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OFFICE OF THE PRESIDENT
Cl. A/Prof Stephen Shumack,
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26 March 2014

The Secretary
Standing Committee on Health
House of Representatives
PO Box 6021
Parliament House
CANBERRA ACT 2600

By email: health.reps@aph.gov.au

Dear Sir

Skin cancer in Australia: awareness, early diagnosis and management

This position paper on skin cancer in Australia is provided by the Australasian College of Dermatologists (ACD).

Dermatologists are the leaders in diagnosis and management of skin cancer in Australia being at the forefront of the development of education to medical colleagues and the general public, research into this important topic, and the development of prevention strategies for skin cancers and their precursor lesions. The ACD recognises the enormous burden of disease this represents to both the community and the economy and would be pleased to be involved in an ongoing manner to work constructively with other peak bodies on strategies and initiatives to manage this important issue.

RECOMMENDATIONS

A. Public awareness campaigns have reduced the incidence of NMSC in people aged 50 years and lower. Continued funding for these public education campaigns is required to maintain public awareness of the positive benefits of protection from UV radiation. These educational campaigns could be extended to include NMSC. It should address all age groups but in particular 50 years plus age group where skin cancers are most prevalent.

B. That consideration is given to either establishing a national registry for NMSC, as with melanoma, to accurately identify the extent of disease, follow its progress against efforts to reduce it, or alternatively undertake periodic surveys at regular intervals (say 5 yearly) to identify trends in NMSC and public knowledge/ behaviours.

C. Dermatologists are trained in the diagnosis and treatment of all skin cancers. Studies confirm that this training significantly improves patient outcomes with early detection and treatment, resulting in fewer excisions of benign skin lesions that may mimic the appearance of skin cancer. Treatment by dermatologists reduces the unit cost of treatment of NMSC to governments. Further health economic studies should be performed to address this important financial issue.

D. Dermatologists play a central role in the management of NMSC. Attention should be given to the man-power required to manage the predicted increase in NMSC prevalence in Australia.

Increased funding of training positions accredited by the Australasian College of Dermatologists would go some way to addressing this.

E. Support of dermatology research will be an important part of an integrated national skin cancer program. This should encompass research support in areas ranging from epidemiology and public health, genetics, cellular biology to clinical studies, new therapies and health economics. In this regard the wider development of academic departments in dermatology than exists today would assist lead enhanced research activity.

F. A review of the MBS item numbers to reflect best practice is currently underway. However, one area should be addressed immediately, namely PBS reimbursement for regional or 'field therapy' for treatment of multiple AKs. This would be in keeping with current DVA reimbursement for topical agents and MBS reimbursement for cryosurgery of multiple (>10) AKs.

G. The ACD has been proactive in the adoption of telehealth in dermatology to service the needs of our geographically diverse population and to support primary care doctors. The exploration and development of store and forward teledermatology offers the potential for rapid access and assessment of suspicious lesions by a specialist. The use of smart – mobile devices and applications in obtaining health information by patients and to support their health care is likely to increase substantially in coming years. There is great potential to utilise the electronic environment for health education, prevention and rapid access to specialist opinion.

Yours sincerely

Stephen Shumack OAM FACD FAICD
President

SUBMISSION TO THE STANDING COMMITTEE ON HEALTH AND AGEING
Re: SKIN CANCER IN AUSTRALIA

INTRODUCTION

Dermatologists are the leaders in diagnosis and management of skin cancer in Australia. Dermatologists are also at the forefront of the development of education to medical colleagues and the general public, research into this important topic, and the development of prevention strategies for skin cancers and their precursor lesions. The ACD recognises the enormous burden of disease this represents and continues to work with bodies such as the RACGP and Cancer Council Australia to manage this important issue.

BACKGROUND

The ACD was founded in 1967 and there are now 454 practicing dermatologists in Australia. Training to become a specialist dermatologist (FACD) requires successful completion of 4 FTE years in accredited training positions (public hospital and private practice based) and examinations. Training and achievement of competency in skin cancer diagnosis, pathology and the range of treatment modalities comprises a major part of the ACD curriculum. Entrance to the training program may commence after a minimum of two postgraduate years of hospital residency. ACD trainees come with a variety of past clinical experience including general medicine, surgery and/or primary care medicine. There are currently 112 dermatology registrars in Australia. Post Fellowship subspecialty opportunities exist, including a one year full time Fellowship in Mohs micrographically controlled surgery. Australia wide there are 48 dermatologists qualified as Mohs surgeons operating out of 10 centres. The benefits from this specialised intervention are explored later in this paper.

The ACD is active in and supports research of skin cancer in areas ranging from epidemiology and public health, genetics, cellular biology to clinical studies and new therapies. Promotion of research and the development of academic departments in dermatology is part of the strategic plan of the ACD. Support of dermatology research will be an important part of an integrated national skin cancer program.

SKIN CANCER IN AUSTRALIA

Australians have the highest rate of skin cancers in the world[1]. In 2010, skin cancer accounted for seven out of every eight new cancers diagnosed in Australia. While the population of Australia increased by 22% between 1997 and 2010, the number of non-melanoma skin cancers treated increased by 87%. The incidence of non-melanoma skin cancers is increasing 2.5 times as fast as other cancers. There is mounting evidence that non-melanoma skin cancer is a marker of a cancer-prone phenotype, especially when it occurs at an early age. This means there is evidence of developing unrelated internal cancers in some patient groups who present with skin cancer. Two thirds of Australians are expected to develop at least one skin cancer before they reach 70 years of age[2]. In fact, we are four times more likely to develop a cancer of the skin than any other type of cancer[3].

Broadly speaking skin cancer can be classified into 2 groups. Malignant melanoma, which are cancers originating in pigment producing cells (melanocytes) and non melanoma skin cancer (NMSC) which develop from other cells of the epidermis (top layer of skin).

NMSC include two distinct forms of skin cancer. Basal cell carcinoma (BCC), which arise from the bottom (basal) layer of the epidermis (basal), and squamous cell carcinoma (SCC), which arise from the layers of epidermis above the basal layers. BCCs are three times more prevalent than SCCs. SCCs are responsible for more deaths than BCCs because of their propensity to metastasise. Men develop more NMSC than women (1.5:1) but are common in both sexes[4]. NMSC tend to have a long latency in development[4] with the disease occurring most often in the 50+ age group[5] however all age groups are affected. NMSC is more prevalent than melanoma.

NMSC also includes a less common (and less well known) group of tumours:

- Merkel cell carcinoma
- Dermatofibroma sarcoma protuberans

- Malignant fibrous histocytoma,
- Atypical fibroxanthoma
- Sebaceous carcinoma and
- Kaposi sarcoma.

These less well known tumours are the cause of significant morbidity and high mortality. They are often not recognized or incorrectly diagnosed and usually require management by a specialist.

Over the last 40 years, there has been the realisation that NMSC incidence is significantly increased in patients receiving systemic immunosuppression as part of their normal medical care. This is particularly pronounced in the solid organ transplant recipient (SOTR) population, where cutaneous malignancies account for 50% of *de novo* malignancies, of which 95% are NMSC. Of interest, the initial report of increased NMSC incidence in renal transplant recipients was reported by an Australian dermatologist at the Prince of Wales Hospital, Dr Brien Walder, in the Lancet 1971[6]. The significant cutaneous morbidity and mortality associated with this disease burden has led to the development of specialised dermatology clinics for Solid Organ Transplant Recipients. BCC risk increases 10 fold, and there is reversal of the BCC: SCC ratio to 1:4 (2003[7]). The risk of SCC increases by up to 80 fold in these patients and is a significant cause of death in this group. Within 5 years of the first SCC, 88% of renal transplant recipients develop multiple NMSC (2006[8]). One article from Sydney indicated that of a cohort of heart transplant patients who survive for 10 years, are more likely to die from metastatic SCC from the skin than for the rejection of their transplanted heart[9]. Dermatologists are expecting increased numbers and complexity of NMSC if this group given the increasing number of people receiving systemic immunosuppression for a wide range of medical conditions, patients receiving multiple transplants during their lives and also with transplantation occurring at an older age.

Unlike melanoma, NMSC is not a notifiable disease. Incidence and prevalence of NMSC in Australia has been extrapolated from Medicare and DVA data. Despite successful advertising campaigns (Sun Smart and 'slip slop slap, slide') the incidence of NMSC is rising due to an increasing and ageing population. It is estimated that 2% of the Australian population is treated annually for NMSC. In 1997 there were approximately 412,500 Medicare related treatments which increased to 767,500 in 2010. It is estimated that this will increase to almost one million treatments by 2015[5]. The total MBS cost will grow from $93.5 million in 2010 to over $109 million by 2015[5]. Morbidity significantly outweighs mortality of NMSC with 545 deaths from NMSC reported in 2010.

The significance of melanoma is readily appreciated by the Australian community. It is one of the most common cancers affecting youth and has a recognised high mortality rate[10]. In 2009 there were 11,545 new cases of melanoma reported, with 1,452 deaths from melanoma reported in 2010. Overall melanoma is the 7th most common cause of death in Australia[10].

The average lifetime risk of an Australian male developing melanoma is 1 in 14, compared with 1 in 23 for women. The risk rises for those living in the higher latitudes of NSW and Queensland[11, 12, 13, 14]. Other risk factors include phenotypes such as light complexion, blue eyes, freckles and red or blonde hair, family history of melanoma, history of childhood sunburn and dysplastic naevus syndrome.

Melanoma survival rates indicate that 96% of patients with thin tumours and localised disease remain alive after 5 years. This drops to 63% if the melanoma has spread regionally. The five year survival rate falls to 34% if the melanoma is found to have metastasised at the time of presentation. Given the improved prognosis of early melanoma, the ACD supports any move to further increase early melanoma diagnostic rates. Currently ~ 80% of melanomas are diagnosed at an early stage (less than 1 mm thick) and this can be further improved. It is only by recognising and treating melanoma at an early stage that we can reduce the substantial morbidity and mortality arising from the 20% who present with more advanced disease[11, 12, 13, 14].

TREATMENT OF SKIN CANCER IN AUSTRALIA

As the behaviour of skin cancers varies, it is understandable that there is a broad range of therapeutic approaches available and specific protocols for individual tumour types.

NMSC AND PREMALIGNANT LESIONS

SURVEILLANCE AND IDENTIFICATION

Dermatologists, family GPs and skin cancer clinic GPs perform full cutaneous examinations. Patients are referred to dermatologists from GPs for general skin examination and/ or for management of suspicious lesions. Such lesions may be biopsied to confirm the diagnosis and help determine the most appropriate treatment. From Medicare data, in 2012/13 845,000 biopsies were performed at a cost of $31,000,000. These biopsies were equally performed by GPs and dermatologists[15]. Note that a significant number of skin biopsies may have been performed for other skin disease rather than for skin cancer diagnosis.

After successful treatment of a NMSC, the patient has a higher risk of further NMSC development [4, 5] and should undergo surveillance by their GP or Dermatologist.

Actinic (or solar) keratoses (AK's) are commonly referred to as 'sun spots'. As they are premalignant lesions, they are a marker for skin cancer risk and may develop into SCC. Dermatologists treat them prophylactically via a number of modalities (see below)[16].

SURGICAL THERAPY OF NMSC

The gold standard of NMSC treatment is surgical excision as this provides confirmation of complete local removal. This is the most common treatment of SCC, BCC and less common NMSC with a high morbidity and/or mortality profiles, eg. Merkel cell carcinoma, Dermatofibroma sarcoma protuberans, Malignant fibrous histocytoma, Atypical fibroxanthoma, sebaceous carcinoma and Kaposi sarcoma. As there are different subtypes and growth patterns of NMSC, the margins of excision vary.

In most circumstances SCCs are excised, except for superficial SCC (Bowens disease) where non surgical options are available. Surgery provides a histological sample for pathology and carries a higher cure rate[4]. Curettage and cautery of superficial SCC and Bowens disease is commonly performed by dermatologists. Using a specialised skin curette, the lesion is saucerised and the base cauterised serially.

Surgical excision is the usual treatment for BCC's. Superficial BCC's or well defined nodular BCC's can be removed by the curettage and cautery technique. Some BCC's are suitable for treatment by one of several non surgical therapies (see below).

MOHs MICROGRAPHIC SURGERY.

Mohs surgery is a form of skin cancer surgery performed by dermatologists in specialised dermatologic surgical units. The aim of Mohs surgery is to achieve optimal clearance of a tumour whilst conserving tissue. This technique is commonly used on high risk, or multiply recurrent NMSC on the face.

Briefly, Mohs surgery involves the serial excision of a lesion under long lasting local anaesthetic. The specimen is processed immediately and then analysed histologically by the dermatologist whilst the patient waits. Due to precise marking and orientation of the specimen, single points of incomplete excision can be precisely identified. The Mohs surgeon then excises this portion only. This technique maximises cure rates for difficult tumours whilst preserving tissue function and cosmesis.

NON SURGICAL THERAPY OF AKs AND NMSC

Actinic (Solar) keratoses are most commonly treated individually by cryotherapy using liquid nitrogen[17]. However where many AKs cover a defined area of skin (a field or area of confluent AKs), a high risk situation for the development of invasive skin cancer, is more effectively treated by applying prescription topical preparations such as Efudix (5 Fluorouracil) cream, Aldara (Imiquimod) cream, Solaraze (Diclofenac) gel and Picato (Ingenol Mebutate) gel. Photodynamic

therapy (application of a topical photosensitizer (Metvix) followed by special illumination with a light is also use as a field therapy for Actinic Keratoses.

Despite the benefits of topically treating entire fields of solar damage and thus reducing the risk of substantial disease burden going forward, cost to patient is a limiting factor in their use. Topical treatment for solar keratoses is not subsidised under the PBS. This compares to DVA where all four agents are subsidised under the RPBS. As PBS does not reimburse topical therapy for AKs there is no data on the frequency of their use. However, it is reported that GPs use single lesion cryotherapy predominantly as compared to the more frequent use of field therapy by Dermatologists[17].

NMSC such as superficial BCC and Bowens disease may be treated non-surgically. Topical Imiquimod, photodynamic therapy (PDT) and superficial radiotherapy are such modalities.

Currently Aldara is PBS subsidised for use in biopsy proven superficial BCCs where surgical treatment is inappropriate. There has not been a great uptake with its use other than by dermatologists to date.

PDT refers to the topical application of a photosynthesiser such as Metvix followed by red light irradiation, producing a photochemical reaction which results in tumour cell death. There is not a lot of data re PDT usage as it is not reimbursed by the MBS or PBS schedules.

Where available, superficial radiotherapy was often used by dermatologists in their offices to treat NMSC. With the prohibitive cost of radiotherapy machines, and with the advent of topical agents and access to Mohs surgery, radiotherapy of NMSC is now mostly performed in Radiotherapy departments of major hospitals.

MELANOMA

a. Surveillance

   Dermatologists, GPs and skin cancer clinics are involved in general skin examinations. Patients can be referred to dermatologists for skin examination or for treatment of suspicious lesions. Dermatologists work from their offices, public hospital outpatients and the Skin and Cancer Foundations (NSW, Victoria and Queensland). Dermatologists are involved with screening of high risk patients, including those immunosuppressed following solid organ transplantation, those with a history of numerous NMSC and/or a past history of melanoma.

b. Identification and biopsy of suspicious pigmented lesions.

   Surveillance is conducted by visual examination with the assistance of adequate lighting, magnified lenses (loupes) and a dermatoscope. This instrument allows the doctor to see the pigment network more precisely and assists in diagnosis. It has been shown to increase dermatologist accuracy resulting in earlier melanoma diagnosis and consequently removal of thinner lesions[18].

   Photography is often used as a reference point for patients in respect to the number, distribution and size of their moles[19, 20, 21]. Photography has been shown to improve diagnostic accuracy of clinicians but is not currently reimbursed by the MBS.

   Studies show dermatologists are more accurate in diagnosing melanoma than non dermatologists[22, 23, 24, 25]. In fact, in Australia a study of GPs and skin cancer clinic doctors indicated that the average number of biopsies required for identification of one melanoma was 30[23]. This compared with dermatologists who required 12 excisions in one study[24] and only 4 in another[25] for the identification of 1 melanoma. This translates to greater efficiency in the diagnosis of melanoma, evidenced by reduced number of unnecessary biopsies and hence reduced costs. Importantly, it also means diagnosis of thinner lesions and thus overall improved melanoma survival rates[26, 27, 28]. The implication for mortality is important but later diagnosis will likely result in greater cost burden[29] and loss of productive years.

After clinical examination a suspicious pigmented lesion is excised with a narrow margin of normal skin for histological examination and definitive diagnosis. Benign melanocytic naevi require no further therapy.

In comparison, a definitive course of therapy is required for melanoma. Surgery is the accepted first line therapy for melanoma[30]. The decision algorithm is based on histological factors including depth of the tumour (Breslow thickness in mm, Clark level), presence of ulceration and mitoses, along with clinical factors such as locoregional spread to lymph nodes and/or haematogenous spread to bone and distant organs eg. Brain, liver and lungs.

c. Definitive treatment

Once a melanoma is diagnosed histologically, the GP may refer the patient to a dermatologist, surgical oncologist or melanoma unit for definitive therapy. Some GPs will perform wider excision themselves if the lesion is thin or low risk. The margin around the tumour site is determined by the depth of the initial lesion[30]. These margins are detailed in the handbook, 'Clinical Practice Guidelines for the Management of Melanoma in *Australia and New Zealand* (2008)[30].

If melanoma thickness is greater than 1.0 mm, guidelines recommend sentinel lymph node biopsy, and if positive, current practice is completion lymph node dissection. This relatively difficult procedure should be performed in specialised melanoma units, currently linked with tertiary referral hospitals around Australia.

Management of metastatic melanoma requires a multidisciplinary approach, involving the family GP, social workers, oncology and palliative care nurses, dermatologists, medical oncologists, surgical oncologists and radiation oncologists.

Management of patients with cutaneous in-transit metastases requires the input of dermatologists for consideration of topical palliative measures. They are co-managed with surgeons undertaking isolated limb perfusion.

Adjuvant systemic therapy of melanoma is offered to patients presenting with late stage melanoma. Interferon alpha 2b has been shown to improve relapse free survival by 10% at 5 years. However, the morbidity of this agent limits it widespread use. Melanoma vaccines and chemotherapeutic agents have failed to demonstrate reproducible benefits in this group. Radiotherapy is used palliatively for symptom control.

Biologic therapies involving targeted monoclonal antibodies offer some hope for these patients. These include CTLA-4 inhibitor (Ipilimumab), BRAF inhibitors (Vemurafenib and Dabrafenib), MEK inhibitor (Trametinib) and most recently PD1-L1 inhibitors. Such immunotherapies come at significant financial cost. For example, Ipilimumab may prevent disease progression in 10% patients for a period up to 3 years. The cost is $30,000 per injection, and 4 or more are required[31].

In 1997 approximately 90% of melanoma costs were attributable to less than 20% of patients. In 2010, 5% of total melanoma costs were expended during the early stages of disease (identification and simple wide excision), in comparison to 95% spent on management of advanced disease[26]. Thirteen years later, despite increasing awareness, the cost of advanced disease management has escalated due in part to sentinel lymph node biopsy and consequent dissection, along with the advent of targeted therapies.

In summary, given the benefits of early melanoma detection and treatment to both the patient and the wider community, it is crucial that funding continues to be increased and directed at this crucial stage.

RECOMMENDATIONS

A. Public awareness campaigns have reduced the incidence of NMSC in people aged 50 years and lower. Continued funding for these public education campaigns is required to maintain public awareness of the positive benefits of protection from UV radiation. These educational campaigns could be extended to include NMSC. It should address all age groups but in particular 50 years plus age group where skin cancers are most prevalent

B. That consideration is given to either establishing a national registry for NMSC, as with melanoma, to accurately identify the extent of disease, follow its progress against efforts to reduce it, or alternatively undertake periodic surveys at regular intervals (say 5 yearly) to identify trends in NMSC and public knowledge/ behaviours.

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