the actual UVR dose that is most commonly received⁸⁶.

The conversion of 7-dehydrocholesterol to pre-vitamin D is balanced by the conversion of pre-vitamin D to inactive photoproducts, so that the concentration of pre-vitamin D reaches a maximum level after a relatively short exposure⁴⁸. Exposure to UVR beyond this low level (less than one MED) only results in further conversion of pre-vitamin D to inactive photoproducts⁸⁷. Figure 4 shows how maximum vitamin synthesis is reached before a tan or sunburn are induced. It also shows that vitamin D photosynthesis cannot occur in the absence of DNA damage. The degree to which a person can tan, burn and photosynthesise vitamin D is largely determined by their skin phototype (Table 1).

Figure 4. UVR dose-response relationships for sunburn, suntan, DNA photoproduct formation and vitamin D synthesis⁴⁸.



Permission to reproduce image granted by Dr B Gilchrest and the Journal of Steroid Biochemistry and Molecular Biology

It is clear that a balance is required to minimise harmful sun exposure and skin cancer risk but without compromising adequate vitamin D synthesis. Some people are at risk of vitamin D deficiency, such as the frail and elderly, and people who cover up their skin with clothing for cultural or religious reasons. It is recommended that these individuals seek advice from their doctors regarding having their vitamin D levels monitored and whether it is necessary to take oral Vitamin D supplements⁷⁸. It has been estimated that 6-12 minutes of winter sunlight, 3-4 times per week is sufficient to produce healthy levels of vitamin D in Brisbane compared with 51 minutes in Melbourne⁸⁸. Therefore, most Australians can achieve adequate vitamin D through incidental sun exposure with the possible exception of people living in

the Southern Australian states in winter⁷⁸. Further medical research is required on the optimal levels of vitamin D in different population groups and a study in this area, newly-funded by the NHMRC grant in 2008, should increase our knowledge in this area in the future.

3.6 Harmful health effects of UVR

There are three main types of skin cancers caused by ultraviolet radiation; melanoma, SCC and BCC. The risk factors involved in acquiring one or more these cancers includes ethnic origin, ambient sunlight at place of residence, migration to areas with a high incidence of skin cancers, skin type, lifetime total exposure, non-occupational exposure (i.e. recreational), history of sunburn and other sunlight-related skin damage. Conjunctival cancer and non-Hodgkin's lymphoma have also been associated the occurrence of melanoma and SCC⁸⁹. Between 68-97% of melanomas are caused by UVR⁹⁰.

In addition to skin cancer, some negative effects from exposure to UVR that contribute to the burden of disease include acute sunburn, reactivation of herpes labialis, photoageing, cortical cataracts^{91,92}, pterygium⁸⁶, photo-induced medication reaction, polymorphous light eruption, blistering, solar lentigines, atypical melanocytic lesions, exacerbation of porphyria⁹³, aggravation of lupus erythematosus and pemphigus⁹⁴, and local and systemic immunosuppression⁸². The suppression of cell-mediated immunity is thought to play a role in UVR-induced skin cancer and infectious diseases⁹.

3.7 The burden of skin cancer in Australia

Australia has the highest rates of skin cancers in the world. Melanoma is the 4th most common cancer in Australia with a total of 9,524 new cases of malignant melanoma diagnosed in 2003⁹⁵. The numbers of new cases of melanomas has increased 41% from 1993-2003, the highest increase of any cancer⁹⁵. Expressed as an incidence rate of 47 per 100,000 individuals, melanoma incidence has increased 14% since 1993. Melanoma claims over a thousand lives each year in Australia, and numbers have increased 34% since 1993⁹⁵. In persons aged 15-24, melanoma is the most common cancer and 215 persons within this age group are diagnosed with melanoma each year⁹⁶. However, generally the survival rates are very high with 90% of males and 95% of females with melanoma expected to live for at least 5 years⁹⁵. In Australia, an estimated 374,000 BCCs and SCCs were treated in 2002⁹⁷. This incidence is higher than for all other cancers together. Mortality from keratinocytic cancers are rare with 390 deaths recorded in Australia in 2003. Despite mortality being low, the morbidity from BCCs and SCCs can be significant with facial scarring, disfigurement, infection and pain being common side effects of treatment

There are many other types of skin cancers, such as Kaposi sarcoma, Merkel cell carcinoma and Bowen's disease, that occur less frequently but add to the

total skin cancer burden. National reports of cancer incidence in Australia do not systematically report data on skin cancers other than melanoma. In addition, solar keratoses (known commonly as 'sunspots') are among the strongest predictors of SCCs and are intermediate biomarkers of skin cancer⁹⁸. The prevalence of solar keratoses in Queensland is very high and in the 1990s was estimated at 55% of men and 37% of women with at least one solar keratosis on examination⁹⁹. Fewer than 1 per 1000 solar keratoses are thought to develop into SCCs.

3.8 Risk factors for melanoma and keratinocytic skin cancers

UVR has been established as the main environmental factor causing melanoma and keratinocytic skin cancers^{100,101}. Skin colour is an important determinant in the risk of melanoma, with figures showing that incidence rates are highest among pale-skinned populations living at low latitudes, such as Australia¹⁰². There is strong evidence about the role of constitutional risk factors in melanoma causation based on a solid body of research performed on this topic. The known risk factors for melanoma include:

- Fair skin that burns easily (i.e., skin type I)
- Green or blue eye colour
- Red hair colour
- Persons with many moles (common naevi; atypical naevi)
- Family history of melanoma

In a meta-analysis of 60 studies¹⁰³ it was concluded that skin type I (versus IV) was associated with a relative risk for melanoma of 2.1 (1.8-2.5), eye colour (blue versus dark) of 1.5 (1.3-1.7) and hair colour (red versus dark) of 3.6 (2.6-5.4). The numbers of common and atypical naevi was also found to be a significant risk factor for melanoma with a relative risk of 6.9 (4.6-10.3) for 101-120 common naevi compared to less than 15, and 6.4 (3.8-10.3) for five versus no atypical naevi¹⁰⁴. Studies have shown that naevus numbers are genetically determined¹⁰⁵⁻¹⁰⁷. It has also been shown that familial history of melanoma is associated with a doubling of risk for close relatives, with the strongest risk occurring where a parent has multiple melanomas¹⁰⁸.

The emerging view is that there are two main causal pathways to melanoma, one through intermittent exposure where having numerous naevi is a risk factor and the other through chronic over-exposure¹⁰⁹. UVR exposure, particularly intermittent exposure, remains the most predictive environmental risk factor for melanoma, with an estimated relative risk of 1.6 (1.3-2.0)¹¹⁰. Sunburn at any age is estimated have a relative risk of 2.0 (1.7-2.4) and increased risk has been associated with sunburn in childhood¹¹¹.

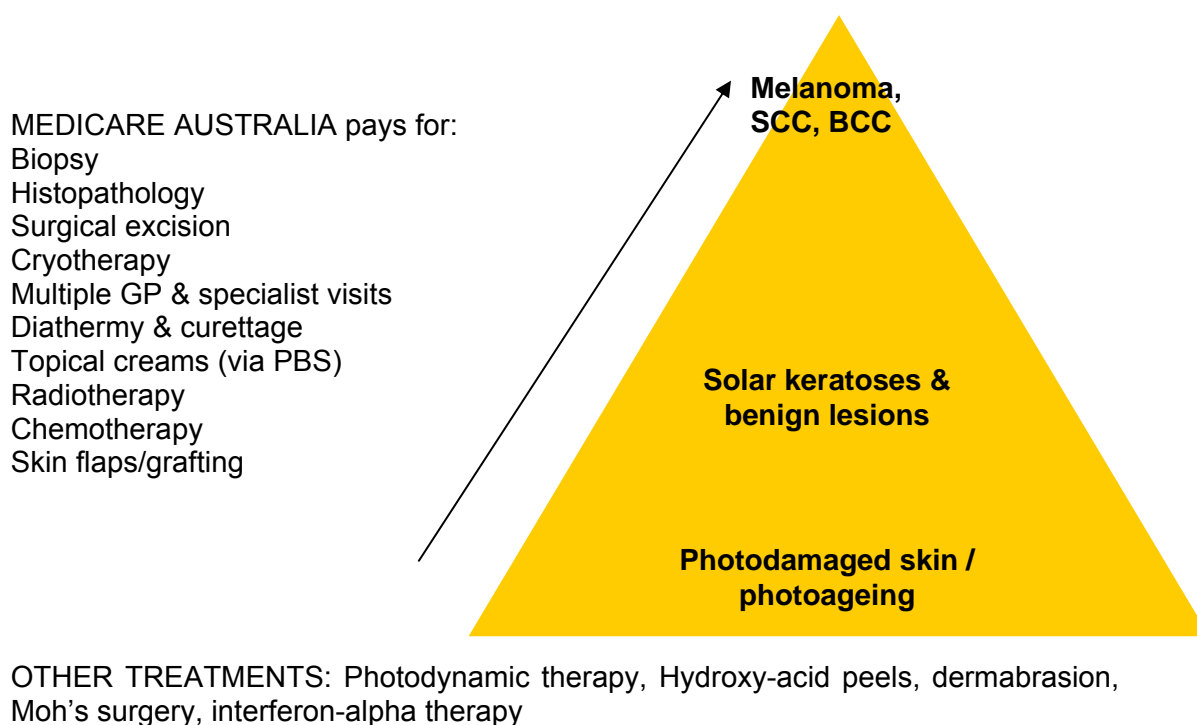
The key risk factors for SCC include chronic UVR exposure and presence of solar keratoses¹¹². Other risk factors contributing to a very small proportion of SCCs found in Australia include human papillovirus, arsenic, polycyclic aromatic hydrocarbons, chronic ulcers, sinus tracts and scars¹¹². Immunosuppressed patients and organ transplantation are also believed to increase a person's risk of BCC and SCC¹¹². The precise etiology of BCC is

unclear but UVR is considered to be the primary causative factor. The relationship between BCC and UVR is complex and unclear. Risk factors for BCC are similar to SCC however the few analytical studies available have produced inconclusive and inconsistent findings¹¹³. Unlike SCC, there is some evidence that BCC is associated with intermittent exposure¹¹⁴. Other risk factors for BCC include exposure to ionizing radiation therapy, arsenic and some dietary factors¹¹². Again, these factors contribute to only a small proportion of all BCCs in Australia.

3.9 Skin cancer costs to the Australian Government

Due to their very high incidence, BCCs and SCCs are the most expensive cancers to treat in Australia and were estimated to cost the health system \$264 million in 2000-01¹¹⁵. In the same year, melanoma treatment costs to the government were \$30 million. Increasing health resources are invested in Australia in the effort to prevent, diagnose and treat skin cancers. From 1993/94 to 2001/02, treatment expenditure rose in real terms by 24% for BCCs and SCCs and 56% for melanoma¹¹⁵. National reports of cost data are unavailable since 2002, however online Medicare Statistics data show that costs for standard BCC and SCC excisions alone have risen between 15-34% over 2000-2006. It is important to note that the cost of melanoma and keratinocytic cancers are likely to represent only a small fraction of all the resources consumed in the health system for UVR-damaged skin (see Figure 5). This is due to the ability of physicians to claim reimbursement through the Medicare Benefits Schedule for various treatments of all skin lesions (benign and malignant) and photodamaged skin. Some treatments for skin cancers are the same as for non-malignant lesions (i.e., cryotherapy, topical creams) and, despite being virtually harmless, they are draining vital health resources.

Figure 5. Pyramid of resource burden for UVR-damaged skin



Health effects of ultraviolet radiation - Key points

- UVB and UVA are classified as carcinogens to humans by the IARC.
- UVR in medical settings is used to treat some conditions like neonatal jaundice, psoriasis and eczema.
- UVB is required for the photosynthesis of vitamin D, necessary for maintaining bone health. Most Australians should achieve adequate vitamin D levels through incidental exposure to sunlight.
- UVR is the predominant cause of melanoma, SCC and BCCs. It also causes or aggravates a number of other health conditions including cortical and nuclear cataracts, herpes labialis, solar keratosis and immunosuppression.
- Australia has among the highest ambient UVR levels in the world with most states having more intense UVR in winter compared to European countries in summer.
- Australia has the highest rates of skin cancer in the world. Melanoma incidence has increased rapidly by 41% from 1993-2003, the highest increase of any cancer in Australia. The change in the incidence of SCCs and BCCs since 2002 is unknown, but is likely to have risen as well.
- Skin cancer is the most expensive cancer to treat in Australia and costs are continuing to rise rapidly in real terms. The known treatment costs to the Government are likely to be a fraction of all costs for the treatment of sun-damaged skin through Medicare Australia.

4. Evidence of health effects of solarium use

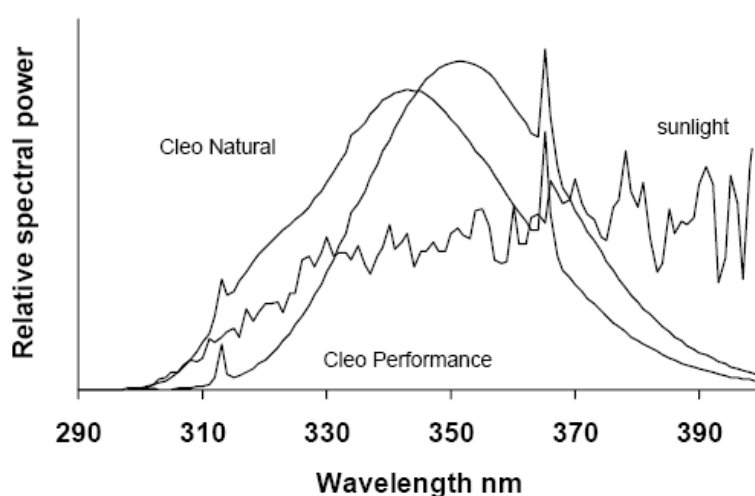
4.1 Introduction

This chapter is designed to provide a general review of the health effects of solaria including both the favourable and harmful effects that are possible. However, the main body of this chapter focuses on the risk of skin cancer development and the results from a systematic review and meta-analysis of the relevant medical literature. As most of these studies have been undertaken in countries outside Australia, we discuss the implications to solarium use in Australia. First, the UVR intensity from solarium units is presented.

4.2 Spectral UVR emissions from solaria

There are no Australian manufacturers of sunbeds for cosmetic purposes and hence, artificial tanning devices operating in Australia are imported primarily from Europe (Peter Gies, personal communication, 2007). Currently in Australia, there is no published information on the level of spectral emissions from solaria. In Europe, the current trend is to increase the proportion of emissions in the UVB wavelength and it is known that UVB is more potent than UVA for many biologic effects¹⁴. Manufacturers of tanning bulbs advertise this trend and claim 'the majority of lamps used in the market today are now in the 5.0-9.5% UVB range'¹¹⁶. Figure 6 shows a comparison between the spectral emission of the sun and two sunbeds. However, there is no standard solar spectral emission as this varies by season, latitude, cloud cover and time of day.

Figure 6. Comparison of the emission spectra of sunlight and two sunbeds⁹



[†] Measured in Melbourne (38° S) at solar noon on 17 January 1990. Measurements were made at the Australian Radiation Laboratory with a Spex 1680B double monochromator with a resolution of 1 nm

The interaction of indoor tanning and sun exposure is an area of concern. The exposure to UVR of the same or different wavelengths has an additive effect known as photoaddition¹⁴. This means that if a sub-MED dose of UVA is received from an artificial UVR device, followed later by a sub-MED dose of UVB from sunlight, the energy is additive and damage such as erythema can occur¹¹⁷.

4.3 Beneficial health effects of solarium use

A common reason for engaging in tanning mentioned by indoor tanners is the psychologic benefit. In a survey of indoor tanners, 83% reported feeling relaxed while indoor tanning⁷⁶. Positive mood effects have been reported from using sunbeds⁷⁶, but studies of primarily UVA emitting sunbeds found that there was no appreciable effect on circulating serotonin or melatonin levels¹¹⁸ or opioid peptides¹¹⁹.

The photosynthesis of vitamin D requires UVB¹⁴, and UVB emitting sunbeds have been reported to improve vitamin D status in people using a sunbed for at least once a week for 6 months¹²⁰. However, the tanning group had much greater proportion of white-skinned people with higher levels of sunlight exposure, a reliance on recall of sunbed use was required and no pre-sunbed use measure of 25(OH)D was established⁹.

Commercial tanning facilities are predominantly UVA-emitting devices and no psoralen is used, and they are therefore less effective than medically controlled treatment. However, one study reported psoriasis severity to be reduced by 35% through commercial tanning parlour use¹²¹, though these results do not rival those of medical therapy.

4.4 Harmful health effects of solarium use

Many people intentionally expose themselves to UVR from the sun or tanning devices for the purposes of gaining a tan that becomes more intense with repeated exposures. This repeated exposure also results in a thickening of the epidermis, particularly the *stratum corneum* (outermost dead layer), which results in the skin feeling dry⁹. The UVA component of solar UVR contributes less than UVB to erythema and tanning. The photoprotection gained from a UVB-induced tan has an SPF of 2-3¹²². UVA-induced tans have no protective effect against erythema¹²².

Like solar radiation, artificial UVR is associated with:

- acute sunburn and blistering^{123,124}
- reactivation of herpes labialis,
- photoageing (wrinkling and loss of elasticity),
- cortical cataracts,
- pterygia,
- photo-induced medication reactions,

- polymorphous light eruption,
- sunbed lentigines,
- atypical melanocytic lesions,
- exacerbation of porphyria,
- and local and systemic immunosuppression^{82,86,93,123,124}.

The incidence of skin-related disorders has been examined in several studies, one finding that 44% of sunbed users had increased erythema³² and another reported that 59% of sunbed users had some resultant skin injury²⁰. A report from the Centers for Disease Control and Prevention showed 700 Wisconsin emergency department visits per year were from adverse reactions to sunbeds¹²⁵. Solar keratoses and Bowen's disease have also been reported in sunlight-protected but sunbed-exposed skin in fair-skinned users after just two to three years of regular sunbed use¹²⁶. Lentiginous melanocytic proliferations that demonstrate some cytologic atypia and architectural features seen in dysplastic naevi have been seen after exposure to artificial UVR^{127,128}. Drugs such as some anti-depressants, antibiotics, psoralens, antifungals, antidiabetics and some cosmetics can also make the skin more photosensitive and prone to burning⁸.

A study assessing the immunosuppressive effects of sunbed use found that cumulative UVR dose-dependent reduction of the primary allergic response occurred as elicitation of the contact hypersensitivity response suggesting that there is no adaptation to these immunological responses¹²⁹. The role of UVB in immunosuppression is well-established, however the role of UVA is less certain. Studies using UVA filtering sunscreens have found improved immune function¹³⁰. There is also evidence of a positive interaction between UVA and UVB in immunosuppression, where the combined effect is greater than the sum of the parts¹³¹.

4.5 Solarium use and photoageing

Solar UVR is associated with photoageing¹³² and the effects of artificial UVR would be expected to be similar. In a mouse model both UVA and UVB produced wrinkling, elastosis, collagen damage and an increase in glycosaminoglycans^{133,134}. While UVB was seen to be more effective in eliciting these responses, only UVA irradiation resulted in skin sagging¹³³. Evidence of elastosis in the mice was seen after only six exposures to UVA¹³⁵. However, the hairless mice in these studies had a thinner epidermis and less had epidermal melanin than humans, and their short life span required high-dose exposures¹⁴. Human UVR exposure is generally low-dose over a long period time. A large dose can result in a burn, but several small doses can result in a tan, which is the goal of purposeful tanning, be it indoor or outdoor. A study of the effect on human skin from regular low-dose exposures¹³⁶ found dermal and epidermal changes consistent with photoageing. Another study comparing UVA exposure to sunlight also found both groups to experience photoageing, however the UVA regimen produced greater cumulative erythema in the first week, as well as epidermal hyperplasia and stratum corneum thickening, depletion of epidermal Langerhans' cells, dermal

inflammatory infiltrates, and evidence of elastin degradation¹³⁷. Artificial UVR devices also emit infrared radiation, like the sun, which has also been implicated in photoageing in some animal studies¹³⁸.

4.6 Solarium use and effects on the eye

Several studies have examined the link between sunbed use and ocular melanoma with inconsistent findings^{9,139-141}. The most recent study¹⁴² provided stronger evidence that sunbed use contributes to ocular melanoma after adjusting for confounding factors, including solar UVR exposure. The study found an odds ratio of 1.7 (95% CI, 1.0-2.8) for 'ever' versus 'never' use, 2.4 (95 % CI, 1.0-6.1) for first use when aged less than 21 years. Another adverse effect on the eye is the development of a cataract. Cataract is a clouding of the lens of the eye or its transparent membrane which obstructs light entry and impairs vision¹⁴³. While there is no conclusive evidence to suggest UVR causes nuclear or sub-capsular cataract, a systematic review of 22 epidemiologic studies found 15 demonstrating a significant association between UVR and cortical cataract⁹¹. The evidence indicates that UVB is the primary cause of cortical cataract⁹².

4.7 Solarium use and the risk of developing skin cancers

4.7.1 Published systematic review (2006)

A growing number of studies have investigated the risk of skin cancers posed by artificial UVR exposure. These studies have produced conflicting results often showing no statistical significance. In 2006, the IARC Working Group on Artificial Ultraviolet Light and Skin Cancer published a systematic review on the link between artificial UVR exposure, melanoma and keratinocytic skin cancers¹⁴⁴. The review found a summary relative risk of developing cutaneous malignant melanoma from 'ever use' of artificial UVR of 1.15 (95% CI: 1.00-1.31), that is, a person who has ever used a solarium has a 15% increased risk of developing a melanoma than a person who has not. This relative risk increased to 1.75 (95% CI: 1.35-2.26) for those first exposed to solarium when aged younger than 35 years (or a 75% increased risk of developing melanoma). While no statistically significant risk was found for BCC, a relative risk of SCC from sunbed use was 2.25 (95% CI: 1.08-4.70), that is, persons who had used solarium had more than twice the chance of developing SCC. Some additional support for the association between skin cancers and sunbed use comes from case reports of cutaneous melanoma¹⁴⁵⁻¹⁴⁹, SCCs and other dysplastic keratoses^{150,151} developing in patients frequently exposed to artificial UVR.

4.7.2 Extended review

A systematic review of the literature was undertaken to determine the relative risk of melanoma and keratinocytic skin cancers from artificial UVR. The search was primarily to capture any additional studies to those found by the 2006 IARC review. We also sought to analyse these studies via meta-

analyses (i.e., pooling the results of the studies to produce a summary result) and explore the studies in greater detail to gauge their relevance to an Australian context.

4.7.3 Methods

We used an identical method for literature searching as used in the IARC review¹⁴⁴. In brief, the following search criteria were used to identify studies that may be relevant to the review: (sunbed OR solari* OR artificial UV OR indoor OR sunlamp* OR *tanning OR suntan* OR artificial light) AND (squamous cell carcinoma OR basal cell carcinoma OR nevi OR naevi OR skin cancer OR melanoma OR NMSC OR keratose*) AND australia*. The search term 'australia*' was also removed to include a wider range of studies. Where available the study results were limited to 'humans' and 'english' papers. The following databases were searched: PubMed, The Cochrane Library, Cinahl, Pre-Cinahl, MEDLINE, HealthSource, ISI Web of Science, EMBASE, Ovid, Health and Medical Complete, Pharmaceutical news index, ProQuest Science. The reference lists of the studies deemed relevant were also considered in the search.

Studies were included in the analysis if they provided a measure of the relative risk of melanoma, SCC or BCC from the exposure to sunbeds or sunlamps for tanning purposes. Studies that were excluded included those from a meta-analysis done prior to the 2006 IARC review and also any case reports of skin cancer in the presence of artificial UVR exposure. Analyses were performed using the computer program *STATA SE/Version 9.0* to calculate summary relative risks of melanoma, SCC and BCC from artificial UVR exposure. We generated summary relative risk statistics for certain subgroups of studies where relative risks were reported in the studies. These subgroups and their rationale include:

1. **Women** Several studies enrolled only women while others reported relative risks for men and women separately. A summary relative risk for women was generated as women in Australia are more likely to use solarium than men^{42,47}.
2. **First use under 35 years** Many studies recorded the age at first use and a relative risk for younger users younger than 35 years as this age group were found to be high solarium users compared to older generations^{44,45}.
3. **Frequent users** When an individual is a frequent user, whether this is defined as 10 times or 25 times per year, the individual is different from an experimental or occasional user because they have adopted this new behaviour repeatedly (as opposed to occasional use for a special event e.g., wedding). Ultimately, this is a marker for assessing dose-response association. Although this category is somewhat crude, as different studies have defined frequent use differently, a summary relative risk of these 'adopters' was generated.
4. **Adjusted relative risk** We assessed studies that controlled for confounding variables (e.g., outdoor sun tanning practices, skin phenotypes, occupational exposure etc) because it is difficult to

attribute solarium use to melanoma in studies that do not account for these factors. In particular, outdoor sun tanning is known to be higher in solarium users compared with non-users¹²⁴ and similarly, use of sunscreen is higher in non-users than solarium users²⁵.

5. **Larger studies** We assessed studies with more than 100+ sunbed users as these are more able to detect significant differences between cases and controls than small studies. Sufficiently large numbers are also necessary to be able to adequately adjust for the potentially confounding variables above.
6. **Population-based samples** We obtained a relative risk for studies with population-based samples only. Studies that use population-based samples rather than clinical or other selective samples are potentially more generalisable to other settings because the results are less influenced by selection bias.
7. **Older studies** We assessed studies published earlier than 1994. This year was chosen because it provides a minimum 15-year lag period for individuals that may have been exposed to the high UVB emitting sunbeds of the 1970s (i.e., UVB exposure from sunbeds in the proportion of 22-40% compared with UVB exposure of 0.1-2.1% in sunbeds after 1980⁷⁶).
8. **Latitude \pm 43** To examine studies at similar latitudes to Australia, we looked at studies at latitudes less than 43. This geographical grouping was an attempt to allow for a similar level of ambient UVR exposure that individuals may have been regularly exposed to during their lives.

4.7.4 Results

Two additional studies were found that were excluded from the IARC review; one study was published after the IARC review¹⁵², while another was for ocular melanoma¹⁴². Five studies did not report relative risk statistics and were omitted from the meta-analysis¹⁵³⁻¹⁵⁷. The studies used in the meta-analyses and their key characteristics are presented in Table 3.

Table 3. Characteristics of case-control studies used in the meta-analyses

Author	Date	Country (Latitude)	Cases	Controls	Solarium users (n)
MELANOMA					
Adam et al ¹⁵⁸	1981	UK (51N)	169	207	39
Holman et al ¹⁵⁹	1986	Australia (24S)	511	511	92
Osterlind et al ¹⁶⁰	1988	Denmark (53N)	474	926	631
Swerdlow et al ¹⁶¹	1988	UK (51N)	180	120	48
Zanetti et al ¹⁶²	1988	Italy (42N)	208	416	36
MacKie et al ¹⁶³	1989	UK (55N)	280	180	44
Dunn-Lane et al ¹⁶⁴	1993	UK (53N)	100	100	32
Garbe et al ¹⁶⁵	1993	Germany (51N)	856	705	116
Westerdahl et al ¹⁶⁶	1994	Sweden (56N)	420	447	160
Autier et al ¹²³	1994	Belg, Fran, Germ (49N)	400	640	500
Holly et al ¹⁶⁷	1995	USA (37N)	452	930	-
Chen et al ¹²⁴	1998	USA (41N)	624	512	236
Walter et al ¹⁶⁸	1999	Canada (43N)	583	608	261
Naldi et al ¹⁶⁹	2000	Italy (42N)	542	538	66
Westerdahl et al ¹⁷⁰	2000	Sweden (56N)	571	913	622

Author	Date	Country (Latitude)	Cases	Controls	Solarium users (n)
Kaskel et al ¹⁷¹	2001	Germany (48N)	271	271	53
Veierød et al ¹⁷²	2003	Norway, Sweden (59N)	34	14343	34
Bataille et al ¹⁷³	2004	UK (51N)	413	416	195
Bataille et al ¹⁷⁴	2005	UK (53N)	597	622	110
Han et al ¹⁵²	2006	USA (38N)	200	804	42
SCC/BCC					
Aubry et al ¹⁷⁵	1985	Canada (45N)	92	174	5
Bajdik et al ¹⁷⁶	1996	Canada (51N)	180	406	18
Corona et al ¹¹³	2001	Italy (41N)	166	158	48
Karagas et al ¹⁷⁷	2002	USA (40N)	603	540	190
Walther et al ¹⁷⁸	2004	Germany (48N)	213	411	31
Han et al ¹⁵²	2006	USA (38N)	558	804	85

Table 4. Relative risk estimates from studies in the meta-analyses

Author	Date	Relative Risk	95% CI	Adjusted for confounding
MELANOMA				
Adam et al ¹⁵⁸	1981	2.93	(1.16-7.4)	No
Holman et al ¹⁵⁹	1986	1.10	(0.6-1.8)	No
Osterlind et al ¹⁶⁰	1988	0.73	(0.53-1.01)	No
Swerdlow et al ¹⁶¹	1988	2.94	(1.41-6.17)	No
Zanetti et al ¹⁶²	1988	0.90	(0.4-2)	No
MacKie et al ¹⁶³	1989	1.30	(0.2-7.9)	No
MacKie et al ¹⁶³	1989	1.20	(0.5-3.0)	No
Dunn-Lane et al ¹⁶⁴	1993	1.16	(0.54-2.47)	No
Garbe et al ¹⁶⁵	1993	1.50	(0.9-2.4)	No
Westerdahl et al ¹⁶⁶	1994	0.97	(0.71-1.32)	No
Autier et al ¹²³	1994	1.30	(0.9-1.8)	Yes
Holly et al ¹⁶⁷	1995	0.94	(0.74-1.2)	Yes
Chen et al ¹²⁴	1998	1.13	(0.82-1.54)	Yes
Walter et al ¹⁶⁸	1999	1.54	(1.16-2.05)	Yes
Naldi et al ¹⁶⁹	2000	0.78	(0.45-1.37)	No
Westerdahl et al ¹⁷⁰	2000	1.20	(0.9-1.6)	Yes
Kaskel et al ¹⁷¹	2001	1.00	(0.6-1.8)	No
Veierød et al ¹⁷²¹	2003	1.55	(1.04-2.32)	Yes
Bataille et al ¹⁷³	2004	1.19	(0.84-1.68)	No
Bataille et al ¹⁷⁴	2005	0.90	(0.71-1.14)	No
Han et al ¹⁵²	2006	2.06	(1.3-3.26)	Yes
SCC/BCC				
Aubry et al ¹⁷⁵	1985	13.42	(1.38, 130.48)	Yes
Bajdik et al ¹⁷⁶	1996	1.4	(0.7-2.7)	Yes
Corona et al ¹¹³	2001	0.6	(0.3-1.2)	Yes
Karagas et al ¹⁷⁷	2002	1.5	(1.1-2.1)	No
Walther et al ¹⁷⁸	2004	0.7	(0.3-1.5)	No
Han et al ¹⁵²	2006	1.32	(0.87-2.03)	Yes

1. This was a cohort study.

The summary relative risks from the meta-analyses undertaken are presented in Table 5. Similar to the IARC review, the overall summary relative risk was 1.22, that is, individuals who have ever used a solarium have a 22% increased risk of developing melanoma. When the analyses were confined to studies which adjusted for other possible explanations for increased numbers

of melanomas (skin cancer history, outdoor exposure behaviours, age etc) the associated risk was even greater at 1.36. This risk increases for women (1.71) and persons younger than 35 years at first use (1.98) (all relevant studies included). Studies at similar latitude to Southern Australia states were not significantly different to studies of Northern Europe and the USA. The summary relative risk for SCC was 1.78 for 'ever users' of artificial tanning devices (Table 6). No association was found for solarium use and risk for BCC in the few studies on BCC that were published. In terms of acute skin damage, two studies reported the prevalence of sunburn after solarium use in their participants. These were 1%¹²⁴ and 57%¹²³ with the lower estimate being sunburn severe enough to require doctors' attention.

Table 5. Results of meta-analyses for associations of solarium use and melanoma risk

Description	No. of studies	Summary Relative Risk	95%CI	
Population subgroups:				
Latitude similar to Southern Australia	6	1.11	0.86	1.43
Women only	6	1.71	1.39	2.10
Population-based studies	10	1.31	1.04	1.63
Studies adjusting for confounding	9	1.36	1.15	1.61
Population-based and adjusted	5	1.33	1.02	1.73
Studies with > 100 solarium users	10	1.17	0.99	1.39
Studies published after 1994	11	1.20	1.02	1.40
Frequent solarium users	6	1.33	0.92	1.93
First used solaria under 35 years	13	1.98	1.60	2.45
All studies pooled ¹	23	1.22	1.07	1.39

1. A total of 21 studies were included in the meta-analyses, however Mackie *et al.* (1989) and Walter *et al.* (1999) reported RRs for men and women separately and are included twice, hence 23 results pooled.

Table 6. Results of meta-analyses for solarium use and SCC and BCC risk

Description	No. of studies	Relative Risk	95%CI	
SCC only	4	1.78	1.19	2.67
BCC only	5	1.18	0.92	1.52
All studies pooled	9	1.34	1.05	1.70

1. A total of 6 studies were included in the meta-analyses, however studies reporting RRs for BCC and SCC separately and are included twice, hence 9 results pooled.

4.7.5 Discussion

On balance, when pooling all the studies in this review, there is a significant positive association consistent with an increased melanoma risk from sunbed use. This result is strengthened when only the higher-quality studies were assessed. In addition, individuals with certain characteristics were assessed and in particular, women and persons under 35 years using solaria have the highest risk of developing melanoma, approaching double the chance than for

individuals not using solaria. Results for frequent solarium users were inconclusive.

These studies rely on accurate participant recall of solarium exposure. With the exception of one study¹⁵², this issue was not addressed. However, a study by Beane *et al.* (2005) assessed the reliability of solarium use recall and stated that self-reported exposure to artificial tanning devices was very high (Kappa statistic = 1.0 cases and 0.71 controls)¹⁷⁹. Some studies in the review reported on research designed specifically to assess solarium use and risk of melanoma while others assessed a wide variety of potential melanoma risk factors (naevi counts, family history, sunburn) where artificial UVR tanning was one of these. The advantages of the former studies is the greater detail focussed on sunbed practices, frequency of use, purpose of use, attitudes etc. However, even with these more focussed studies, little detail is provided on sunlamp types, specifications and UVR wavelength emissions. Knowledge of this sunbed spectral output data would be valuable in further research as would year of first use, frequency of use and age-exposure relationships^{124,167,170}. A further limitation with this literature is the actual interpretation of 'ever used' artificial tanning devices because the purpose of use may be for either cosmetic tanning or medical purposes¹²³ and often authors did not specifically state this purpose. However, it is reasonable to assume that cosmetic tanning was the primary reason for using sunbeds in the majority of the studies.

Bataille *et al.* (2004) have suggested that case-control studies that assess the associations of certain exposures to disease may be insensitive or inadequate to apply to the complex relationship between melanoma risk and UVR. As shown in Figure 3, many factors will influence this relationship including environmental, constitutional and personal behaviours. Outdoor sun protection in particular is likely to have a strong influence on solarium use and skin cancer development. Adolescents who use sun protection on a consistent basis, are much less likely to use artificial UVR than those who do not take protective measures¹⁹. Similarly, adolescents who use solaria are also more likely to engage in unprotected outdoor sunbathing²⁹. However, in this review of 21 studies, with many adjusting for most of these confounding factors, the associations of solarium use with melanoma and SCC remained significant.

Our results show a strong association between first use under 35 years and increased melanoma risk. Harmful exposure to UVR in childhood has been hailed as exposure in a 'critical period' for the later development of skin cancer¹⁵⁹. In 2005, a systematic review to assess childhood UVR and melanoma risk was undertaken by Whiteman *et al.* (2005)¹¹¹. Despite relying on self-reported sun exposure, the overall conclusions from the analysis of 90 studies, were that exposure to high levels of sunlight in childhood is a strong determinant of melanoma risk, while sun exposure in adulthood also plays a role¹¹¹. Given that our results show that younger individuals are particularly vulnerable to developing melanoma relative to older solarium users and that teenagers are among the key users of solaria in Australia, our results coupled

with the review by Whiteman *et al.* (2005) would support the public health message to this population segment to avoid solarium use.

Our findings show no significant differences among study populations residing at different latitudes. Although latitude was expected to act as a crude proxy for general level of solar UVR exposure, patterns of UVR exposure and other behavioural, cultural and constitutional factors appear to outweigh this influence. It may also suggest a 'replacement effect' is occurring with solarium users in very low solar UVR locations replacing outdoor with indoor UVR exposure to produce similar increased risks of skin cancer. This would appear to be supported by very popular solarium use in Scandinavian countries relative to low use in Australia. Although unsupported by the current literature and in the absence of a well-designed Australian-based study, the question remains, what is the additive and cumulative effect of increasing solarium use in Australia against a background of extremely high solar UVR exposure?

Health effects of solarium use - Key points

- The few studies that report on beneficial health effects of solarium use are inconclusive.
- The results of 21 studies show that individuals who have 'ever used' solarium have a 22% increased risk of developing melanoma compared to never users. This risk is elevated when persons first use solarium under the age of 35 years (98%) and for women (71%).
- The results of 4 studies shows that individuals who have ever used solarium have a 78% increased risk of developing SCC.
- The results of 5 studies shows that individuals who have ever used solarium have an 18% increased risk of developing BCC, however this finding was inconclusive.
- The results of 6 studies shows that individuals who regularly used solarium have a 33% increased risk of developing melanoma, however this finding was inconclusive (due to borderline significance of the result).

5. Estimation of annual melanoma deaths attributable to solarium use

5.1 Introduction

In 2003, Brian Diffey devised a model to estimate the number of melanoma deaths per year attributable to artificial UVR in the UK⁶² (hereafter called ‘the Diffey model’). The Diffey model made assumptions about the tanning behaviour of the population in order to estimate an annual UVR dose attributable to outdoor sunbathing. The model used UK data inputs on sunbed emission measurements and number of sessions reported in the published literature to estimate the annual artificial UVR exposure in the population. An overall proportion of artificial UVR exposure to total UVR exposure was calculated. Based on the estimate that 80% of melanomas are UVR related¹⁰¹, the number of melanoma deaths that were attributable to artificial UVR was approximately 100 each year and within a range of 50 to 200 (or 3-12% of total UVR exposure attributed to melanoma deaths)⁶². The model assumed equal carcinogenicity from solar and artificial UVR, and that the case-fatality of melanomas from each source was equal.

Despite some important caveats, the Diffey model is an attempt to estimate the annual mortality burden from artificial UVR and has the advantage of being applicable to other settings if the parameters are adjusted accordingly. As such, we have replicated this model to derive an estimate of the annual incidence and mortality of melanoma thought to be attributable to artificial UVR in Australia.

5.2 Methods

The analysis follows the Diffey model and, ultimately, generates a fraction of total UVR exposure that is attributable to artificial UVR exposure. Our model differs from the Diffey model because we use the reported CIE erythemally weighted doses for solar and artificial UVR to obtain our final fraction. The basic equation for total UVR exposure is as follows:

Total personal UVR exposure (J cm^{-2}) = solar UVR exposure + artificial UVR exposure
 where solar UVR exposure = population that sunbathe outdoors (%) x annual average solar exposure (J cm^{-2}), and
 where artificial UVR exposure = population that use indoor tanning devices (%) x annual average sunbed exposure (J cm^{-2}).

The first step in the model requires an estimation of the annual UVR dose from sunlight. UVR dose is a function of irradiance and time, with time in this instance being a one-year period. Recent Australian studies on various population groups using polysulphone badges (which objectively capture actual UVR received)⁶⁵ have provided this data and allows us to bypass some of the more dubious assumptions used in the Diffey model. The annual UVR

dose is multiplied by the proportion of the population who engage in outdoor tanning⁴² to obtain an annual population solar UVR dose from tanning.

The second step in the model is estimation of the annual UVR dose from artificial sources, a function of UVR dose from solarium use multiplied by prevalence of use. The intensity of UVR emissions from solarium units is required and, in the absence of published Australian sunbed measurements, we have used those reported by Oliver *et al.* (2007) from the UK¹². As all sunbeds in Australia are imported, this would appear to be a reasonable estimate. Sunbed emissions were multiplied by estimated frequency of use over 12 months⁴² followed by multiplying by Australian prevalence of use estimates^{42,47} to derive an annual artificial UVR dose.

These data inputs are subject to some variability and uncertainty (Table 7). To encompass this data variability, we undertook Monte Carlo simulation modelling to derive our mean solar and artificial UVR estimates with 95% confidence intervals. Using this technique, the Monte Carlo simulation performs a probabilistic sensitivity analysis and incorporates all parameter uncertainties within a multivariate model. Monte Carlo simulation recalculates a model multiple times, randomly sampling from the variability of the data inputs to produce different configurations of the various data components. In addition, data distributions were assigned to accurately reflect the nature of the data (e.g., number of solarium sessions per year is believed to follow a lognormal distribution^{45,62}). Distributions were assigned to all data inputs and, following Diffey's method, the model was set to perform 5,000 samples. Finally, we used these model estimates of mean solar and artificial UVR to calculate the estimated proportion of melanoma incidence and mortality attributable to artificial UVR in Australia.

Table 7. Model parameters, data sources and distribution information

Parameters	Values		Data Sources & Notes	Distribution
	Estimate	Range		
Annual solar UV Exposure	12000	8000-16000	Australian range ⁶⁵ , mean used	Normal
Proportion of population involved in outdoor suntanning	19%	13-30%	SunSmart Evaluation ⁴² (high range is persons 14-29 years)	Normal
Sunbed exposure per session	15 J cm ⁻²	7-29 J cm ⁻²	UK estimates ¹²	Lognormal
Number of sessions per year	10	1-25	SunSmart Evaluation ⁴² 57% attended > 5 times per year, 19% more than 25 times per year	Lognormal
Proportion of population using indoor tanning	6.7%	0.9-12.4%	Range Qld ⁴⁷ to NSW ⁴⁵	Normal
Annual number of melanoma deaths	1146	na	AIHW 2003 mortality rates ⁹⁵	na
Percentage of melanoma attributable to UV	0.825	na	Mean of 0.68-0.97 ¹⁰¹	na

5.3 Results

The proportion of melanoma deaths attributable to artificial UVR was estimated at 0.4% (range 0.2-0.8%) of all UVR-attributed melanoma deaths (see Table 8). The results show that the estimated number of deaths from melanoma in Australia that would be attributable to indoor tanning devices is approximately 4 per year and in the range of 1 to 7. The number of new cases of melanoma attributable to indoor tanning devices was found to be in the range of 12-62 per year.

Table 8. Results of estimation of annual deaths and new cases of melanoma attributable to solarium use in the UK and Australia

Parameters	UK Model	Australian Model	
		Estimate	Range
<i>Exposure to sunlight UVR</i>			
Percentage of population exposing trunk/limbs	30-80%	na	
Days per year exposed	10-40 days	na	
Hours per day exposed	1-5 hours	na	
Ambient UV at midday +/- 3 hours	6 mW cm ⁻²	na	
Percentage of exposed body	10-60%	na	
Annual UV Exposure ¹	30-2000J cm ⁻²	12000	8000-16000
Population involved in outdoor suntanning	30-80%	19%	13-30%
Estimated solar UVR - J cm ⁻²	not stated	2283	1333-3504
<i>Exposure to artificial UVR</i>			
Exposure per session	4-40 J cm ⁻²	15 J cm ⁻²	7-29 J cm ⁻²
Time per session	10-30 min	5-30 min	
Number of sessions per year	11	10	1-25
Average annual dose	10-3000J cm ⁻²		
Proportion of population using solaria	5-9%	6.7%	0.9-12.4%
Estimated artificial UVR - J cm ⁻²	not stated	10	2-28
Annual number of melanoma deaths	1640	1146	
Percentage of melanoma attributable to UVR	0.80	0.82	
Number of melanoma deaths attributable to UVR	1312	940	
Proportion of national UV exposure from solarium use	3-12%	0.2-0.8%	
Number of melanoma deaths due to solarium use	100 (50-200)	4 (1-7)	
Annual number of new cases of melanoma	8,989 (2004)	9,524 (2003)	
Proportion of national UV exposure from solarium use	3-12%	0.2-0.8%	
Number of new cases of melanoma due to solarium use	360	34 (12-62)	

1. The Australian model uses erythemally effective solar and artificial UVR doses (unlike the Diffey model that used unweighted solar UVR dose)

5.4 Discussion and Conclusions

Despite the annual counts of new melanomas being similar in Australia and UK, our Australian estimates of melanoma deaths from artificial UVR are considerably lower than those for the UK (Table 8). This is explained by the fact that Australia has very high levels of ambient UVR causing the solar UVR dose estimate to be very high driving melanoma mortality rates. Also, Australia has a substantially lower percentage of the population using sunbeds, and using them less frequently, than the UK population. The smaller fraction of artificial UVR exposure to a higher overall UVR, due to very high solar UVR, has resulted in a lower proportion of melanoma deaths attributable to solarium use in Australia. Despite a lower estimate of outdoor tanning prevalence in Australia compared to that reported in the UK, the annual solar UVR dose is higher in the Australian model. The number of sessions per individual over 12 months appears to be much lower than in the UK where it has been found that 20% of the UK population use a sunbed at least 100 times over 12 months³⁶ compared to 19% of a NSW school-aged population using solariums more than 25 times.

A significant limitation of this model is the parallels that are drawn between recent UVR exposure (2004±2) and the incidence of melanoma (2001) and ignores the lag between exposure and development of melanoma. This would indicate that our results are underestimated given that background numbers of annual melanoma deaths will increase over time.

These results are subject to a number of inherent assumptions: the patterns of exposure from solar and artificial UVR are equally carcinogenic; the melanomas from these two sources are equally fatal; and the Australian UVR irradiance for solar and sunbed emissions are erythemally weighted. While the model considers differences in individuals using solariums with different skin types (with equal proportions of skin type I, II, III found in the literature⁶²), it does not make adjustments for age, naevus counts or number of sunburns, which have been shown to be risk factors associated with melanoma.

Estimated annual melanoma deaths from solarium use in Australia - Key points

- Using a crude model, less than 1% of all UVR-attributable melanoma deaths would be attributable to solarium use or approximately 1-7 melanoma deaths each year.
- The number of new cases of melanoma attributable to indoor tanning devices was found to be in the range of 12-62 per year.

6. Potential cost-effectiveness of regulating the Australian solarium industry

6.1 Introduction

The role of cost-effectiveness analysis in health care decision making is increasing due to budgetary constraints across most health portfolios. Their goal is to explicitly quantify and compare the costs and health outcomes of different health interventions and strategies. Ultimately, the aim is to produce an estimate of the potential efficiency of one course of action compared to another (or many others). In this light, it is a relative concept where at least two choices are in question. As opposed to a cost-benefit analysis where the 'benefit' side of the analysis is measured in dollar terms (using 'willingness to pay' or contingency valuations), a cost-effectiveness analysis is more commonly used in health care as it uses clinical measures of outcome that are easier to interpret and have strong clinical relevance (e.g., persons treated to lower cholesterol targets, persons avoiding a cancer diagnosis, lives saved). Using a generic outcome measure such as 'life years gained' is desirable because we are able to view the results in the context of other health care options.

The data sources used in a cost-effectiveness analysis are generally derived from primary data (e.g., a randomized controlled trial) or they involve a consolidation of available published literature (often called a modelling study). Modelling studies are increasingly more common in economic evaluations because health care policy decisions are more complex, more urgent and in the case of public health issues, are often not conducive to experimental designs for ethical reasons.

The objective of the cost-effectiveness analysis here is to answer the question;

What are the expected costs and health effects if the Australian Commonwealth Government were to enforce regulations in the solarium industry?

6.2 Analytical scope

This analysis compares the expected outcomes from regulating the solarium industry with the expected outcomes from allowing the industry to continue as it has been. There are a variety of costs and consequences that will be involved in regulating the solarium industry. Our cost analysis is undertaken from the perspective of the Department of Health & Ageing. As such, the costs analysed are only those incurred by the Department of Health & Ageing (via Medicare Australia) and do not encompass those incurred by other health bodies (e.g., administrative and legislative costs for State and Territory governments), businesses (e.g., lost income for UVR tanning and

sunbed/sunlamp distributors) or individuals. While the legislation and enforcement costs are relevant to the analysis, a uniform model to enforce regulations is yet to be proposed by the State regulatory bodies. Possible strategies that may be considered for a national regulatory framework are listed in Appendix C.

6.3 Methods

A cost-effectiveness analysis was undertaken to compare outcomes between current practices and government enforcement of practices based on the current Standard. Three measures of effectiveness were used for assessing the expected outcomes of regulating versus not regulating. These include;

- 1) *Counts of melanomas or SCCs.* Melanoma and SCC were found to have an elevated relative risk from 'ever use' of solarium. These are the most thoroughly studied cancers resulting from exposure to UVR and are therefore the primary cancers that have been included in the analysis. The meta-analysis of publications studying the relationship between artificial UVR and BCC found no increased risk of BCC from solarium use. Therefore, we have not included an assessment of the impact of regulation on BCC.
- 2) *Life years gained.* Although survival rates from melanoma are very high, it is helpful to use this measure because it is a generic outcome used commonly in economic evaluations, thereby allowing comparisons with other health policies.
- 3) *Potential life years lost.* Melanoma causes more premature years of life lost than many cancers because it is a common cancer in younger age groups. This outcome measure is chosen to reflect these lost years of life among younger persons due to melanoma mortality.

The costs in our analysis include only the medical care costs for treating skin cancers incurred by Medicare Australia. By estimating these for current practice and for regulation, we expect cost-savings will accrue to the Government through skin cancers avoided following regulation. Ultimately, the cost-savings will be offset by the direct State government regulation costs. Costs are presented in 2006 Australian dollars.

Epidemiological data drawn from the literature reviews in the previous chapters of this report are used to populate the model (e.g., prevalence of solarium use estimates, relative risk of skin cancers and solarium use). Two separate models were constructed for melanoma and SCC outcomes and use an identical framework. The time horizon for the analysis is over the long-term; as such a lifetime model is used.

A decision-analytical model with Markov chains was constructed to perform the cost-effectiveness analysis (see Appendix D for an illustration). A hypothetical cohort of 100,000 individuals aged 12 were set to travel through

each cycle (one year interval) and faced probabilities of specific health outcomes each cycle. At the end of each cycle members of the cohort were allotted to specific health transition states (i.e. dead from melanoma, dead from other causes, ex-melanoma, no melanoma or previously exposed to sunbeds) and faced slightly altered probabilities over subsequent cycles based on their current state and due to being one year older. These cycles were repeated until the termination point was reached, in this case, when cohort members reached age 85. For each health state or transition through the tree there may be a 'payoff' or outcome assigned, such as a 'life year lived' or a diagnosis of 'melanoma' or treatment cost. In this model, the accumulation of these payoffs over the life of the model is expected to differ between cohorts with differing prevalence rates of solarium attendance and the risk attached to exposure to artificial UVR. The difference in diagnosis and treatment costs, number of skin cancers, life years saved and potential life years lost due to melanoma are the primary outputs of the model.

6.4 Model parameters, sources and assumptions

Details of the model parameters, sources and assumptions are summarised in Table 9. Where appropriate, we have used age-specific data to encompass time-dependent information so that the model is dynamic as the cohort ages.

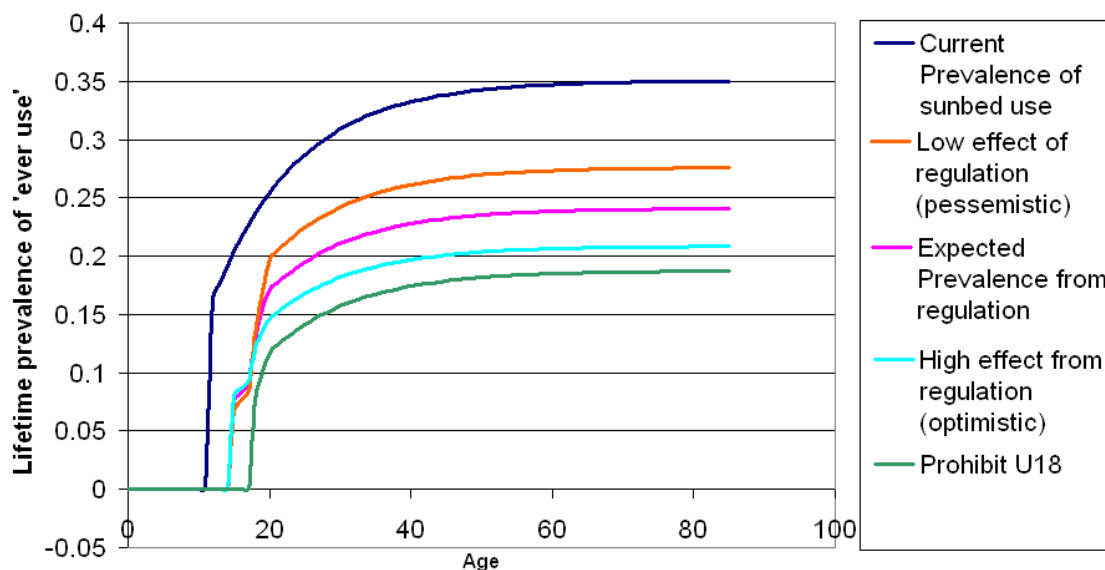
a) Data regarding a lifetime prevalence of 'ever use' of solaria in Australia are not available. In other words, the annual number of first-time users of sunbeds in each age group has never been studied. Data from the *NSW School Students Health Behaviours Survey* has shown that 16.3% of 12 year-olds surveyed had used a sunbed in the previous 12 months⁴⁵. In the absence of data on prevalence of use in younger age groups than this we have assumed 16.3% to be a good indicator of the proportion of 12 year-olds ever exposed to sunbeds. Studies have shown that a gradually lower proportion of people in older age groups have ever used sunbeds^{23,26,34,36}. This indicates a diminishing incidence of first time sunbed exposure as people get older. If the rate at which incidence diminishes (assumed to be 8%) is held constant then the lifetime prevalence of exposure to specific age groups is estimated as shown in Figure 7.

Figure 7 indicates that at age 85 the number of people who have ever used a sunbed will peak at around 35% of the population. This figure is highly sensitive to the initial incidence of new exposures (1.5%) during the teenage years. The assumption of an 8% annual reduction in incidence rates was required based on the other parameters, to allow the incidence rates to approach zero in the oldest age groups. The figure of 35% however is not unlikely as while it is a significant proportion of the population it is still lower than it other countries with higher rates of solarium attendance^{18,20,25}.

Table 9. Decision model inputs, descriptions and sources

Parameter	Description	Source
Prevalence of solarium use (no regulation)	Current proportion of the population ever exposed to artificial UVR for cosmetic purposes See a) below	NSW School Students Survey ⁴⁵ , Lawler <i>et al</i> ⁴⁷ , Dobbinson ⁴²
Prevalence of solarium use (regulation)	Expected proportion of the population ever exposed to artificial UVR for cosmetic purposes if industry is regulated See a) below and Table 10	Assumptions and compliance data (see a) below)
Melanoma mortality rates	Mortality rates in specific age brackets.	AIHW – Cancer Survival in Australia 2001 ¹⁸⁰
Mortality rates (all cause)	Background mortality rate of Australians at each age.	ABS Australian Life Tables 2003-2005 ¹⁸¹
Relative risk of melanoma (no regulation)	Baseline level of risk (1.0) resulting in current melanoma incidence rates	AIHW – Cancer Survival in Australia 2001 ¹⁸⁰
Relative risk of melanoma (regulation)	Inverse risk of ‘ever used’ solarium for under 35 years, and overall risk of ‘ever used’ See d) below for latent period factor.	Meta-analysis results (see Chapter 4) Latent period ¹⁸²⁻¹⁸⁶
Diagnosis of multiple melanomas	Proportion of all melanoma diagnoses that involve more than 1 melanoma. See b) below	Multiple melanomas ^{187,188}
Risk of additional melanoma	Proportion of all melanoma diagnoses that go on to develop additional melanomas. See b) below	Additional melanomas ¹⁸⁷⁻¹⁹⁷
Diagnosis of single melanoma	Proportion of all melanoma diagnoses that involve a singular melanoma. The inverse of the rate of multiple melanomas.	See multiple melanomas
Relative risk of SCC (no regulation)	Baseline level of risk (1.0) resulting in current SCC incidence rates	2002 National Non-Melanoma Skin Cancer Survey ⁹⁷
Relative risk of SCC (regulation)	Inverse risk of ‘ever used’ solarium See d) below for latent period factor.	Meta-analyses results (see Chapter 4) Latent period ¹⁸²⁻¹⁸⁶
Risk of additional SCC	Proportion of all SCC cases that go on to develop additional SCCs.	QIMR analyses (unpublished)
Cost of single and multiple melanomas	Cost to Medicare Australia for doctor visits, excision, pathology services. See c) below.	QIMR analyses (see Appendix E)
Cost of single and multiple SCC	Cost to Medicare Australia for doctor visits, excision, pathology services. See c) below.	QIMR analyses (see Appendix E)

Figure 7. Estimated prevalence of 'ever use' of sunbeds in the Australian population and the effect of enforcing the Standard



The impact of enforcing the regulations (shown in Figure 7) on the prevalence of use is broken down into four effects. Exclusion of under 15 year olds, reduction in under 18 year olds due to parental consent requirements, exclusion of people with skin type I, and a small behavioural effect from increased awareness of risks due to warning signs, absence of non-cosmetic health benefit promotions, and an increased use of client consent forms. As there are no data suggesting a lack of compliance with lamp output standards, no effect from this component has been included in the model. The assumptions are summarised in Table 10.

Table 10. Assumed impacts on prevalence of use from enforcing regulations

Regulatory effect	Impact	Source
Prohibit use by U15	-100%	Appendix F
Require consent forms by U18	-50%	Appendix F
	(40-60%)	
Jump in incidence rates in persons		
18 years old	3% (2-4%)	Assumption
19 years old	2% (1-3%)	
20 years old	1% (0.5-2%)	
Exclusion of skin type 1	-19% (14-24%)	Lawler <i>et al</i> 2006
Behavioural effect	-10% (5-15%)	Assumption

The prohibition of use of children aged under 15 years will, in theory, reduce the prevalence of use to 0% in those aged 14 and under. The requirement for parents to sign consent forms allowing children aged 15-17 to use sunbeds is assumed to have a 50% (range of 40% to 60%) reduction in incidence of first time users. This is based on the compliance with this part of the Standard of between 30-50%^{46,49,54}. The increase in solarium use at age 18 is assumed to occur due to latent demand being fulfilled once parental consent is no longer required. This effect is assumed to taper over the following two years.

b) The proportion of diagnoses of multiple melanomas will have an impact on the treatment costs. A literature search found studies with the proportion of diagnoses of multiple melanomas ranging from 1.5%¹⁸⁸ to 2.8%¹⁸⁷. A weighted average of 1.78% was used in the model. The proportion of melanoma sufferers who go on to acquire further melanomas was also considered, with studies showing a rate range of 1.3%¹⁹⁵ to 10.4%¹⁹⁰. A weighted average of these studies^{139,189,191-194,196,197} produced a rate of 3.44%. Some of these studies also found the mortality rate between single and multiple incidences of melanoma to be comparable^{187,193}, therefore the case fatality rate has been assumed to be the same between these two groups.

c) Data estimates for medical care costs to diagnose and treat melanoma per individual have been derived through current (unpublished) analyses undertaken by researchers at QIMR (see Appendix E). These medical costs involve initial and follow-up, doctors' visits, standard excisions, pathology, and in a small number of cases, flap repairs and grafting procedures. Mean costs for singular (\$1,238) and multiple (\$2,231) melanomas and their 95% CIs were derived from cost analyses of melanomas diagnosed in a large population-based cohort study. Specific details are provided in Appendix E. For cases that could be fatal in their first year, we have assumed these are predominantly advanced stage melanomas and additional treatment costs with a mean of \$2,200 were applied. The mean cost for SCCs (\$993) was also derived from the previous QIMR analyses (Appendix E).

d) The effect of a latent period between a carcinogenic exposure and the clinical onset of melanoma or SCC has also been considered in the development of the model. Studies of a latent period for melanoma have compared spikes in solar activity (sunspots) with subsequent rises in the incidence of melanoma. Two such studies found the period between increased UVR from solar activity and the onset of melanoma to be two years^{182,185}. It was suggested that perhaps the rises in melanoma incidence were being linked to the wrong periods of solar activity and that the latent period could be closer to 10 years¹⁸⁶. Further studies have referred to a short latent period for melanoma¹⁸³ and a longer latent period for SCCs and BCCs¹⁸⁴. The model has used a two year latent period before any effects of regulation will be seen on melanoma incidence rates and a 10 year latent period for SCC.

6.5 Analysis

The end results from the decision model and Markov cohort analyses are considered in a cost-effectiveness analysis. The incremental costs and effects were generated which are interpreted as the cost-savings and the additional health benefits produced from regulating the industry. Discounting is the process where expected costs and effects in the future are adjusted to reflect present day values. A rate of 4% per year was used to discount future costs and outcomes back to present values¹⁹⁸.

Due to the data variability and the assumptions made in the model, the sensitivity of the findings to variations in the model inputs was tested in order to consider the possible range of results that might feasibly occur. This was done in two ways. One-way sensitivity analyses adjusted key parameters over a range of high and low values to test the variation in results. The second approach was to undertake a multivariate probabilistic sensitivity analysis. It is common to use probability distributions in the place of point estimates for parameters. We assigned beta distributions for all parameters expressed as probability (rates were first converted to probabilities in the model) and gamma distributions for cost values¹⁹⁸. This allows the model to be run several thousand times in a Monte Carlo simulation, each time drawing parameter values from their probability distribution, thereby producing a range of cost and effect outcomes as 95% confidence intervals. Analyses were performed using the *TreeAge Pro Suite 2007* software package.

6.6 Results

The expected health and cost outcomes are summarised in Table 11. Undiscounted results are provided in Appendix F. When results are discounted to the present, it is expected that there will be approximately 27 melanomas and 281 SCCs saved over the life of a cohort of 100,000 persons. This will result in a saving of approximately 40 years of life lost due to melanoma mortality in this group, and an overall gain of 35 life years lived. The discounted reduction in costs over the life of the cohort is estimated be \$313,846 in diagnosis and treatment costs.

Table 11. Discounted results of costs and effects

	Cohort of 100,000			Cohort of 3.9 million ¹
	Current practice	Enforce the standard	Incremental effect	
Melanomas	907	880	-27	-1034
SCCs	11198	10917	-281	-10978
Life years lived	2337653	2337688	35	1358
Life years lost	1128	1088	-40	-1542
Costs (melanoma)	\$1,174,454	\$1,140,112	-\$34,342	-\$1,339,331
Costs (SCC)	\$11,120,057	\$10,840,553	-\$279,504	-\$10,900,671
Total costs	\$12,294,512	\$12,015,007	-\$313,846	-\$12,240,003

1. There are approximately 3.9 million persons aged 0-14 in Australia¹⁹⁹. This is a crude extrapolation of the results to consider the lifetime effect on this cohort.

Results from the one-way sensitivity analyses can be seen in Table 12. The model results above were sensitive to the discount rate and the relative risks of melanoma/SCC after solarium use. The change in the lifetime prevalence of 'ever use' sunbed exposure following enforcement of the Standard was also considered. Using the lower limits of the assumptions used to derive the initial estimate the number of melanomas, SCCs and associated costs saved fell by just over a third, while the higher limits saw an increase in the estimates of just over 25%. The results were also sensitive to the change in policy of

prohibiting the use of solarium by persons aged less than 18. The number of melanomas and SCCs saved increased to 41 and 429 respectively, and expected cost-savings increased to nearly \$426,000.

Table 12. Results of one-way sensitivity analyses on key parameters
(per 100,000 persons)

	Melanomas saved	SCCs saved	Life years gained	Life years lost	Cost-savings melanoma \$	Cost-savings SCC \$
Base result	27	281	35	-40	34,342	279,504
Discount rate 3%	37	390	55	-64	48,521	153,665
Discount rate 5%	19	208	23	-25	25,150	83,854
RR ¹ low 95% CI	19	101	28	31	24,217	99,942
RR high 95% CI	33	407	41	47	43,202	404,084
RR U35 low 95% CI	23	na	29	33	29,856	na
RR U35 high 95% CI	29	na	40	45	37,967	na
Low effect on prevalence of use	19	196	25	-29	24,699	194,689
High effect on prevalence of use	34	362	44	-50	43,542	359,796
Effect of prohibiting U18 from solarium	41	429	-54	61	52,495	425,986

1. RR = relative risk

We generated 95% CIs around our base results in a multivariate probabilistic sensitivity analysis using Monte Carlo simulation methods. Most of the variation in the mean results could be expected for numbers of SCCs and associated cost-savings.

Table 13. Results of probabilistic sensitivity analyses on all parameters
(per 100,000 persons)

	Incremental effect (cohort of 100,000)		Incremental effect (cohort of 3.9 million)	
	Mean ¹	95% Confidence Interval	Mean	95% Confidence Interval
Melanomas saved	26	(19 - 34)	1,030	(758 - 1,315)
SCCs saved	278	(242 - 321)	10,856	(9,426 - 12,513)
Additional life years lived	34	(26 - 43)	1,331	(1,023 - 1,692)
Reduction in life years lost	40	(30 - 49)	1,554	(1,152 - 1,925)
Melanoma cost-savings	\$33,965	(\$25,155 - \$43,709)	\$1,324,625	(\$981,043 - \$1,704,648)
SCC cost-savings	\$273,909	(\$238,105 - \$320,692)	\$10,682,455	(\$9,286,095 - \$12,506,970)

1. The mean results from the probabilistic sensitivity analysis will differ slightly from the initial results which are derived using the mean values of input variables

6.7 Discussion

To our knowledge, this is first analysis to assess the potential cost-effectiveness to a government for implementing solarium regulations. We have constructed a detailed and complex model using the best epidemiological data available. Our findings indicate that over the lifetime of a population of 100,000 persons, between 19-34 melanomas and 242-321 SCCs could be

avoided, around 35 years of life could be gained through reduced melanoma deaths, and approximately \$300,000 could be saved through enforcing regulations to the current Australian Standard. The cost-savings are derived primarily through a reduction in SCCs, while the additional life years lived result from the melanoma reductions. As would be expected, the change in the number of skin cancers is most substantial for SCCs given the higher incidence and the higher relative risk of SCC from solarium use. This translates into higher cost-savings for the government. The model is grounded in a number of assumptions involving the prohibition of persons under 15 years, reducing the prevalence of use in those under 18 years and excluding persons with skin type I that will produce a lower overall use of solaria in Australia.

As with most modelling studies, some assumptions have been necessary and these may be open to challenge. Our sensitivity analyses show that the base results are sensitive to potential data variability. As would be expected from a model with long-term outcomes, the discount rate has a moderate effect on the discounted results. A discount rate of 5% reduced the number of melanomas and SCCs saved to 19 and 208 respectively. With a rate of 3% increasing the numbers saved to 37 and 390 respectively. Total costs varied from around \$109,000 to \$202,000 over the range of discount rates tested. A key aspect of this report is the reported relative risk of acquiring skin cancer from exposure to artificial UVR. The sensitivity analysis testing the effect on results from using the upper and lower estimates of relative risk found a moderate effect on the results. With the variation in melanomas saved due to overall relative risk of melanoma being 19 to 34 melanomas in the 100,000 person cohort. This was slightly less variation than the under 35 relative risk variation of 23 to 29 melanomas saved. The range of SCCs saved was much larger (101 to 407) but still provided a minimum level of cost-savings with a present value of around \$100,000.

The sensitivity of the results to prohibiting the use of solaria to persons aged less than 18 suggests that this would be an effective strategy to reduce the incidence of skin cancers. However, caution must be taken when interpreting this result and the model assumes a similar annual incidence of sunbed use to current practice. It is possible that the incidence of exposure will increase sharply at age 18 when parental consent is no longer required.

These findings are likely to be conservative and will underestimate the potential health effects and cost-savings. First, the Standard is currently under review and as a result may be tightened to produce fewer solarium users than expected here (i.e. prohibition of persons under 18 years). Second, we have not included costs from any BCCs, solar keratoses, ocular diseases and photoageing treatment resources that may also be reduced from persons avoiding solaria services. Third, we have not included other deleterious health effects from UVR that may also be avoided and their associated medical costs. However, as indicated earlier, our analysis is limited to medical care costs for treating skin cancers and does not include costs of regulation enforcement strategies that will be incurred by the State regulatory bodies involved in radiation health protection. It is unknown how this will affect these

cost estimates. This will depend on the potential mix of resource outlays (Appendix C) which may or may not be offset by appropriate government cost-recovery initiatives. The above analyses could be updated if this information becomes available.

The beneficial effects of reducing population exposure to artificial UVR will possibly be offset to some degree by the substitution of artificial UVR for solar UVR where it is available. Public education campaigns will be an important component in ensuring population exposure to UVR in Australia is minimised.

It is important to note that the consequences of reducing total UVR exposure are substantial and may include reduced photoageing, fewer BCCs, SSCs, melanomas, solar keratoses, ocular melanomas, cataracts, sunburns and other skin irritations, immunosuppression and also less enjoyment from having a suntan. The benefits from reduced photoageing include less wrinkling and an even pigmentation of the skin, resulting in a younger appearance. The quality of life benefits and cost-savings from cosmetic treatments are potentially substantial but are not documented in the literature and therefore have been excluded from the formal analysis. While the number of solar keratoses or common and atypical naevi a person are risk factors for melanoma, solar keratoses and naevi are not in themselves a threat to quality of life. Furthermore, the relationship between solar keratoses and artificial UV has not been studied as comprehensively as skin cancers and has therefore been excluded from the analysis. Sunburn, particularly earlier in life is also a risk factor for skin cancers, and although it could also be considered to be detrimental to quality of life, the short term nature of any sunburn and the absence of adequate literature on which to base a disability measure has resulted in its exclusion from the analysis. The same is true for other skin disorders arising from sunbed use. The deleterious impact of artificial UVR on immune function has been suggested by several authors, however the effect attributable to artificial UVR has not been the focus of adequate research to able it's inclusion in this model.

Potential cost-effectiveness of regulating the Australian solarium industry - Key points

- A decision-analytic model was created to project the future cost and health effects comparing current solarium practice with enforcing solarium regulations, based on the current Standard.
- The health effects were measured in terms of new cases of melanomas and SCCs, life years gained and life years lost due to premature melanoma mortality.
- The costs were limited to those incurred by Medicare Australia for the diagnosis, treatment and care of individuals with skin cancers.
- Model inputs included Australian data on prevalence of solarium use, compliance with the Standard, background incidence of skin cancers, mortality due to all causes and melanoma, relative risks of skin cancers using meta-analyses results and cost-analyses of skin cancers from a large cohort study.
- If the Government were to enforce regulations to the current Australian Standard, we could expect that over the lifetime of 100,000 persons that between 19-34 melanomas and 242-321 SCCs would be avoided, around 35 years of life would be gained through reduced melanoma deaths, and approximately \$300,000 in diagnosis and treatment costs would be saved.
- For all young Australians, we could expect that over their lifetime, over 1,000 melanomas will be saved, over 12,000 SCCs would be avoided and at least \$12.2 million would be averted.
- The estimations here are most sensitive to the relative risk estimates of skin cancers, the discount rate applied and the effect on prevalence of sunbed use.

7. Conclusions and Recommendations

7.1 Conclusions

This report has drawn together the current knowledge on the Australian solarium industry, the prevalence of solarium use and consolidates the published evidence reporting the risk of skin cancer among solarium consumers. The existing body of knowledge and medical evidence culminates in an economic model to investigate the costs to the government and health benefits to Australians should regulations become mandatory in Australia.

There is a strong case for national regulation of the solarium industry in Australia. The economic burden of skin cancer to the Australian Government is the highest of any cancer and continues to grow with the rising incidence of this disease. Australians are faced with some of the highest ambient UVR levels in the world and the worst rates of skin cancer. UV radiation is an established carcinogen to humans and it is the primary cause of skin cancer. Yet unlike other risk factors for disease that may not be modifiable (ageing, genetic predisposition), personal exposure to UVR can be controlled through behavioural, educational and health promotion initiatives. Numerous campaigns over the last three decades to promote sun protection behaviours at a population level, the development of industry standards that specify SPF-rated clothing and sunscreens, SunSmart policies within schools and early childhood settings and the promotion of UV index warnings through the mass media, are the products of steady collaborative and dedicated efforts to protect Australians from developing skin cancer. It is highly possible that many of the benefits from these initiatives will be reversed if the solarium industry is not regulated.

While the prevalence of solarium use in Australia is low relative to use in Europe and the US, the rapid growth in the supply of solariums suggests demand for these services is rising. Young females are the key users of solariums in Australia. There is consistent and plausible evidence that solarium users are increasing their risk of skin cancer. Reports indicate that there is market failure in this industry as operators are unaware of and/or failing to comply with the voluntary code of practice which aims to minimize these increased risks. Given the huge burden imposed by skin cancer in Australia now, growth in the solarium industry will inflate this human and economic burden in years to come. Our cost-effectiveness analysis suggests that by enforcing solarium regulations which effectively restrict youths under 15 years and prohibit persons with skin type I, we can expect to avoid significant numbers of skin cancers, melanoma deaths and in doing so generate cost-savings to Medicare Australia.

There are a number of issues and questions arising from this report that warrants further research. Further research will increase our knowledge, lead

to more informed decision-making and enable close monitoring of industry practice and strengthen future evaluations. These issues include:

- Measurement of the current emissions from sunbeds in Australia and the precise proportion of UVB irradiance – are we importing the new high power lamps seen in Europe and what is the impact of these?
- A comprehensive study on sunbed use in Australia and predictors of use – do people who use sunbeds engage in unprotected solar UV tanning also?
- The impact of sunbed use and other photodamaged skin conditions;
- The patterns of sunbed exposure and the risk of skin cancer; and
- More detailed cost-analyses for other health effects from sun-damaged skin (e.g., solar keratoses, photoageing).

7.2 Recommendations

Based on the findings in this report, the following recommendations are made for further consideration;

1. A national uniform approach for mandatory regulation of the solaria industry is warranted and should proceed.
2. If the regulations are based on the recommendations in the current Australian/New Zealand Standard on Solaria for Cosmetic Purposes, this Standard needs improvement and review. Specifically, the Standard needs to be clearer, simplified and accessible to a wider non-scientific audience. The Standard should be modified to align with the same recommendations for solarium use by the WHO and ICNIRP that prohibit consumers younger than 18 years and persons with skin type I and II.
3. A coordinated monitoring system should be developed to monitor the levels of compliance by the industry with both the behavioural and technical elements of the Standard. This is to ensure that any future evaluations are based on high-quality data.
4. It is not recommended that taxation be used as a disincentive for solarium use due to the inefficiency and ineffectiveness of such a strategy.
5. Cost-effectiveness analyses provided in this report could be updated at a later time as new pertinent information becomes available and this process could be undertaken at both Federal and State levels.

Appendices

- Appendix A Summary of studies reporting prevalence of solarium use
- Appendix B Summary of studies on industry compliance with guidelines
- Appendix C Potential strategies for enforcing regulations
- Appendix D Illustration of the Markov decision trees, Melanomas and SCCs
- Appendix E Methods used to derive costs of skin cancers
- Appendix F Additional tables for undiscounted results and sensitivity analyses
- Appendix G Persons consulted in the preparation of this report

Appendix A: Summary of studies reporting prevalence of solarium use

Authors	Year	Size	Sample	Study Type	Usage criteria	% of sample using solaria	Usage	
							Males	Females
AUSTRALIA								
NSW Dept of Health	2006	2618	Age 12-17 School children	Cross-sectional survey	≥1 in past 12 months	12.4%	11.5%	13.3%
NSW Dept of Health	2006	11241	NSW Population	Cross-sectional survey	≥1 in past 12 months	2.3%	2.0%	2.6%
Dobbinson & Borland	1999	601	VIC Population	Cross-sectional survey (doorstep)	≥1 in past 12 months	3%	-	-
Lawler et al	2006	9419	QLD Population	Cross-sectional survey (telephone)	≥1 in past 12 months Ever use	0.9% 8.8%	0.51% -	1.27% -
Dobbinson	2004	1426	VIC Population	Cross-sectional survey (telephone)	≥1 in past 12 months	3%	-	-
US & CANADA								
Lazovich et al	2004	1273	Adolescents age 14-17	Random telephone survey	Ever use	30.3%	12.0%	41.6%
Oliphant et al	1994	1008	High school students 14+	Cross-sectional survey	Ever use	34%	15.0%	51.0%
Stryker et al	2007	5514	National Survey	National cross-sectional survey (telephone)	≥1 in past 12 months	7.3%	5.1% (3.3-8.2)	11.3% (9.3-13.6)
Cokkinides et al	2007	1192	Representative sample of US youth	Cross-sectional survey (telephone)	≥1 in past 12 months	10.1%	4.8%	15.6%
		1187	Caregivers to youths			8.1%	2.5%	10%
Demko et al	2003	6903	Representative sample, white non-Hispanic youth, 13-19	Longitudinal study of adolescent health	Ever use	17.6% (14.4-21.3)	6.9% (4.7-10.1)	28.1% (23.2-33.8)
Robinson et al	1997	658	Teenagers age 11-19	Cross-sectional survey (telephone)	≥1 in past 12 months	8.5%	1.2%	16.4%
Geller et al	2002	10079	Age 12-18, white children of participants in the Nurses Health Study	Cross-sectional survey, self-report	≥1 in past 12 months	10%	2.8%	15.0%
Magee et al	2007	364	364 parents of (687) children at pediatric and dermatology clinics	Survey of dermatology and pediatrics users	Ever use	65.0%		
					7.0%			
		687			Current use	6.0% 3.0%		
Poorsattar et al	2007	375	Undergrad college students	Cross-sectional survey	Ever use	33%	17.0%	42.0%
					≥1 in past 12 months	22%	-	-
Zeller et al	2005	1275	Youth age 14-17	Telephone interview	≥1 in past 12 months Ever use	20.9% 30.3%	6.8%	28.0%

Rhainds et al	1999	1003	White persons age 18-60	Cross-sectional survey (telephone)	Ever use	20.2%	16.9%	23.4%
Authors	Year	Size	Sample	Study Type	Usage criteria	% of sample using solaria	Usage	
							Males	Females
EUROPE								
Boldeman et al	1997	1239	School children age 14-19	Cross-sectional survey	> 3 x 30min session in past year	56.6%	44.2%	70.4%
Boldeman et al	2001	6678	Urban area, ages 13-50	Cross-sectional survey	Current use	28.2%	17.2%	37.7%
McGinley et al	1998	205	Solarium users	Cross-sectional survey	Current use	100%	17.1%	82.9%
Hamlet & Kennedy	2004	1405	School children age 8-11	Cross-sectional survey	≥1 in past 5.5 months	6.8%	-	-
Ezzedine et al	2007	7200	National cohort	Cross-sectional survey (self-report)	Ever use	14.9%	6.8%	26.4%
Lazovich & Forster	2005		-	Systematic Review	Ever use	24-30%	25-33%	67-75%

Appendix B: Summary of studies on industry compliance with guidelines

Authors	Year	Location	No. of Cases	Guideline	Compliance (%)
Culley et al	2000	San Diego	54	Shut-off switch present and compliant	57.4%
				Danger labels present	85.2%
				Danger statement legible/correct	74.1%
				Other (exposure) labels present	85.2%
				Other (exposure) labels legible/correct	74.1%
				Frequency allowed to tan	5.6%
				Duration allowed to tan	97.7%
				Protective eye-wear provided	100.0%
				Eyewear sanitised between uses	100.0%
				Eyewear required for facility use	88.9%
				Warning sign posted in tanning area	20.4%
				Warning sign legible/correct	14.8%
Dobbinson et al	2006	Melbourne	30	Parental consent for ages 14-18	42.6%
				Require protective goggles	87%
				Prohibit use for Skin Type 1	10%
Forster et al	2006	Minnesota & Massachusetts	200	Parental consent for U18	48%
				Parental consent for U16	31%
				Prohibit use for U13 without parent and physician consent	23%
Hester et al	2005	Texas	100	Parent accompany for 13-15	11%
				Parental consent for 16-17	-
		Illinois	100	Prohibit use for U14	74%
				Parental consent for U18	76%
		Wisconsin	100	Prohibit use for U16 - (for 12yo)	89%
				Prohibit use for U16 - (for 15yo)	77%
		Colorado	100	Prohibit use for a 12 year old	18%
				Parental consent for 15+	86%

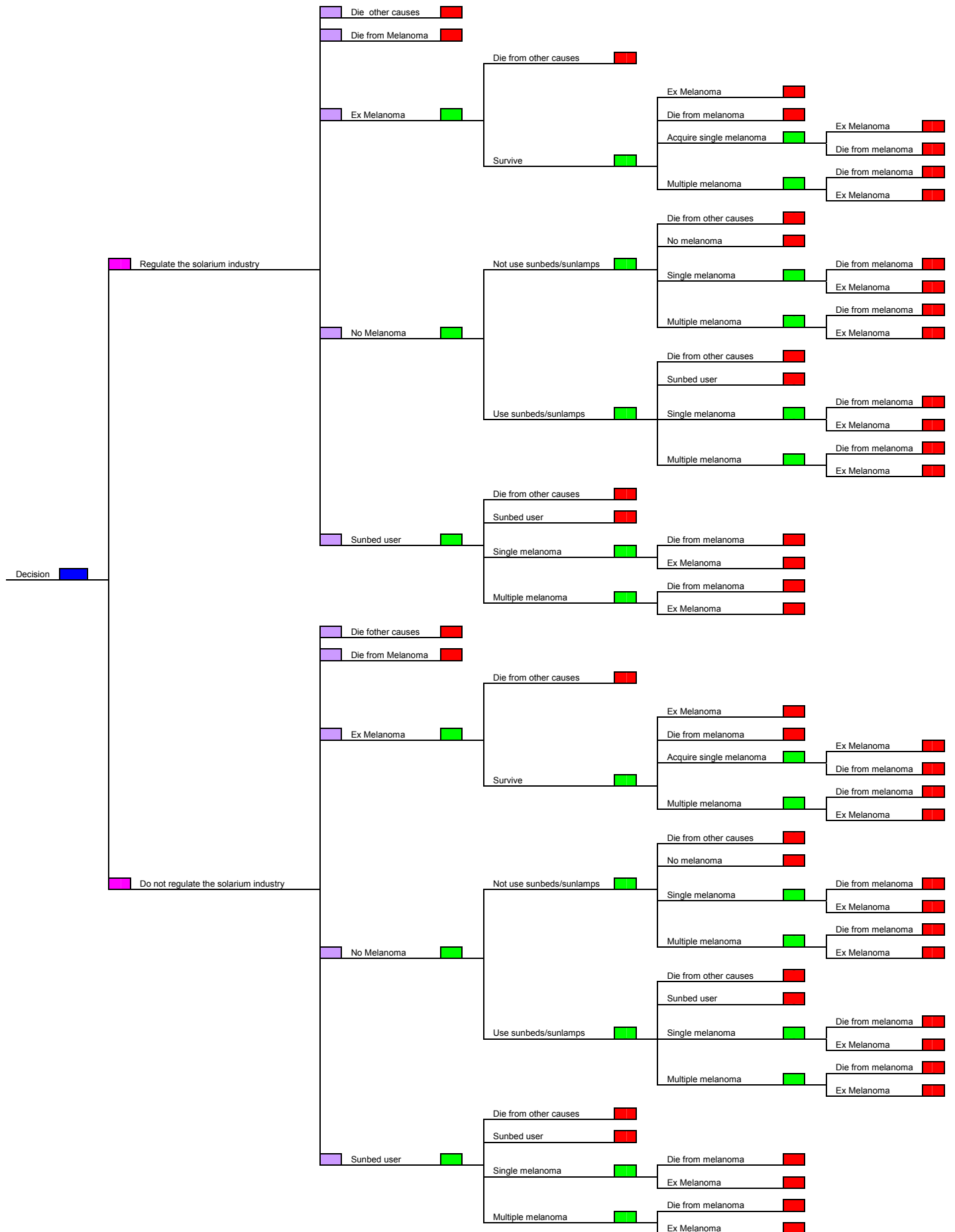
Authors	Year	Location	No. of Cases	Guideline	Compliance (%)
Hurd et al	2006	San Diego (USA)	115	Max 3 visits per week	25.5%
				Parental consent for U18	73.3%
				Max 3 visits per week	17.5%
				Parental consent for U18	80.8%
Paul et al	2005	Sydney region	176	Recommend non-use by Skin Type 1	76.4%
				Provided information on age restrictions	26.7%
				-and required a consent form	28.7%
				Advised on minimum exposure gap of 48h	72.1%
				Informed of supervision procedure	12.0%
				Advised to use safety goggles	68.5%
Szepietowski et al	2002	Poland	55	Advised that age restrictions apply	62.5%
				Promotion of UV as healthy	90.1%
				Prohibit U15	18.2%
				Provision of protective eyewear	41.80%
Team & Markovic	2006	Australia	22	Prohibit claims of non-cosmetic health benefits	50%
WA Dept of Health	2006	Western Aus	50	Survey 1:	
				Awareness of standard	62%
				Copy of standard on premises	32%
				Consent form for new clients	84%
				Warning notices displayed	22%
				Clients required wear goggles	100%
				Aware of minimum age for use	34%
				Time restriction of 48 hours between use	82%
				Prohibit skin type 1	60%
				Are all clients supervised	100%
				Staff trained in operation and use	80%
				Monitor exposure time based on skin types	98%
				Disinfection of solaria after each use	98%
				Knowledge of increased cancer risk from UVA	84%

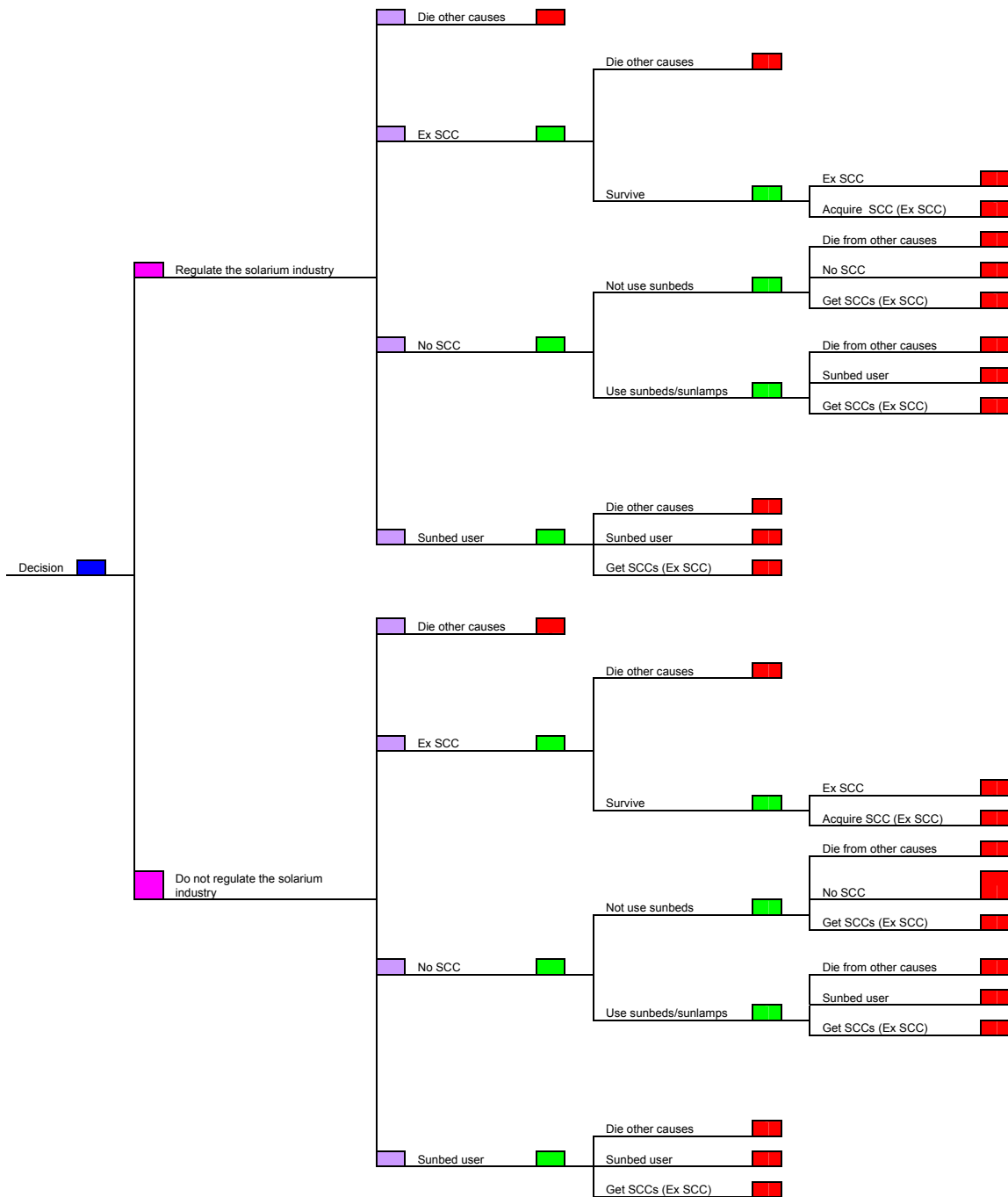
				Survey 2:	
				Awareness of standard	84%
				Copy of standard on premises	63%
				Consent form for new clients	81%
				Warning notices displayed	68%
				Clients required wear goggles	97%
				Aware of minimum age for use	41%
				Time restriction of 48 hours between use	87%
				Prohibit skin type 1	66%
				Are all clients supervised	92%
				Staff trained in operation and use	87%
				Monitor exposure time based on skin types	18%
				Disinfection of after each use	100%
				Knowledge of increased cancer risk from UVA	97%
Hornung et al	2003	North Carolina	50	This study looked at the exposure times and time during first use. Finding that exposure times exceed FDA recommendations in both regular and first time users.	
Lawler et al	2006	Queensland	83	Consent form signed by all users	42.8

Appendix C: Potential enforcement strategies

The following strategies may be considered for implementing regulations by State regulatory radiation health and public health agencies:

- public education of solaria risk at point of service
- auditing consent forms (for age, records of skin type, customer contact details and matching number of consent forms to number of sales)
- licensing solaria services following an approved training course
- certificate of training and license to be displayed clearly
- monitoring of solarium promotional messages
- customer sign-in to allow record of frequency of use
- availability of protective goggles and spares
- enforcement notices requiring goggles
- existing UVR equipment to be tested and certified as maximum UVR intensity
- UVR equipment on sale certified to max output levels
- re-testing on annual basis
- make solaria liable for customers with erythema
- enforce appropriate financial penalties





Model information

- = Decision node: The model evaluates each branch as a competing option
- = Markov node: All transition/starting state payoffs are accumulated under this node
- = Starting state: At the end of each cycle all members of the cohort will sit in one of these states
A payoff may be attributed to the cohort members starting each cycle in a given state
- = Probability node: All branches from this node have specific probabilities of occurring. The sum of all branches from a probability node is equal to one.
- = Terminal node: All paths along the tree end in terminal node, which designates which starting state the cohort member must commence the next cycle in.

The 'Regulate' and 'Do not regulate' sub-trees of the model are the same in design, but effects of regulation will alter the probabilities at the probability nodes. These probabilities also change through time as the cohort ages

Appendix E: Methods used to derive costs of skin cancers

The medical management costs of skin cancer used in the decision model were derived from current analyses undertaken at QIMR and based on a large population-based cohort as part of the Nambour Study. This cohort enrolled 1,621 persons who have been followed from 1992 to 2006 and originally commenced with The Nambour Skin Cancer Prevention Trial, investigating the effectiveness of daily sunscreen use. The trial was conducted over 4½ years (1992-1996) in the subtropical township of Nambour, located in southeast Queensland (latitude 26° South) approximately 100 km north of Brisbane. Full details of the study protocol and key findings have been previously reported^{200,201}. Ethical approval for The Nambour Study was obtained from the QIMR Human Research Ethics Committee prior to commencement.

We estimated the medical costs of treating and managing skin cancers (melanoma, SCC and BCC) in the Nambour cohort. Individual-level data were available through the ongoing monitoring of skin cancers diagnosed in the trial participants from 1992-2006. Arrangements were made with the local pathology laboratories to provide the QIMR project staff with original histopathology reports of any skin lesions treated among the participants during the trial and post-trial periods enabling complete clinical data records. Individual treatment pathways for the established histopathologically confirmed cancers were not available. We searched MEDLINE to find Australian studies in the last 10 years that described management strategies for skin cancers in population-based samples in primary care. We found four publications that matched this criteria²⁰²⁻²⁰⁵ and applying these distributions, we randomly imputed management strategies for each skin cancer²⁰⁶. Treatment services were valued using Medicare fees by assigning the relevant Medicare code and the most recent Medicare Scheduled Fee (representing the cost to the Federal Government, through Medicare Australia)²⁰⁷. We also examined diagnosis dates to take into account the potential cost-efficiencies relating to doctors visits, treatment and pathology, where a person may have had several cancers treated simultaneously. We made a further cost adjustment to allow for medical costs for skin lesions that are treated in actual practice but are subsequently confirmed as benign lesions by histopathology. This estimate was derived from a positive predictive value of 70%²⁰⁸ reported among Queensland primary care physicians and is the proportion of BCC, SCC and melanomas clinically diagnosed as skin cancers and confirmed by pathology diagnosis.

We did not apply discounting adjustments to costs as this was not necessary in a retrospective cost analysis. Individual-level cost data is often right-skewed with some individuals incurring very high costs while others have zero or minimal costs. We obtained bootstrapped mean costs per participant in our analysis. Bootstrapping involves re-sampling from the original skewed distribution a large number of times with replacement. We generated 1000 bootstrapped samples using the bias-corrected-accelerated approach as recommended for handling cost data in economic evaluations²⁰⁹. We obtained 95% CIs around all mean costs and we obtained costs among individuals with singular and multiple diagnoses of melanoma, SCC or BCC. The low and high confidence intervals were tested in one-way sensitivity analyses to investigate their variation on the final cost-effectiveness modelling results.

These cost analyses are incorporated into current research by QIMR researchers are yet to be published. For further information, please contact Dr Louisa Gordon, Louisa.Gordon@qimr.edu.au or 07 3845 3542.

Appendix F: Additional tables for undiscounted results and sensitivity analyses

Undiscounted results:

	Do not Regulate the Industry	Cohort of 100,000 Regulate the Industry	Difference	Cohort of 3.9 million
Melanomas	5781	5649	132	5131
SCCs	36098	34854	1244	48517
Life years lived	6695505	6695763	-258	-10049
Life years lost	10210	9899	311	12115
Costs (melanoma)	\$7,488,985	\$7,318,536	\$170,449	\$6,647,529.63
Costs (SCC)	\$35,845,088	\$34,609,768	\$1,235,319	\$48,177,447.74
Total costs	\$43,334,073	\$41,928,304	\$1,405,769	\$54,824,977.37

Other one-way sensitivity analysis results:

First year case-fatality rate of melanoma:

1st year Melanoma CFR	Cost	Melanomas	Life years lived	Life years lost
Regulate				
0.028	\$11.39	0.00880	23.37694	0.01081
0.02875	\$11.40	0.00880	23.37686	0.01091
0.0295	\$11.41	0.00880	23.37678	0.01100
0.03025	\$11.42	0.00879	23.37669	0.01110
0.031	\$11.44	0.00879	23.37661	0.01119
Do not regulate				
0.028	\$11.74	0.00907	23.37660	0.01120
0.02875	\$11.75	0.00906	23.37651	0.01130
0.0295	\$11.76	0.00906	23.37642	0.01140
0.03025	\$11.77	0.00906	23.37634	0.01150
0.031	\$11.78	0.00906	23.37625	0.01160
Difference *100,000				
0.028	\$34,318	26.52	34.6	39.3
0.02875	\$34,349	26.51	34.9	39.6
0.0295	\$34,379	26.50	35.2	39.9
0.03025	\$34,409	26.49	35.4	40.2
0.031	\$34,439	26.48	35.7	40.6

Lifetime case-fatality rate of melanoma (as an annual risk):

Lifetime melanoma CFR	Costs	Melanomas	Life years lived	Life years lost
Regulate				
0.005857	\$11.41	0.00881	23.37706	0.01068
0.00602525	\$11.40	0.00880	23.37690	0.01086
0.0061935	\$11.40	0.00880	23.37675	0.01104
0.00636175	\$11.39	0.00879	23.37660	0.01121
0.00653	\$11.38	0.00879	23.37644	0.01139
Do not regulate				
0.005857	\$11.75	0.00907	23.37671	0.01107
0.00602525	\$11.75	0.00907	23.37655	0.01125
0.0061935	\$11.74	0.00906	23.37640	0.01144
0.00636175	\$11.73	0.00906	23.37624	0.01162
0.00653	\$11.72	0.00905	23.37608	0.01180
Difference *100,000				
0.005857	\$34,372	26.5	34.1	38.8
0.00602525	\$34,346	26.5	34.7	39.4
0.0061935	\$34,320	26.5	35.3	40.1
0.00636175	\$34,294	26.5	35.9	40.8
0.00653	\$34,268	26.5	36.5	41.4

Risk of additional SCC:

Additional SCCs	Cost	SCCs
Regulate		
0.01	\$82	\$0.082
0.0175	\$92	\$0.092
0.025	\$102	\$0.102
0.0325	\$112	\$0.113
0.04	\$122	\$0.123
Do not regulate		
0.01	\$84	\$0.084
0.0175	\$94	\$0.095
0.025	\$104	\$0.105
0.0325	\$115	\$0.115
0.04	\$125	\$0.126
Difference *100,000		
0.01	\$214,730	\$216
0.0175	\$239,172	\$241
0.025	\$263,432	\$265
0.0325	\$287,510	\$290
0.04	\$311,409	\$314

Appendix G: Persons consulted in the preparation of this report

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