Melanoma Institute Australia

‘SKIN CHECKS’ FOR MELANOMA IN AUSTRALIA

Addressing the national conversation around melanoma screening

MELANOMA INSTITUTE AUSTRALIA AND NATIONAL MELANOMA EXPERTS POSITION STATEMENT

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POSITION STATEMENT AND RECOMMENDATIONS

Executive Summary

- Many Australians seek out regular skin checks for the diagnosis of skin cancers.
  - There are many types of skin cancer, of which melanoma is the most lethal.
  - Keratinocyte (non-melanoma skin) cancers (including basal cell carcinoma and squamous cell carcinoma) are more common than melanoma, but much less likely to cause serious illness or death.
- Regular skin checks for melanoma, in the absence of a new and/or changing skin lesion (i.e., screening skin checks), are not recommended for most people in the general population.
  - There is no strong evidence of benefit.
  - There are multiple potential harms.
- A screening program restricted to individuals at the highest risk of melanoma should be considered.

Extended Summary

Many Australians in the general population present for regular skin checks, largely to primary care (general practitioners), but also to specialised skin cancer clinics and dermatology centres, in the absence of skin symptoms such as a new or changing pigmented lesion. However, research on the benefits and harms of having regular skin checks to screen for melanoma, in the absence of symptoms, by a health professional is limited.[1,2] The current evidence does not show clear evidence of a benefit from screening for melanoma in the asymptomatic general population and it is not currently recommended in Australia. There is some emerging evidence that screening of the general population may lead to some harms, including overdiagnosis and overtreatment.[3]

Instead of screening for melanoma and other skin cancers for everyone in the general population, we recommend efforts be directed toward early diagnosis (secondary prevention) via (a) a national awareness campaign to 'know the skin you're in' and (b) a National Targeted Screening Program for people at high risk of melanoma. Critically, there must also be a renewed focus on contemporary primary prevention campaigns. The former (a) would encourage people to become familiar with their own skin and to visit a doctor as soon as they see something new or changing. The latter (b) would entail a funded national skin checking program to screen for melanoma in the people at the highest risk. This program would aim to address inequities in the current opportunistic approach to skin checks and provide clarity on the definition of a 'high-risk individual' for practitioners. There is evidence that a structured surveillance program for people at very high risk of melanoma is more effective and less expensive than usual care,[4-6] and that Australian melanoma risk assessment tools can help to distinguish people at higher and lower risk. A multidisciplinary committee of national experts in skin cancer are currently working on the Melanoma Screening project. This project aims to determine how risk-targeted screening should proceed, including consensus on what constitutes a high-risk individual and approaches to improving the accuracy of skin examination, including the role of skin imaging technologies, and standardising the quality of skin checks, in the context of cost–effectiveness and workforce availability. The committee met on July 31, 2023, to begin drafting a protocol for a possible targeted melanoma screening trial which would be instrumental in defining future melanoma screening strategies.

Future research priorities include defining the high-risk population for melanoma screening in Australia, quantifying the true benefits, harms, and costs of screening, and ensuring equitable access. Ultimately, the most important approach to reducing the burden of melanoma in Australia is primary prevention (i.e., using sun protection),[7-9] as 63–96% of melanomas in Australia are estimated to be caused by overexposure to ultraviolet radiation (UVR) exposure from the sun and are thus preventable.[10,11] It is essential that primary prevention is integrated alongside skin awareness and early detection initiatives.

INTRODUCTION

Melanoma is Australia's national cancer. Australia experiences the highest incidence rates of melanoma and keratinocyte (non-melanoma skin) cancers in the world,[12] with skin cancer accounting for over 80% of all new cancer diagnoses.[13-16] In 2021, invasive melanoma was the second most common reportable cancer in males (after prostate) and the third most common reportable cancer in females (after breast and colorectal)[i] and is the eleventh most common cause of cancer death.[13] In addition to the approximately 18,000 invasive melanomas diagnosed in Australia each year, another 28,000 in situ melanomas (an early and non-lethal form of melanoma, stage 0) are diagnosed (see **Figure 1** for information on melanoma staging).[13] Around 10% of people with a melanoma develop additional primary melanomas. The 5-year survival rate for invasive melanoma in Australia is 92%, driven by the fact that 89% of melanomas are diagnosed early (when thin and confined to the skin[ii]).[13,17] Patients with thin melanomas are typically treated with surgical excision (with costs of ~A$644 in the first year of diagnosis); at the other extreme, a patient with distant metastatic (stage IV) melanoma will require complex investigation and management likely including imaging, drug therapies, and hospitalisation (with costs ~A$101,000 in the first year of diagnosis).[17] In the 2021/22 financial year, the Australian government spent A$0.46 billion on drug therapies for advanced melanoma.[18] Reducing the burden of melanoma, particularly late-stage disease, is a national health priority. It is also a priority to optimise the diagnosis and management of keratinocyte skin cancers, as the sheer volume of the more common keratinocyte cancers (squamous cell carcinoma and basal cell carcinoma) contributes to an estimated annual health expenditure for skin cancer in Australia of A$1.7 billion.[7]

For decades, there has been discussion in clinical, academic, and political circles as to the role of screening for melanoma in Australia. Cancer screening is defined as the search for disease in an apparently healthy population, which facilitates early detection and treatment to stop the disease course before it becomes morbid or fatal. In routine care, diagnosis at an earlier stage is linked to a better chance of survival,[19,20] which lends an intuitive appeal to 'catching melanoma early' by implementing regular skin checks to screen for melanoma in the general population.[21] Regrettably, the high-quality evidence from clinical trials essential to implement such a screening program – i.e., evidence showing that screening for melanoma results in diagnosis at an earlier stage that then improves prognosis – is lacking. Efforts to conduct a randomised control trial in Australia in the early 2000s did not receive the necessary funding to proceed.[3,22] Alongside a chorus of national and international experts,[3,9,23-28] the US Preventive Services Task Force continues to conclude that there is insufficient evidence to make a recommendation either for or against skin cancer screening in the general population.[1,2]

In this document, we provide a comprehensive review of the evidence for systematised melanoma screening using skin checks in Australia and, on behalf of Melanoma Institute Australia and national experts, provide a clear position statement on the question of whether, and if so, how, melanoma screening should be implemented in Australia.

i The most common cancer in Australia, non-melanoma skin cancer, is not reportable by law to most cancer registries and excluded from these figures. This is because it is very common and rarely life-threatening.

ii The 89% includes melanomas ≤1 mm in thickness (in situ [stage 0] melanoma and stage I melanoma). Diagnosis at later stages is less common: 7.1% at stage II, 1.5% at stage III, and 1.1% at stage IV. Stage is unknown in 1.5%.

2 PRINCIPLES OF CANCER SCREENING

In the typical pathway to a cancer diagnosis, people either develop symptoms that lead them to seek medical attention or have signs of disease that are detected opportunistically by a healthcare professional. The aim of a cancer screening program is to identify cancers at a much earlier stage, before symptoms arise (i.e., in people who are apparently healthy). A cancer screening program will involve a screening test or examination, designed to identify people who may have that cancer. Screening tests are not diagnostic; rather, they are designed to identify individuals who should undergo further investigation, which may include monitoring, diagnostic testing, and/or referral to specialist care.[29,30] Early diagnosis and treatment through screening can lead to better health outcomes; however, cancer screening can also cause harm (**Box 1**).

Box 1. Benefits and harms of a cancer screening program

The **benefits** of cancer screening mainly apply to positively screened individuals who receive an early cancer diagnosis. Most individuals who undergo screening have a negative test and will receive little-to-no benefit.

Improved outcomes may include secondary prevention[iii] (e.g., early removal of a precancerous lesion) or reduced risk of severe disease, morbid interventions, and death (e.g., treatment of a localised cancer prior to it spreading).

Screening programs can also provide reassurance to negatively screened individuals who are truly disease free and improve disease education and awareness, including prevention.

Cancer screening can also cause **harms**. Screening tests make errors by negatively screening some individuals who do have disease (risking false reassurance, delayed diagnosis, loss of trust, and legal consequences) and positively screening some patients without disease (risking unnecessary investigations and treatment with possible complications, psychological ramifications, and strain to both individuals and the health system, including financial stress).

Even when the screening test is correct, harm can ensue in the form of 'overdiagnosis.' Overdiagnosis refers to detection of cancers that would not have progressed during a person's lifetime, and where knowledge and treatment of the cancer does more harm than good.[31,32]

iii There are several tiers of cancer prevention. Primary prevention is the most effective and refers to actions which prevent cancer from arising (e.g., clothing and availability of shade). Secondary prevention refers to early detection and treatment which prevents cancer from progressing (e.g., removing an in situ melanoma).

3 THE ‘SKIN CHECK’ AND SUPPORTING TECHNOLOGIES

The availability of an accurate, high-quality screening test or examination (**Box 2**) is a key principle of whether it is possible and appropriate to implement cancer screening.[29]

The current ‘test’ for melanoma is a whole-body skin check using the naked eye, performed by a healthcare professional during a clinical consult; typically, this is a general practitioner or a dermatologist.[33-37] Any suspicious lesions identified during the consult can be monitored using serial imaging approaches or surgically biopsied for a histopathological diagnosis. Skin checks can be used to detect melanoma in both screening and surveillance settings (**Box 3**).

It is recommended that a naked-eye examination is supplemented by dermoscopy,[33-37] which is the use of a hand-held magnifying device (a dermatoscope) to inspect suspicious skin lesions more closely. Dermoscopy allows visualisation and digital image capture of diagnostic features not seen by the naked eye and is known to improve diagnostic accuracy in primary care and dermatology settings. There are several practical challenges to the use of dermoscopy,[38,39] including interobserver subjectivity[40,41] and a high level of required skill,[42,43] as well as a lack of training in Australian medical curricula.[38,44]

Detecting melanomas can be difficult, given the variety of new and changing benign age-related lesions that resemble melanoma, occurring particularly in people with high cumulative sun damage. In addition, some melanomas have subtle features or lack features typical of melanoma, such as dark pigmentation. In clinical trials and other research settings, whole-body skin checks (with or without dermoscopy) are increasingly supported by a range of established and emerging non-invasive adjunctive technologies, including total body photography, sequential digital dermoscopy imaging, and cutaneous confocal microscopy, to improve the accuracy of screening. Automated diagnostic implements and artificial intelligence are increasingly being integrated into skin imaging technologies to assist with monitoring and diagnosis of lesions, though none are currently recommended for use outside of a clinical trial.[34] Accuracy, cost-effectiveness, and acceptability of these techniques in a screening setting remains unclear. It is unclear exactly how a ‘skin check’ would be defined in a modern-day screening scenario in Australia.

Box 2. Quality and accuracy of skin checking approaches

It is important that a cancer screening test has good accuracy (i.e., results in a low number of false positives and false negatives). Minimising false positives is particularly important for screening tests like the skin check that can lead to an unnecessary surgical biopsy. The accuracy of a skin check varies depending on a range of factors, including the clinician performing the check, their use of supporting technology, and their level of training in skin checking and dermoscopy. Dedicated services, including experienced general practitioner-led clinics and dermatology-led clinics in high-risk patients, have demonstrated between 1–4 benign lesions biopsied for every one melanoma.[6,45] However, it is likely that there is significant variability among the accuracy of skin checks.

3.1 AUTOMATED DIAGNOSTIC IMPLEMENTS AND ARTIFICIAL INTELLIGENCE

Automated diagnostic implements and artificial intelligence programs used for the diagnosis of primary melanoma typically work by digitally analysing and categorising images (either dermoscopic photos or clinical photos) of skin lesions.[iv] While these approaches are not ready for implementation,[46] automated diagnostic tools[47,48] and artificial intelligence programs[49,50] have shown promise for matching or improving the accuracy of skin cancer detection by clinicians. In a recent study, cooperation between a dermatologist and convolutional neural network provided the better outcomes than either agent alone.[51] There is also some evidence that after interaction with artificial intelligence (as with other forms of educational interventions), decision-making of less experienced doctors may improve.[52] Artificial intelligence has the potential to address equitable access to care by addressing geographic, clinical, financial, and other barriers to care.[52]

However, many systems to date have lacked or had poor performance in individuals with skin of colour and non-pigmented melanomas, and more real-world evidence is required to assess performance of algorithms in community-based settings. Evidence increasingly shows that artificial intelligence algorithms developed in one setting may not be transferrable or accurate in another, and any such systems planned to be used within a screening program would need to be tested and validated with Australian image datasets. Even large simulated diagnostic studies of artificial intelligence instruments may not predict diagnostic accuracy when transferred to a real clinical scenario.[49] More research and development are required before artificial intelligence technologies could be useful in Australia.

Box 3. Screening versus surveillance

It is not uncommon for people to be diagnosed with multiple primary melanomas, either simultaneously or over time. In Australia, up to 18% of patients with a melanoma will develop subsequent melanomas,[53-57] representing a ~10-fold increased risk compared with the general population.[58,59] Patients with a personal history of melanoma may be monitored for recurrence of existing melanomas as well as development of new primary melanomas as a part of their cancer care; this practice of routine, systematic follow-up of pre-existing melanoma patients is defined as “surveillance” rather than “screening”. However, if a targeted screening program for individuals at the highest risk of melanoma was implemented, it should consider pathways for people with and without a previous melanoma.

Total body photography is the process of systematically recording the skin surface, typically as a reference point to check whether lesions are new or changing. Total body photography is known to improve the early detection of melanoma.[60] It is recommended as the primary adjunct to clinical examination for surveillance of those at very high risk of melanoma in Australia[33] (see Section 8 for information on melanoma risk stratification). There is currently no evidence from randomised controlled trials supporting this use of total body photography in surveillance or screening settings, however a trial in the surveillance setting is ongoing.[61] Total body photography can now be used to construct 3D patient avatars for automated analysis.[62]

iv Importantly, human decision-making is still embedded in automated and artificial intelligence approaches, including lesion selection.

4 INVESTIGATING MELANOMA SCREENING

It is essential that decisions about whether to implement a cancer screening program are founded on high-quality evidence assessing feasibility, benefits, harms, and costs. It is critical that the various components of the screening model are directly linked, from the screening test achieving early detection to early screen-detection achieving meaningful health benefits.[63] Cost–effectiveness of the program is essential and discussed separately in **Section 6**.

4.1 STUDY TYPE

A randomised control trial is the best way to assess the effectiveness of a screening intervention, although knowledge may be supported by well-designed retrospective or non-randomised prospective studies.[21,64] In a randomised cancer screening study, individuals or groups are randomly allocated to receive either a scheduled screening intervention or usual care and then followed over time.[22] Randomisation is important in cancer screening trials for several reasons. Individuals who prospectively volunteer for (or have a habit of participating in) health interventions such as skin checks are likely to be in good health and have good health awareness (known as the healthy volunteer bias).[65,66] Thus, an observed correlation between skin cancer checks and better melanoma outcomes could be confounded by other health-conscious behaviours of non-randomised individuals.[67]

However, randomised cancer screening trials are large, logistically complex, and expensive; it can take years or decades for sufficient statistical evidence to accrue to decide definitively whether screening is effective in improving health outcomes and reducing mortality. To date, there have been no completed randomised controlled trials of melanoma screening[v], with some suggesting they are prohibitively resource-intense[68] and will likely never be conducted with mortality as a primary outcome (see **Section 4** below for an in-depth discussion on trial outcomes). Others argue that such a trial would have multiple tangible benefits,[69] such as improved quality assurance.

4.2 STUDY OUTCOMES

4.2.1 Reduction in Deaths

Cancer screening programs are primarily designed to reduce deaths, traditionally measured as a reduction in mortality and/or disease-specific mortality.[21,70] However, measuring changes in melanoma-specific mortality is difficult and costly, because most melanomas are low risk and mortality data (i.e., a 'saved life') following early intervention may take decades to accrue. While mortality can still be tracked, there is keen interest in defining surrogate outcomes (i.e., substitutes) that accrue more quickly.[70]

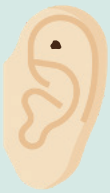
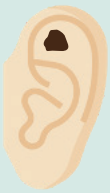
Diagnosis with melanoma at an advanced stage is linked to poor survival outcomes, while diagnosis at an earlier stage is linked to much better survival outcomes (**Figure 1**).[19,20] It follows that inducing a 'stage shift' in the screened population (i.e., seeing more cases of early disease and/or fewer cases of advanced disease) would correlate with a reduction in mortality, and therefore be a useful surrogate outcome. Tumour thickness is a key indicator of stage for locoregional melanoma, with thicker tumours indicating a worse prognosis[20,71-73] and a more advanced stage[19,20] (although thin melanomas can also spread). Several observational screening studies have hence used thickness at diagnosis as a surrogate for early detection and mortality.

v The randomised controlled trial study in Queensland was discontinued after the pilot due to lack of funding.

There are several problems with this interpretation of tumour thickness. Firstly, the assumption that an increase in the detection and treatment of thin melanomas will reduce the burden of thicker melanomas in the population is intuitive, but not necessarily true.[28,32] Skin cancers detected by screening tests are more likely to be slow-growing than those detected symptomatically, simply because the more rapidly growing lesions will draw attention more quickly and may arise during screening intervals.[21,67] Not all melanomas appear to have an intrinsic metastatic or lethal potential, with some remaining idle and others actively regressing.[74-76] Counter-intuitively, this means that an increase in screen-detected thin melanomas might actually worsen outcomes at the population level, as resources are spread more thinly and lesions requiring urgent attention are diluted in an abundance of less dangerous lesions. A corresponding decrease in the number of thicker tumours may strengthen the argument that mortality will also decrease, but this is not guaranteed. Hence, tumour thickness may not be an ideal endpoint, especially if measured and interpreted in isolation.

A reduction in the number of patients with significant morbidity or need for extensive treatment (e.g., systemic drug therapy) are important benefits,[21] and may be more appropriate endpoints for a trial. These could be supported by existing data capture systems (e.g., Pharmaceutical Benefits Scheme service data). Quality of life might be another key endpoint for screening trials.

Figure 1. Stages of melanoma[19,20]

	IN SITU MELANOMA	INVASIVE MELANOMA		
	In situ melanoma	STAGE I and II	STAGE III	STAGE IV
	Non-invasive local disease	**Invasive local disease**	**Regional disease**	**Distant disease**
				
	Tumour is confined to the topmost layer of the skin (the epidermis)	Tumour is invading into deeper layers of the skin, with stage and sub-stage depending on thickness and ulceration	Tumour has spread to locoregional sites (locoregional lymph nodes or in-transit/ satellite metastases)	Tumour has spread to distant sites (distant lymph nodes, or organs like the brain, lung, liver, and bone)
Primary skin tumour	✔	✔	Any	Any
Locoregional spread	✘	✘	✔	Any
Distant spread	✘	✘	✘	✔

4.2.2 Harms and Safety

There are several potential harms resulting from skin checking for melanoma that would be important to track in a melanoma screening trial, including but not limited to:

- The surgical burden of false positives, including negative sequalae like pain, infections, and scarring,
- Psychosocial harms, including from the skin check examination or following a false positive result,
- Financial costs to the individual and health system, and
- Overdiagnosis of melanoma.[77-80]

4.2.3 Quality Assurance and Monitoring

Screening programs require a dedicated registry of invitations to screen, screening examinations conducted and outcomes. In this way, programs can contribute to reductions in inequity as people have a fair chance to be invited regardless of their proximity to services, and improvements in service provision through standardisation of screening approach, central adjudication of complex pathology cases and monitoring of quality. A screening trial also allows the integration of translational research questions and can thus progress the evidence in multiple ways.

5 EVIDENCE FOR SKIN CHECKS IN THE GENERAL POPULATION

There is limited evidence for or against the use of screening skin checks to improve skin cancer outcomes in the general population. In the absence of randomised trials, observational studies provide the only evidence, which is discussed below. Note that cost–effectiveness is considered separately, in Section 6.

5.1 MORTALITY

A large ecological study conducted in the early-to-mid 2000s in northern Germany[81,82] reported an association between skin cancer screening and a reduction in skin cancer mortality. However, subsequent implementation of the proposed program nationwide provided no mortality benefit.

The original study involved an 8-hour training course for relevant physicians (including general practitioners and dermatologists) that covered basic skin cancer education, performance of the whole-body skin check, and recommendations for patient communication and follow-up. Twenty per cent of the population (N=360,288) participated in the program by receiving a skin check within a 12-month period. The study reported a 34% increase in the incidence of invasive melanomas and, after five years, a 48% reduction in melanoma mortality.[81,82] Following the study, national population-wide screening was implemented in Germany in 2008.[83] By 2013, however, no mortality benefit had been observed, possibly due to a less thorough screening process than used in the original pilot study.[83] Concerns were also raised about plausibility of the original study (i.e., how a study with only ~20% community uptake could result in a halving of melanoma mortality within five years).[68,84]

An Australian population-based cohort study found that melanomas diagnosed through routine skin checks were associated with a 59% reduction in melanoma-specific mortality compared with patient-detected melanomas (adjusting for age and sex). After accounting for patient, sociodemographic, and clinicopathological factors, the reduction was 32%, but no longer statistically significant (i.e., a chance finding could not be ruled out).[67]

5.2 TUMOUR THICKNESS

Several studies have compared tumour thickness at diagnosis of screening-detected versus symptom-detected melanomas, but few have examined how screening a group impacts the thickness of melanomas detected in future. In the prospective QSkin study (N=38,854), people with a history of getting skin checks had thinner melanomas on average than those with no history of getting skin checks (0.78 mm versus 1.39 mm).[85] A reduction in the diagnosis of thicker melanomas was reported by one large (N=7,586) Australian case-control study. Individuals who reported a whole-body skin check within the previous three years were 14% less likely to have a thick (>0.75 mm) melanoma and 40% less likely to have the thickest of melanomas (≥3 mm), but no resulting impact on mortality was discussed.[86] In a second study (N=595,799), screened and unscreened individuals were followed up for five years, at which point there was no difference in the thickness of subsequent melanomas.[87] A longer follow-up period may have allowed this data to mature further.

5.3 PSYCHOSOCIAL HARMS

There has been some research into the possible harms of skin cancer screening (and related diagnostic follow-up) to the individual. Available evidence suggests that embarrassment and discomfort are not significant factors for most people;[88] in one study, only 8% of participants reported embarrassment at their first whole-body skin check[89] while in a second study, whole-body checks were associated with no additional psychosocial harms compared with less thorough checks.[90] A Canadian study found that draping practices (i.e., using a sheet, gown, or paper cloth) to preserve privacy during whole-body skin examination were considered important to around 50% of respondents.[91] When surveyed, most people felt that skin checks were valuable[88,89] and would prefer they be performed regularly.[88,89] To our knowledge, no research on psychosocial harms of skin cancer screening has been conducted in Australia. An Australian-specific study into psychosocial harms of screening would be useful.

5.4 SKIN BIOPSIES

Positively screened patients typically receive a diagnostic skin biopsy. Skin biopsies are usually a minor and safe surgical procedure but can lead to complications including pain, bleeding, damage to local structures, infection, and scarring.[92] The cosmetic impact of deep shave excision biopsy as a component of screening was investigated and found to carry no meaningful cosmetic harms.[93] However, it should be noted that an excision biopsy (full-thickness, with a scalpel) is currently recommended for lesions suspicious for melanoma, as partial biopsies increase the rate of false negative diagnoses.[94-96]

6 COST–EFFECTIVENESS OF MELANOMA SCREENING

Cost–effectiveness of a screening intervention is affected by multiple factors, including cost of the screening examination/investigations, frequency of screening, size of the screened population, frequency of disease in the screened population, the frequency of off-target findings, and administrative costs, among others. It is impossible to assess whether screening for melanoma in Australia would be cost–effective without clarity on what the program specifications would be. Some considerations and currently available evidence are discussed below.

Non-melanoma skin cancers are the most common cancers diagnosed in Australia. They are typically indolent and non-life-threatening lesions that are diagnosed and excised in general practice without complication but do recur and cause death in comparatively few cases (but still causing ~600 deaths per year in Australia). In 2019/20, A$1.46 billion was spent by the Australian health system on diagnosis, treatment, and pathology services for non-melanoma skin cancer.[97] As the risk factors for melanoma and keratinocyte skin cancer are similar, it is likely that the cost–effectiveness of any melanoma screening program would be primarily determined by the burden of incidental non-melanoma skin cancer findings. Interestingly, an educational intervention targeting Australian males aged 50 years and older was found not to be cost–effective due to the resulting number of keratinocyte skin cancers and benign lesions detected and requiring management and treatment.[98] Increasing use of checkpoint immunotherapy in non-melanoma skin cancer, particularly advanced squamous cell carcinoma,[99-104] may create a need for earlier detection of aggressive squamous cell carcinoma that could add to the value of melanoma screening (although these are less likely to be diagnosed in general population screening, due to their association with particular risk factors and fast-growing nature).

An indication of how many skin cancers would likely be identified through population screening is provided by the randomised community-based pilot study of melanoma screening (for adults aged 30 years and older) conducted in Australia.[105] In this study, a total of 16,383 skin checks were performed and 4,129 suspicious lesions identified (in 2,304 people, resulting in a 14% referral rate). Excision and/or biopsy was performed on 1,417 lesions, resulting in histopathological diagnosis of 33 melanomas and 356 non-melanoma skin cancers. Overall, the probability of detecting any skin cancer in the community was 2.4%, and the probability of detecting a melanoma was 0.2%. Importantly, 15 of the 33 diagnosed melanomas had a suspected clinical diagnosis that was not melanoma; for the 161 lesions with a suspected clinical diagnosis of melanoma, only 15 were true melanomas on histopathological examination. This suggests that restricting a screening program to only those skin lesions suspected to be melanomas would miss a substantial number of cases.

Few studies have investigated the cost–effectiveness of primary and secondary approaches (e.g. screening, surveillance, and other methods to detect melanoma at early stage) to reducing skin cancer deaths in Australia.[106] It is known that primary prevention methods are far more cost–effective than intervention at later stages.[7,8,98,106] Evidence is available from countries other than Australia,[107-110] but may not be relevant to an Australian setting. Based on the available evidence, screening of the general Australian population may result in a low number of melanomas diagnosed per skin check, with a high cost per each melanoma.

7 CURRENT RECOMMENDATIONS AND PRACTICES IN AUSTRALIA

7.1 RECOMMENDATIONS

Australian clinical practice guidelines and health authorities do not recommend screening for melanoma in the general population. As discussed, there is very little evidence available on which to make high-quality, evidence-informed recommendations,[24] including who should receive screening skin checks and how regularly.

The current approach to skin checking in the general Australian population is opportunistic and non-standardised, with very little guidance to general practitioners or skin specialists other than taking a reasonable, risk-based approach.

Patients with a prior primary melanoma should undergo surveillance for new primaries (**Box 3**), as recommended by current melanoma guidelines. Clinical practice guidelines recommend regular 12-monthly whole-body skin checks with a healthcare professional,[33,35,37,111] supported by dermoscopy and digital monitoring, and total body photography where possible.[33] The current high-risk guidelines also include individuals with extreme risk factors, including some genetic mutations. More information on melanoma risk factors is provided in Section 8.1.

7.2 CURRENT PRACTICES

7.2.1 Skin Checks Performed by a Medical Professional

It is estimated that about one in three Australian adults have had a clinical skin check within the previous 12 months, with around 60% of those presenting for whole-body screening without a specific skin lesion of concern and 40% for a specific body part, or a mole or skin lesion of concern.[112] Whole-body skin checks were more common among older respondents (aged 45–69 years), females, and also varied by residence location (most common in Queensland and least common in the Northern Territory), skin sensitivity, skin colour, risk perception, and socio-economic status.[112] A study of skin check behaviours in rural Victoria found approximately 40% had had a clinical skin check within the past two years.[113]

Most melanomas (77%) are diagnosed in a primary care setting, indicating that skin checks are typically being performed by general practitioners (although this has changed over time and likely varies from state to state and practice to practice; **Box 4**).[114,115] In a study of general practice registrars, it was found that 49% had received training in dermoscopy and that dermoscopy was used in 61% of clinical skin checks.[38]

Several studies suggest that there is an awareness of skin cancer risk factors in the Australian community, with individuals at higher risk among those more likely to have presented for clinical whole-body skin checks.[112,116,117] Individuals were more likely to report a skin check if they had higher skin sensitivity, fairer skin, or a higher risk perception of skin cancer.[112] Socioeconomic status is also a key driver.[112]

7.2.2 Skin Self-Examination

Skin self-examination is the process of scheduled, structured self-examinations by the individual. Around one in three individuals from regional Queensland reported conducting a self-skin examination within the previous three years.[118] In a study of skin-checking intentions for the next 12 months, 45% of individuals intended to have a clinical skin check and 72% intended to conduct a skin self-examination.[117] Research also suggests that individuals with a history of clinical skin checks were more likely to perform self-examinations. Overall, however, it is believed that thorough self-examination (while possibly effective[119]) is perceived as demanding by individuals, and rarely performed, even among those at high risk of melanoma.[120-122]

Box 4. Who first detects melanomas in the general population?

Historically, most invasive melanomas were detected either by a patient or their partner/family member, rather than in a clinical setting.[67,123] Patterns of detection may vary from clinic to clinic and around the country. Up-to-date, population-based evidence is needed to understand patterns of melanoma detection and presentation in more depth and may help to inform screening recommendations.

7.2.3 Consumer-directed Technologies

Consumer-directed technologies such as mobile phone apps to aid in the self-monitoring and self-detection of melanoma are currently emerging. It is unclear whether they will be helpful or harmful in the effort to reduce melanoma deaths, and how they impact the health system. [124,125] In an Australian study, the use of consumer-led mobile teledermoscopy was feasible, but did not improve detection of skin cancers compared with a naked-eye skin self-examination.[126]

8 LOOKING TO THE FUTURE: RISK-STRATIFIED MELANOMA SCREENING

8.1 ASSESSMENT OF SKIN CANCER RISK

The benefit of screening is proportional to the incidence of disease within the screened population and must be weighed against the harms to persons screened without disease, and the overall cost of the program. A structured program of screening skin checks targeting only those Australians at highest risk of melanoma is likely to be the most appropriate way to balance these factors.[26-28,127,128] Research indicates that a risk-stratified approach will be acceptable to the Australian public.[131] While Australian guidelines agree that high-risk individuals should receive regular skin checks, there is no consensus on what constitutes a 'high-risk individual'.

This target population must be clearly defined (including relevant cut-offs) and comprehensively identified. This will require targeted research, expert discussion, and modelling[128,130] within the context of the unique geographic, ethnic and racial, migratory, and generational characteristics of Australia. This will also need to be considered in the context of the number and location of trained and participating clinicians.

8.1.1 Risk Factors

Important risk factors for developing a first primary melanoma include high naevus count (~7-fold increased risk) and presence of atypical naevi (~10-fold increased risk).[131] History of keratinocyte skin cancer is another key risk factor (~3–4-fold increased risk),[132] as is history of over-exposure to UVR[134] and sunbed use.[134,135] Other important factors include pigmentary characteristics (including fair skin, fair hair, and light eye colour) and tanning ability.[136] Special groups at elevated risk include those with immunosuppression (e.g., solid organ transplant recipients, people with HIV/AIDS, and people with non-Hodgkins lymphoma; ~3–4-fold increased risk).[137] Melanoma is the most common malignancy diagnosed during pregnancy, but it is believed that pregnancy or other hormonal and reproductive factors do not affect melanoma risk.[138] In the QSkin study of 41,954 people from Queensland (aged 40 years and older), the strongest predictors for melanoma were age, sex, tanning ability, number of moles (recalled at age 21), and number of skin lesions treated destructively.[128]

Australian clinical practice guidelines for individuals at high risk of developing new primary melanomas were published in 2019[34] and guidance is also available in the Cancer Council/Melanoma Institute Australia guidelines.[33] The publications informing these guidelines define high-risk individuals as those with a) moderate or severe atypical mole syndrome (>100 naevi and/or ≥10 clinically atypical naevi and/or ≥1 dysplastic naevi per histopathological examination); a personal and/or family history of melanoma; carrying genes with high susceptibility for melanoma (e.g., *CDKN2A*); or carrying other cancer risk conditions (medium-to-giant congenital naevi, immunosuppression, or genodermatoses), or b) differing combinations of personal and family melanoma history, dysplastic naevi burden, and confirmed *CDKN2A* mutation.[4,139,140] Once a person has been diagnosed with a first melanoma, they have a much higher risk of developing a subsequent primary melanoma compared with others in the general population, and there are several risk factors that influence subsequent melanoma risk.[141-143]

8.1.2 Polygenic Risk Scores

Certain genetic mutations are highly pathogenic and associated with increased risk of developing cancer (for example, *BRCA1/BRCA2* mutations and breast cancer). In the absence of one highly pathogenic mutation, a polygenic risk score can be calculated that from a broader constellation of genetic variations (typically, single-nucleotide polymorphisms) that combine to confer a significant risk of developing cancer. In melanoma, several polygenic risk scores have been developed[144,145] and were recently examined in an Australian cohort.[146] Ultimately, polygenic risk scores are not currently ready for clinical use.[147]

8.1.3 Risk Prediction Tools and Calculators

A range of risk prediction tools have been developed to assess the lifetime risk of an individual developing melanoma and may be helpful in identifying high-risk individuals appropriate for targeted screening. Tools to predict the risk of a first primary melanoma based on demographics and self-assessed risk factors have been developed;[135] three currently available tools include: the **Melanoma Risk Assessment Tool** from Melanoma Institute Australia, the **Melanoma Risk Predictor** from QIMR Berghofer, and the **Melanoma Risk Calculator** from Alfred Health.[128] Current calculators include key risk factors mentioned above, including hair colour, naevus count, skin cancer history, and solarium usage;[135] future approaches to risk prediction will likely combine clinical and environmental risk factors with polygenic risk scores.[26,145,148,149]

8.2 A ROADMAP TOWARD TARGETED MELANOMA SCREENING

In Australia, the multidisciplinary Melanoma Screening project is underway to develop a roadmap toward targeted melanoma screening.[150] This project brings together a large team of clinicians, researchers, and consumers across multiple states to address some of the above-mentioned challenges and provide evidence on the optimal approach, feasibility, and costs of a proposed future screening program. This proposed model could then be tested in a randomised trial compared with the current best practice approach.

In Australia, there is a strong consumer sentiment toward ‘getting a skin check’ with a primary care physician or dermatologist, as often as once per year. This is reinforced by many private skin clinics. Implementation of a risk-targeted melanoma screening program will require a shifting of this sentiment toward ‘knowing the skin you’re in’ and for people at lower-risk seeking clinical care only in the case of new and/or changing skin lesions. For many in the general population, this may involve a de-escalation of care.

9 SKIN CHECKS ACROSS RACIAL AND ETHNIC GROUPS

Most of the research into melanoma has been conducted in white populations, in whom most melanomas occur. In white populations, most melanomas are cutaneous, caused by over-exposure to UVR, and are either a superficial spreading or lentigo maligna subtype, or a nodular melanoma. We have a relatively good understanding of which white individuals are at risk of these melanomas and have devoted significant resources to preventing them (for example, the Slip! Slop! Slap! campaign) and detecting them (from the simple ABCDE mnemonic to the fact that over 80% of images in dermatology textbooks are sourced from light-skinned individuals[151] and AI technologies are trained on majority white-skinned image databases).

The risk of melanoma is significantly lower in non-white populations compared with white populations; hence, organised skin checking approaches may not be an effective approach to reducing deaths from melanoma in non-white populations. Melanomas that do occur in non-white individuals are typically diagnosed at late-stage and are more likely to result in death. This is likely due in part to the differences in typical subtype, presentation, and cause of melanoma in non-white populations that are not accounted for in prevention and detection efforts. In black- and brown-skinned populations, including individuals from South Asia and South-East Asia, the most common melanomas are acral (on the palms, soles, and under the nails) and not caused by over-exposure to UVR.[152-155] Acral melanomas are also the most common subtype in people from East Asian countries including Japan and China.[156] It is unknown how residence in Australia might affect these patterns.

Melanoma has not been well-studied in Indigenous Australians. We have no meaningful data about the rates of melanoma and other skin cancers in Indigenous peoples, with existing estimates based on hospital databases that inadequately capture Aboriginal and/or Torres Strait Islander status.[157] In a review of skin cancer cases in Indigenous peoples in urban Sydney between 2003 and 2017, the two documented cases of melanoma were both diagnosed at stage III and both resulted in death.[158] Workforce education is essential to improve early diagnosis of melanoma in First Nations Australians, including addressing the myth that melanoma and other skin cancers do not occur in this population. There is a range of skin phenotypes (from fair to darkly pigmented) among First Nations Australians. There also exists a prevalence of disease-related and iatrogenic immunosuppressive conditions that increase melanoma risk; better awareness of this risk is essential among the workforce of people caring for Indigenous patients. Australia needs additional research and engagement to develop appropriate approaches to reducing deaths from melanoma in First Nations Australians, with a key focus on workforce education and addressing social determinants of health, as well as ensuring clear, transparent, and accurate capturing of Aboriginal and/or Torres Strait Islander status in private and public sectors, including registries for the Australian Cancer Database.

10 CONCLUSIONS

Melanoma is a deadly, expensive, and preventable cancer. Based on the current evidence, a program of regular screening skin checks for the asymptomatic Australian general population is not recommended, as there is no high-quality evidence that such a program would improve cancer prognosis or prevent deaths, and there is a lack of data on cost–effectiveness.

The accuracy of skin checks currently varies considerably. New technologies may improve accuracy, but further research is required. Methods of risk stratification are available and improving, including online calculators that predict risk of a first primary melanoma based on an individual's risk factors. This may help to inform a National Targeted Screening Program for people in the community at high risk of melanoma.[159] A committee of Australian skin cancer experts, including clinicians, scientists, and health economists, is currently investigating the potential design and logistics of such a program.

While not the focus of this position statement, primary prevention initiatives are the most effective way to reduce the burden of melanoma across the entire population and should be the cornerstone of any future policies.

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Melanoma Institute Australia recognises the Traditional Custodians of the lands on which we work, and is proud to include traditional country names in all our site addresses.

Cammeraygal Land – The Poche Centre, Sydney, New South Wales

Gadigal Country – The University of Sydney, New South Wales

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Nipaluna – Hobart, Tasmania

We pay our respects to the Traditional Custodians of the lands on which Melanoma Institute Australia works, and their Elders both past and present, and acknowledge the deep, continuing connection of Aboriginal and Torres Strait Islander peoples to the land, waters, and sky.

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