4

Treatment and Management

4.1 More than 750 000 Australians are treated for skin cancer each year, representing over 2000 patients each day.[1] Once diagnosed, the treatment and management of skin cancer involves a complex range of different health professionals including general practitioners, dermatologists, oncologists, radiologists and a multitude of other specialists. It may also include substantial non-medical or psychosocial support of patients and their families such as counselling services, the facilitation of ongoing carers, and accommodation support.

4.2 Although the management of this myriad of health professionals is a complex challenge to navigate for patients, practitioners and policy makers alike, proper treatment and management of the care provided has a critical impact on the outcome for patients.

4.3 Further, the importance of research into new treatments and treatment options for patients with skin cancer is highlighted by national statistics which indicate that the rate of skin cancer in Australia is increasing.[2] With increasing prevalence, comes increasing costs to the national health care system. Ongoing research into skin cancer brings with it the possibility of lifesaving treatments and improved quality of life for patients. These possibilities also may bring long-term economic savings in the treatment of Australia's 'national cancer' for the public health budget.

4.4 This chapter discusses these treatment and management challenges as well as these research opportunities. It addresses the following:

- existing treatment options and clinical practice guidelines;
- other treatment challenges such as the accessibility for patients in regional and remote centres, and early treatment;

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1 Cancer Council Australia and Clinical Oncology Society of Australia, *Submission 26*, p. 1.

2 See Chapter 2 for more information on the statistics, trends and prevalence of skin cancer in Australia and globally.

- strategies of managing patients' treatment;
- psychosocial and non-medical support for patients and their families; and
- new treatments, as well as emerging research and clinical trials to further develop improved treatment options.

Existing Treatments

4.5 There is a broad range of treatment approaches available to patients diagnosed with skin cancer allowing for specific protocols to be applied for individual tumour types. The most effective treatment will depend on the type of skin cancer, the stage of the disease, the severity of symptoms, and the patient's overall health.[3]

4.6 The recommended and most common treatment option for skin cancer is a complete surgical excision, and may include the removal of an appropriate margin of normal tissue.[4] This treatment option is considered 'the most appropriate treatment modality for both melanoma and non-melanoma skin cancers (NMSC) which provides the highest chance of curing the patient'.[5] However, depending on the individual patient and their presentation of melanoma or NMSC, two clinical guidelines provide further details on treatments and strategies.

4.7 The *Clinical Practice Guidelines for the Management of Melanoma in Australia and New Zealand (2008)* stipulates that the standard treatment for primary melanoma should be wide local excision of the skin and subcutaneous tissues around the melanoma based on the maximum Breslow thickness of the primary melanoma (that is, the thickness or depth of the melanoma is measured from the top layer of skin to the base of the tumour).

4.8 As stated above, further treatments of melanomas will largely depend on the stage of the disease and the severity of symptoms. Of the greatest severity, advanced melanoma (unresectable stage III to stage IV or metastatic melanoma) is an aggressive and invasive disease, with a median survival of approximately 6 to 9 months. The aim of treatment in advanced melanoma is to optimally manage each stage of disease with a view to extending overall survival. Therapies for advanced melanoma are limited and include systemic therapy (dacarbazine, fotemustine or

3 Department of Health, *Submission 12*, p. 7.

4 Department of Health, *Submission 12*, p. 7.

5 Department of Health, *Submission 12*, p. 7.

temozolomide), palliative care/radiotherapy, palliative surgery or no treatment.[6]

4.9 The *Basal cell carcinoma, squamous cell carcinoma (and related lesions) – a guide to clinical management in Australia (2008)* also recommends complete surgical excision with appropriate margins of normal tissue. These two clinical practice guidelines are discussed further in later parts of this chapter.

4.10 NMSCs may also be removed by micrographically (Mohs surgery), a highly specialised surgical technique by which individual layers of cancerous tissue are removed one at a time and examined under a microscope, by the same medical practitioner, until all cancerous tissue has been removed.[7] Typically used to treat high-risk or recurring NMSC on the face, Mohs surgery aims to achieve optimal clearance of a tumour whilst conserving tissue. The techniques involved with this treatment option 'maximises cure rates for difficult tumours whilst preserving tissue function and cosmesis'.[8]

4.11 Some stakeholders also discussed non-surgical treatment options, including topical treatments and photodynamic therapy.[9] Some of these non-surgical treatments are supported by Australian guidelines while the efficacy of others have been questioned by regulators.[10]

4.12 Australian guidelines support a number of non-surgical techniques for the treatment of NMSCs (including solar keratosis), including, cryotherapy (direct application of liquid nitrogen to cause the destruction of cancerous tissue); curettage and diathermy/electrodesiccation (electrosurgery); topical agents or creams; photodynamic therapy; and radiotherapy.[11] If the cancerous cells have spread beyond the skin and sentinel lymph nodes, chemotherapy may be used to kill the cancer cells present in the patients' body.[12] Importantly however, the Department of Health stated that 'while [some] non-surgical techniques have been used in recent years for the treatment of melanoma, including imiquimod cream, cryotherapy and radiotherapy, their efficacy has not been established'.[13]

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6 Pharmaceutical Benefits Scheme, *PBS & Ipilimumab*, http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2012-11/ipilimumab, viewed November 2014.

7 Department of Health, *Submission 12*, p. 7

8 Australasian College of Dermatologists, *Submission 15*, p. 5.

9 Australasian College of Dermatologists, *Submission 15*, p. 5.

10 Department of Health, *Submission 12*, p. 7.

11 Department of Health, *Submission 12*, p. 8.

12 Department of Health, *Submission 12*, p. 9.

13 Department of Health, *Submission 12*, p. 7. See also Trans-Tasman Radiation Oncology Group, *Submission 47.1*, p. 1.

4.13 A list of the full range of medications for the treatment of skin cancer (both melanoma and NMSCs) which have been approved by the Therapeutic Goods Administration (TGA) was provided in a submission from the Department of Health.[14]

Clinical Practice Guidelines

4.14 As briefly introduced above, two clinical practice guidelines have been developed for health practitioners in Australia for the treatment and management of skin cancer: one for melanoma and one for NMSC. Both guidelines were developed and released for clinicians in 2008. Their purpose is to 'ensure as far as possible that treatment is of the same high standard wherever sought, and in both public and private systems [and therefore] need to be updated regularly to be useful to doctors and patients'.[15]

4.15 The *Clinical practice guidelines for the management of melanoma in Australia and New Zealand*, provides information about prevention, classification and staging, biopsy, treatment of primary melanoma, management of locoregionally recurrent melanoma, psychosocial issues, palliative care, and follow-up care.[16]

4.16 *Basal cell carcinoma, squamous cell carcinoma (and related lesions) – a guide to clinical management in Australia* provides information for clinicians in the treatment of NMSC, including pathology, surgical treatment, radiotherapy, cryotherapy, curettage and diathermy/electrodessication, other treatments, prevention, metastasis from NMSC and follow-up care.[17]

4.17 During the Committee's Inquiry, the relevance and efficacy of these guidelines were questioned by a number of stakeholders. The chief criticism has been that these guidelines have not been updated since an initial release in 2008.

4.18 Although Cancer Australia 'supports the development of clinical practice recommendations', the organisation recognised the 'need for promoting and maintaining currency of these recommendations'. Cancer Australia stated:

> As these guidelines are based on evidence published to early 2007, they do not take into account new evidence, such as the role of sentinel node biopsy and the [recent] drugs… listed on the Pharmaceutical Benefits Scheme in 2013 for the treatment of

14 Department of Health, *Submission 12,* p. 30.

15 Cancer Voices New South Wales, *Submission 59*, p. 1.

16 Cancer Australia, *Submission 23*, p. 9.

17 Cancer Australia, *Submission 23*, p. 9.

> advanced melanoma. Further, new therapies for melanoma, based on research on tumour biology and targeted to the molecular profiles of tumours are likely to emerge.[18]

4.19 Cancer Australia therefore recommended that 'new key clinical practice recommendations on the treatment and management of skin cancer for general and specialist health professionals' be developed. Cancer Australia argued:

> This would enable the incorporation of new evidence and new treatments in melanoma, including those based on greater understanding of genomics and the molecular basis of cancer, and assist health professionals in implementing evidence-based best practice care. Cancer Australia also recognises the need for promoting uptake and maintaining currency of these recommendations.[19]

4.20 However, a joint submission by Cancer Council Australia and the Clinical Oncology Society of Australia stated the challenges of updating printed guidelines:

> To date, interventions to improve implementation of clinical practice guidelines to GPs have shown limited and variable effectiveness… Clinical practice guidelines aim to enhance the quality of care by promoting consistent clinical decision-making based on the best evidence. Traditional printed guidelines cannot be updated as new evidence is published; written guidelines also have other inherent cost and dissemination limitations. [20]

4.21 Cancer Council Australia and the Clinical Oncology Society of Australia were of the belief that the challenges of producing clinical practice guidelines which reflect evolving best practice can be overcome through the use of modern technology. They explained:

> Development of online guidelines on a Wikimedia platform allows for content to be electronically searched by users, instantly updated by guideline developers as new evidence becomes available, widely disseminated among users online, and provided in a format in which stakeholders can comment or submit new evidence to developers at any time. … Paper-based clinical practice guidelines for melanoma and NMSC were published separately in 2008 and have not been updated since. Both sets of guidelines require updating; Cancer Council Australia is in the

18 Cancer Australia, *Submission 23*, p. 9.
19 Cancer Australia, *Submission 23*, p. 11.
20 Cancer Council Australia and Clinical Oncology Society of Australia, *Submission 26*, p. 2.

planning stages of the review of melanoma guidelines and will transition these to the interactive, Wikimedia platform.[21]

4.22 While the joint submission noted that in-principle acceptance of online clinical practice guidelines is high, only a small proportion of physicians regularly access them. To ensure greater clinical access and use, Cancer Council Australia and the Clinical Oncology Society of Australia indicated that they will continue to promote the benefits of online guidelines to the clinical community through all available mechanisms, including dissemination strategies for new guidelines.[22]

4.23 In addition to the concerns that the guidelines are not sufficiently up-to-date, there were also concerns that their content was not reflective of rural regional and remote general practice. The National Rural Health Alliance stated that 'best practice clinical guidelines for general practitioners on skin cancer need to take account of the particular challenges and circumstances of people in rural and remote areas who are affected by skin cancer'.[23]

4.24 The Alliance consequently recommended that 'best practice clinical guidelines for general practitioners on skin cancer need to take account of the particular challenges and circumstances of people in rural and remote areas who are affected by skin cancer'.[24] Other patient treatment and management issues associated with regional and remote locations are discussed further below.

Other Treatment Issues

4.25 Two other treatment issues were discussed throughout the inquiry: the impact of regional and remoteness on patient treatment and management, and the importance of treating skin lesions early.

Regional and Remote

4.26 A number of organisations discussed the additional challenges faced by regionally or remotely located patients and their access to appropriate

21 Cancer Council Australia and Clinical Oncology Society of Australia, *Submission 26*, pp. 2-3.

22 Cancer Council Australia and Clinical Oncology Society of Australia, *Submission 26*, pp. 2-3.

23 National Rural Health Alliance, *Submission 7*, p. 20. See also, Mr Gordon Gregory, Executive Director, National Rural Health Alliance, *Official Committee Hansard*, Canberra, 25 March 2014, p. 3.

24 National Rural Health Alliance, *Submission 7*, p. 20.

treatment options.[25] For example, Hunter Medicare Local stated that 'there is an inequity in access to care for people from low socioeconomic groups and those living in rural areas'.[26]

4.27 A similar account was provided by the Kimberley-Pilbara Medicare Local:

> The major identified need in the [Kimberly-Pilbara] region relates to access to a range of efficacious health services and practitioners both at the primary and acute level to enhance the individual's and population's health status. The factors that contribute to this gap are seemingly simple in identification however complex to analyse and even more convoluted to redress. It is paramount to understand that for the Kimberley population each of these individual social determinants of health are intrinsically linked yet also arbitrarily to the next creating a meandering cyclical pattern of inaccessibility to improve health status.[27]

4.28 However, there were reports which appeared to show some duplication in the coordination of service delivery in regional and remote Australia.[28]

4.29 The Royal Flying Doctor Service noted that the ongoing lack of (dermatology and specialist) services in rural locations requires patients to travel 'very large distances for treatment services, including significant personal costs'.[29] In the view of the Royal Flying Doctor Service, two strategies can address the difficulties faced by rural patients.

4.30 First, general practitioners (GPs) and primary care teams already located in these rural locations must be better supported. These practitioners are 'critical in the detection, treatment and management of skin cancer'.[30] The role of GPs in diagnosing and treating skin cancer is discussed in chapter 3

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25 Medicare Local Hunter, *Submission 54*, p. 4; Royal Flying Doctor's Service, *Submission 34*, p. 3; Cancer Voices South Australia, *Submission 35.1*, p. 1; Kimberley-Pilbara Medicare Local, *Submission 39*, p. 1; WA Country Health Service – Kimberley, *Submission 44*, pp. 1-4; National Rural Health Alliance, *Submission 7*, p. 15; Skin & Cancer Foundation Inc, *Submission 9*, p. 10; The Pharmacy Guild of Australia, *Submission 30*, pp. 1-2; Professor David Atkinson, *Submission 40*, p. 1; Lions Cancer Institute, *Submission 41*, p. 2; HealthCert International, *Submission 43*, p. 2; 9-10.

26 Hunter Medicare Local, *Submission 54*, p. 4.

27 Kimberley-Pilbara Medicare Local, *Submission 39*, p. 2.

28 Mr Darren Armitage, Population Health and Community Director, Kimberley Pilbara Medicare Local, *Committee Hansard*, Broome, 2 May 2014, p. 6; Dr Jeanette Ward, Acting Regional Medical Director, WA Country Health Service – Kimberley, *Committee Hansard*, Broome, 2 May 2014, pp. 16-17.

29 Royal Flying Doctor Service, *Submission 34*, p. 3.

30 Royal Flying Doctor Service, *Submission 34*, p. 3.

of this report. The second strategy proposed by the Royal Flying Doctor Service is to better utilise new technologies in telehealth.[31]

Telehealth and Teledermatology

4.31 It was the view of a number of stakeholders that some of the challenges associated with regional and remote health care can be overcome by the possibilities brought by new technologies, particularly teledermatology.[32]

4.32 Teledermatology is the practice of dermatology using information technology and communications systems to exchange medical information between a patient, clinician and a dermatologist – at the same or different times and in different geographic locations. This transfer of information can be done in real-time via the use of video conference technology or at different times using digital images transferred via a secure web-based platform, known as 'store and forward teledermatology'.[33] The capacity of teledermatology in early diagnosis was discussed in chapter 2 of this report.

4.33 In the ongoing treatment of skin cancer, the Australasian College of Dermatologists was of the view that:

> the adoption of telehealth in dermatology [can] service the needs of our geographically diverse population and to support primary care doctors… 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.[34]

4.34 The Victorian Department of Health also advocated for greater use of teledermatology however also noted that, as skin cancer is a 'national issue with similar challenges faced by each state and Territory', there is an 'opportunity for the Commonwealth Government to drive a more coordinated response at the national level'.[35]

4.35 The Trans-Tasman Radiation Oncology Group advocated that teledermatology is best used in combination with primary health care

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31 Royal Flying Doctor Service, *Submission 34*, p. 3.

32 National Rural Health Alliance, *Submission 7*, p. 15; Skin & Cancer Foundation Inc, *Submission 9*, p. 11; The Pharmacy Guild of Australia, *Submission 30*, pp. 1-2; Professor David Atkinson, *Submission 40*, p. 1; Lions Cancer Institute, *Submission 41*, p. 2; HealthCert International, *Submission 43*, p. 2; 9-10.

33 Victorian Department of Health, *Submission 22*, p. 3.

34 Australasian College of Dermatologists, *Submission 15*, p. 6.

35 Victorian Department of Health, *Submission 22*, p. 3.

practitioners (GPs) who are generally more geographically accessible to patients. The Trans-Tasman Radiation Oncology Group stated:

> Skin cancer in rural and regional centres can be neglected. It can be difficult for patients from these areas to access the most modern treatments which are available in the capital cities. A way of solving this would be to support the concept of virtual high-risk skin multidisciplinary clinics. Rural and regional GPs could send patient information such as history, physical examination, scan information and histology via e-mail to groups of specialists in the cities that could comprise at least a Surgeon, a Dermatologist, a Radiation Oncologist and a Medical Oncologist. That way they could receive a multidisciplinary team opinion. This would help to triage patients at their home address.[36]

4.36 The Trans-Tasman Radiation Oncology Group consequently recommended the creation of virtual multidisciplinary skin cancer teams for regional and rural patients.[37]

4.37 Seeking to address these broad locality challenges, the Australian Government invested $685 million in the establishment of 26 Regional Cancer Centres and patient accommodation facilities across Australia and a further $666.6 million in centres of excellence located in Sydney and Melbourne. According to the Commonwealth Department of Health, 'these regional centres will improve access to surgical and radiation therapy for people living in regional Australia with melanoma'.[38]

Early Treatment

4.38 Chapter 3 of this report discussed the importance of early diagnosis and the challenges faced by the stakeholders engaged in the diagnostic process. However, early treatment of skin cancer is also important for the prognosis of diagnosed patients.

4.39 The predecessor Committee's 2013 roundtable heard evidence from Professor Rodney Daniel Sinclair where early treatment following early diagnosis can reduce the cost of treatment from $3000 in a public hospital to $300 in a skin cancer triage clinic.[39]

36 Trans-Tasman Radiation Oncology Group, *Submission 47.1*, p. 3.

37 Trans-Tasman Radiation Oncology Group, *Submission 47.1*, p. 3.

38 Department of Health, *Submission 12*, p. 11.

39 Professor Rodney Daniel Sinclair, Evidence given to the House of Representatives Standing Committee on Health and Ageing, 43rd Parliament, *Official Committee Hansard*, Canberra, 21 June 2013, p. 10.

Patient Management

4.40 For complex and serious skin cancers, patients' treatment will include a number of practitioners including GPs, dermatologists, oncologists, radiologists and other specialists. As previously noted, navigating through these complex treatments can be confusing for patients and their families.

4.41 The Committee heard evidence that multidisciplinary care is the best practice approach to evidence-based cancer care and leads to better outcomes for patients. Cancer Australia, a government agency, stated:

> Multidisciplinary care is the best practice approach to providing evidence-based cancer care, including skin cancer care. Multidisciplinary care is an integrated team-based approach to cancer care where medical and allied health care professionals consider all relevant treatment options and collaboratively develop an individual treatment and care plan for each patient.[40]

4.42 Accordingly, Cancer Australia developed its *Principles for Multidisciplinary Care*, providing a flexible definition of multidisciplinary care which allows for variation in implementing these principles according to the cancer type and the location of services. These principles can be summarised to include the following:

- a *team approach*, involving core disciplines integral to the provision of good care, including general practice, with input from other specialties as required
- *communication* among team members regarding treatment planning
- access to the *full therapeutic range* for all patients, regardless of geographical remoteness or size of institution
- provision of care in accordance with nationally agreed *standards;*
- *involvement of patients* in decisions about their care.[41]

4.43 Although specific to breast cancer, Cancer Australia has also developed *Principles of Shared Care* in the treatment of patients with breast cancer. These principles included a patient-centred approach; coordination, communication and continuity of care; support for primary care providers; support for specialist treatment team; and, care that is delivered according to best practice standards.[42]

4.44 Further to the work developed by Cancer Australia, a number of stakeholders have also worked to provide better patient management, and

40 Cancer Australia, *Submission 23*, p. 9.

41 Cancer Australia, *Submission 23*, p. 16.

42 Cancer Australia, *Submission 23*, p. 19.

identified various opportunities and challenges associated with coordinated care.

4.45 For example, Professor Alexis Andrew Miller, a registered practising senior radiation oncologist on the South Coast of New South Wales identified a practical example of an opportunity for improved patient management. Professor Miller advocated that evidence-based practice could be improved by ongoing multidisciplinary interaction between clinicians in the form of a Multidisciplinary Team (MDT) meeting to discuss particularly challenging cases. In the view of Professor Miller, this would include pathologists, radiation oncologists, doctors undertaking surgical procedures (surgeons, dermatologists, community health specialists and GPs).[43]

4.46 A MDT service for the treatment of melanoma is currently provided in Western Australia by the Western Australian Melanoma Advisory Service. This is a free, statewide, multidisciplinary service and the only melanoma-specific MDT in Western Australia. The panel of 22 doctors comprises specialists, involving dermatology; general and plastic surgery; radiation and medical oncology; and pathology. The Western Australian Melanoma Advisory Service is also staffed by a nurse coordinator who is capable of assessing and referring patients in need allied health involvement or psychological intervention.[44] The scope of the MDT panel is to:

> provide comprehensive advice regarding the management of complex advanced and metastatic malignant melanoma. This includes advice regarding the adequacy of surgical margins of excision for primary melanomas; the role for further investigations and staging; identifying patients potentially suitable for inclusion in clinical trials; the need for local systemic therapy; and information regarding prognosis.[45]

4.47 Similar MDT structures exist in some parts of New South Wales[46] and Victoria.[47]

4.48 Other opportunities identified include establishing centres of excellence in treatment and management to set protocols and draft programs with a

43 Professor Alexis Andrew Miller, *Submission 61*, p. 1.

44 Western Australian Melanoma Advisory Service, *Submission 45*, p. 1.

45 Mrs Julie Teraci, Clinical Nurse Consultant/Coordinator, Western Australia Melanoma Advisory Service, *Official Committee Hansard*, Perth, 1 May 2014, p. 30.

46 NSW Government, *South Eastern Sydney Local Health District – Cancer Services Multidisciplinary Care,* http://www.seslhd.health.nsw.gov.au/POWH/services/cancerservices/multicare.asp, viewed November 2014.

47 Victorian Department of Human Services, *Alfred Health Cancer Services,* http://humanservicesdirectory.vic.gov.au/SiteDetails.aspx?SiteID=54845, viewed November 2014.

collaborative approach adopted in the treatment and management of patients.[48] Cancer Voices South Australia also recommended a 'triaging mechanism for referral to specialists, so urgent referrals are treated in a timely manner'.[49]

4.49 To better address the challenges posed by regionally and remotely located patients, the National Rural Health Alliance stated that Medicare Locals have a clear role to play in the diagnosis, prevention and management of skin care, further noting their heightened importance in regional and remote Australia.[50] Hunter Medicare Local was in support of this identified role, and also commented on the role that GPs have in clinical management of patients located in regional Australia.[51]

Psychosocial and Non-Medical Support for Patients and their Families

4.50 A number of organisations raised the importance of psychosocial and non-medical support for patients of skin cancer, most particularly for melanoma.[52] For example, Melanoma Patients Australia stated:

> Patients are (and will most likely continue to) articulate feelings of anxiety, stress and confusion in dealing with their disease. As melanoma gradually shifts to being a chronic disease in the long term, for now, melanoma must still be recognised as a serious condition and patient's referred to support and advocacy services as an integral component of their care.[53]

4.51 Similarly, the Western Australian Melanoma Advisory Service commented on the need for the management of a broad range of patients' needs:

> Melanoma is not straightforward. It is not like some of the other cancers where you have got these really nicely defined treatment pathways. There are always ifs and buts. … Melanoma has quite a big emotional impact on patients. I refer quite a bit to

48 Skin & Cancer Foundation Inc, *Submission 9*, p. 7.

49 Cancer Voices South Australia, *Submission 35.1*, p. 1.

50 National Rural Health Alliance, *Submission 7.1*, p. 5.

51 Hunter Medicare Local, *Submission 54.1*, p. 2.

52 Melanoma Patients Australia, *Submission 14*, p. 3; Mr Clinton Hall, Chief Executive Officer, Melanoma WA, *Official Committee Hansard*, Perth, 1 May 2014, p. 25; Cancer Support WA, *Submission 38*, p. 1; Cancer Voices New South Wales, *Submission 59*, p. 2; and Mr Terry Slevin, Education and Research Director, Cancer Council WA, *Official Committee Hansard*, Perth, 1 May 2014, p. 1; Western Australian Melanoma Advisory Service, *Submission 45*, p. 1..

53 Melanoma Patients Australia, *Submission 14*, p. 3.

> psychologists and counsellors. Counsellors have said to me, 'Out of all of the patients I see, melanoma patients are the most anxious'.[54]

4.52 The founder of Melanoma WA, and now Chief Executive Officer, Mr Clinton Hall, was diagnosed with melanoma and, as a patient, described the important role of support services:

> It was the realistic hope of seeing someone else who was living past their prognosis or their diagnosis. … [G]etting that sense of realistic hope, I felt almost obligated to give other people the same chance to feel that... But it is to meet those people who are in front of you, so to speak, or further down the journey, so you can say I can feel and touch and see this person; they are a real person and they are living. …
>
> In my case I had to fall down in order to learn how to walk forward... I had pharmacological depression which was attributed to the chemotherapy and the interferon chemotherapy agent that I was on. That was a big learning curve for me. There is nothing like talking to someone who knows exactly what you are going through and that is another person living with melanoma.[55]

4.53 To ensure that skin cancer patients receive the psychosocial support they require, Cancer Support WA were of the view that health care systems should automatically trigger a range of free, psychosocial and non-medical services upon diagnosis, including:

- immediate referral to a cancer support service upon receiving a prognosis 'to ensure they are provided with immediate emotional support from a qualified counsellor';[56] and
- be provided with information about 'wellness and lifestyle programs [like that] offered by Cancer Support WA which may improve their outcome from cancer and help prevent recurrence'.[57]

4.54 Cancer Council WA also discussed the importance of non-medical support services in providing basic logistical support to skin cancer patients. In addition to providing a cancer helpline (which receives over 400 calls a year from skin cancer patients located in Western Australia), Cancer Council WA also provides accommodation support for those regional and

54 Mrs Julie Teraci, Clinical Nurse Consultant/Coordinator, Western Australian Melanoma Advisory Service, *Official Committee Hansard*, Perth, 1 May 2014, p. 31.

55 Mr Clinton Hall, Chief Executive Officer, Melanoma WA, *Official Committee Hansard*, Perth, 1 May 2014, p. 25.

56 Cancer Support WA, *Submission 38*, p. 1.

57 Cancer Support WA, *Submission 38*, p. 1.

rural patients who are required to travel into centres for their treatment. In the past financial year, 57 advanced melanoma patients used the accommodation services provided by the Council (out of a 4 000 guests including cancer patients and their families or carers).[58]

4.55 Melanoma WA also advocated the importance of similar psychosocial and non-medical support services being made available to the family, friends and carers of skin cancer patients:

> [Patients] might be going through something but the carers have their own things that they are going through as well. It is important to really acknowledge that, without the carers and the support crew around that person—I know, for example, if my mum and dad were not coping when I was diagnosed, I would not have been very good at all. So we really want to support the supporters as well.[59]

4.56 Cancer Voices New South Wales advocated for more financial support to be dedicated to the support services required by 'those going through a serious skin cancer journey'.[60]

New Treatments and Emerging Research

4.57 The enormous personal and economic burden of skin cancer 'underscores the priority for research efforts to find better ways to control these cancers'.[61] This section details new treatments and the emerging research which is hoped will provide life-saving treatments, improved quality of life outcomes for patients, and also reduce the economic costs of treatment to the national health budget.

New Treatments

4.58 Recent advances in pharmaceutical research have led to the development of two new immunotherapy medicines to treat advanced melanoma: ipilimumab and dabrafenib.

4.59 As discussed, the aim of treatment in advanced melanoma is to optimally manage each stage of disease with a view to extending overall survival of approximately six to nine months. Treatment for advanced melanoma is

58 Mr Terry Slevin, Education and Research Director, Cancer Council WA, *Official Committee Hansard*, Perth, 1 May 2014, p. 1.

59 Mr Clinton Hall, Chief Executive Officer, Melanoma WA, *Official Committee Hansard*, Perth, 1 May 2014, p. 25.

60 Cancer Voices New South Wales, *Submission 59*, p. 2.

61 Professor David Whiteman, *Submission 3*, p. 2.

limited, and includes systemic therapy, palliative care/radiotherapy, palliative surgery or no treatment.[62] It was stated during the Committee's inquiry that ipilimumab may prevent disease progression in 10 per cent patients for a period up to 3 years,[63] and extend a patient's life expectancy up to 16 months.[64] The Committee received similar evidence on dabrafenib in regards to extended life expectancy.[65]

4.60 The TGA released its *Australian Public Assessment Report on Ipilimumab* in August 2011 and referred to positive results in double-blind, controlled clinical trials. The report concluded the efficacy of ipilimumab, and the TGA subsequently approved ipilimumab for sale in Australia.[66] The drug was listed on the Pharmaceutical Benefits Scheme (PBS) in August 2013, however the efficacy of the drug was questioned by some stakeholders in this inquiry.[67]

4.61 Similarly, the TGA's *Australian Public Assessment Report of Dabrafenib* was released in January 2014 after receiving initial registration on the Australian Register of Therapeutic Goods in August 2013.[68] The drug was subsequently listed on the PBS in December 2013. More information on the pharmaceutical make-up, clinical trials and assessment of these drugs can be found in the TGA's reports.[69]

4.62 In regards to their listing on the PBS, the Department of Health stated:

> Without Australian Government subsidy these drugs would cost up to $94 000 and $110 000 respectively per patient per year for treatment, with a further cost of up to $230 for diagnostic testing.[70]

4.63 However, Melanoma Patients Australia advocated for 'improved equality of access for all Australians to potentially life saving treatments through

62 Pharmaceutical Benefits Scheme, *PBS & Ipilimumab*, http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2012-11/ipilimumab, viewed November 2014.

63 Australasian College of Dermatologists, *Submission 15*, p. 7.

64 Mr Colin Richardson, *Official Committee Hansard*, Perth, 1 May 2014, p. 42.

65 Merck Sharp & Dohme, *Submission 32*, p. 4.

66 Therapeutic Goods Administration, *Australian Public Assessment Report for Ipilimumab*, August 2011, http://www.tga.gov.au/auspar/auspar-ipilimumab-0, viewed November 2014.

67 Mr Martin Leonard Ashdown, Collaborating Investigator, Australian Melanoma Research Foundation, *Official Committee Hansard*, Adelaide, 14 April 2014, p. 20.

68 Therapeutic Goods Administration, *Australian Public Assessment Report for Dabrafenib*, January 2014, http://www.tga.gov.au/auspar/auspar-dabrafenib-mesilate, viewed November 2014.

69 Therapeutic Goods Administration, *Australian Public Assessment Report for Ipilimumab*, August 2011, http://www.tga.gov.au/auspar/auspar-ipilimumab-0, viewed November 2014; Therapeutic Goods Administration, *Australian Public Assessment Report for Dabrafenib*, January 2014, http://www.tga.gov.au/auspar/auspar-dabrafenib-mesilate, viewed November 2014.

70 Department of Health, *Submission 12*, p. 10.

the prompt listing on the PBS'.[71] The Department of Health explained that there can be many reasons why the time taken for PBS listing of a medicine may vary, such as:

- the drug manufacturer may decide not to make a submission to the [Pharmaceutical Benefits Advisory Committee] PBAC to list their medicine on the PBS following approval from the TGA;
- the PBAC may reject the submission for PBS listing due to the application not being clinically effective or cost effective from the evidence provided;
- the drug manufacturer may also decide not to progress PBAC recommendation to list the medicine on the PBS; and
- the drug manufacturer may not be satisfied with the PBAC recommendation (can be due to agreed priced offered or other pricing arrangements) and may pursue to reapply to the PBAC for further consideration.[72]

4.64 During the inquiry, the Committee received evidence on the efficacy of other treatments, including topical treatments and their affordability for patients.[73] Evidence was also received from stakeholders noting the important work of the PBAC and advocated that 'restrictions on prescribing these expensive drugs are deeply respected by the medical profession'.[74]

4.65 The Australian Medical Association (NSW) similarly stated:

> A number of new treatments, predominantly medical therapies, have recently been introduced but tend to target advance stages of non-melanoma skin cancer or melanoma and are expensive. Careful consideration of these agents, as to their place and reimbursement in the Australian situation, needs to occur with all the relevant stakeholders involved. These new agents do not help in the management of the vast majority of Australians affected by non-melanoma skin cancer or melanoma and it would not be appropriate to reduce expenditure on current MBS items in relation to skin cancer to allow for increased PBS expenditure on new items.[75]

4.66 Responding to the new treatments discussed in submissions to the inquiry, the Department of Health stated:

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71 Melanoma Patients Australia, *Submission 14*, p. 5. See also Cancer Voices New South Wales, *Submission 59*, p. 1.

72 Department of Health, *Submission 12.2*, p. 8.

73 Cancer Council Australia and Clinical Oncology Society of Australia, *Submission 26*, p. 3; Merck & Co Inc, *Submission 63*, p. 1;

74 Professor Richard Kefford, *Submission 11*, p. 1.

75 Australian Medical Association (NSW), *Submission 4*, p. 6.

> There are further submissions to be considered by the PBAC for the treatment of melanomas… However, the Australian Government does not interfere with the decision making process of the PBAC. Further, the Australian Government cannot compel a sponsor to make a submission for PBS listing to the PBAC.[76]

4.67 As many of these treatments are either being evaluated by the TGA or the PBAC, the Committee does not consider it appropriate to further engage with this evidence in the report.

Research

4.68 Research into finding new skin cancer treatments, as well as the trial of different combinations of existing treatments, is critical to improvements in initial detection, early treatment and ongoing care of patients diagnosed with skin cancer. Starkly put, Melanoma Patients Australia argues that despite 'improved survival outcomes offered to some patients by these new and emerging therapies, there is still no cure for advanced melanoma'. [77]

4.69 Similarly, without investment in research, NMSC will continue to remain Australia's most costly form of cancer to treat and will continue to be an increasing burden on the healthcare system as the Australian population ages.[78]

4.70 Noting these points, a number of participants advocated for the importance of greater investment in research into skin cancer.[79] The Australasian College of Dermatologists recommended:

> 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 [currently] exists … would assist lead[ing] enhanced research activity.[80]

4.71 Specifically on melanoma research, the Melanoma Institute of Australia discussed the value that genetic and behavioural research has added to the

76 Department of Health, *Submission 12*, p. 10.

77 Melanoma Patients Australia, *Submission 14*, p. 3.

78 LEO Phama, *Submission 24*, p. 3.

79 Melanoma Patients Australia, *Submission 14*, p. 3; LEO Phama, *Submission 24*, p. 3; Australasian College of Dermatologists, *Submission 15*, p. 6; Trans-Tasman Radiation Oncology Group, *Submission 47*, p. 2; Melanoma Institute Australia, *Submission 58*, p. 1; Cancer Voices New South Wales, *Submission 59*, p. 2.

80 Australasian College of Dermatologists, *Submission 15*, p. 6.

understanding of personal risk of melanoma. The Institute consequently recommended continued research into how more precise risk assessment and specialised surveillance for those at highest risk of melanoma may improve prevention and early detection.[81]

4.72 The Melanoma Institute of Australia also commented that recent advances in diagnosis and treatment of melanoma have come from 'basic molecular and genomic research, which is now driving the first way of successful treatments of advanced melanoma'. [82] In light of these advances, the Institute recommended greater 'strategic investment into determining the role of genomics in patient care in cancer'. [83] The Institute also identified an opportunity for improved collaborative platforms between clinicians and researchers. [84]

4.73 Melanoma Patients Australia recommended that epidemiological research into skin cancer should receive ongoing investment, focussing on treatments and patient management systems. Further, Melanoma Patients Australia argued for improved 'consultation and involvement of the patient community in the development, delivery and review of skin cancer and melanoma research projects'.[85]

4.74 Cancer Australia supports ongoing research on the treatment and management of melanoma and NMSC through the Priority-driven Collaborative Cancer Research Scheme (PdCCRS). Between 2007 and 2012, the PdCCRS has supported nineteen research projects on skin cancer with a total value of $3.83 million. Of these nineteen research projects, fifteen projects (with a total value of $2.92 million) had a focus in melanoma, one project focused on Merkel Cell Carcinoma (total value $0.19 million) and a further three projects addressed skin cancer in general (total value $0.72 million). Cancer Australia advised that it plans to fund a further project this financial year supporting research into melanoma.[86]

Clinical Trials in Australia

4.75 A number of organisations advocated the importance of research and clinical trials in working towards improved treatment options for patients.[87] Clinical trials drive both improved patient treatment through

81 Melanoma Institute of Australia, *Submission 58*, p. 3.
82 Melanoma Institute of Australia, *Submission 58*, p. 3.
83 Melanoma Institute of Australia, *Submission 58*, p. 3.
84 Melanoma Institute of Australia, *Submission 58*, p. 3.
85 Melanoma Patients Australia, *Submission 14*, p. 4.
86 Cancer Australia, *Submission 23*, p. 10, pp. 20-21.
87 Trans-Tasman Radiation Oncology Group, *Submission 47*, p. 2; Melanoma Patients Australia, *Submission 14*, p. 4; Cancer Australia, *Submission 23*, p. 24.

testing the efficacy of existing treatment options to different presentations, but also can provide a firm basis for the introduction of new treatments into clinical practice. Melanoma Patients Australia stated:

> Clinical trials are an integral part of the development of new and improved therapies for skin cancer and melanoma. While efforts have been made to centralise information on current clinical trials available to patients, there is still a great deal of work to be done in ensuring accuracy, currency and accessibility of the information in a patient friendly format. [88]

4.76 Similarly, the Trans-Tasman Radiation Oncology Group stated that properly regulated and reviewed clinical trials result in improved treatment and patient care. For example, one clinical trial managed by the Trans-Tasman Radiation Oncology Group found that the chance of skin cancer reappearing was reduced by approximately 30 per cent when radiotherapy followed standard surgical treatment.[89] Consequently, the Trans-Tasman Radiation Oncology Group recommended that clinical trials for skin cancers be expanded in Australia as the evidence gained through these trials has directly improved the treatment of these cancers and therefore delivered improved patient care and outlook.[90]

4.77 The capacity of clinical trials to improve patient care and outlook led a number of organisations to advocate for more investment in clinical trials. The Trans-Tasman Radiation Oncology Group submitted that as skin cancer is Australia's 'national cancer', specific funding for it should be a priority, especially specific funding for randomised trials in skin cancer.[91]

4.78 Currently, there are thirteen Australian clinical trials groups which receive financial support from the government agency, Cancer Australia, to conduct clinical trials in Australia for cancer research.[92] A number of these groups have received funding from Cancer Australia's Support for Cancer Clinical Trials Program which have specifically related to skin cancer research. These groups include, the Australia New Zealand Melanoma Trials Group, Trans-Tasman Radiation Oncology Group, Psycho-Oncology Co-operative Research Group, Primary Care Collaborative Cancer Clinical Trials Group and Australian and New Zealand Children's Haematology/Oncology Group.[93]

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88 Melanoma Patients Australia, *Submission 14*, p. 4.

89 Trans-Tasman Radiation Oncology Group, *Submission 47*, p. 4.

90 Trans-Tasman Radiation Oncology Group, *Submission 47*, p. 5.

91 Trans-Tasman Radiation Oncology Group, *Submission 47.1*, p. 2.

92 Cancer Australia, *Support for clinical trials*, http://canceraustralia.gov.au/research-data/support-clinical-trials, viewed November 2014.

93 Cancer Australia, *Submission 23*, p. 24.

4.79 More specifically, Cancer Australia advised it had alone funded the Australia New Zealand Melanoma Trials Group over $2.66 million over five years (to 30 June 2013) to support the development of clinical trial protocols in melanoma. Cancer Australia will provide the Australia New Zealand Melanoma Trials Group with a further $1.38 million over three years to 30 June 2016 to continue this important work. In addition, Cancer Australia is supporting the Genomic Cancer Clinical Trial Initiative, providing $1.35 million (between 1 July 2013 and 30 June 2016) to establish and lead the collaborative development of mutation-specific clinical trials for mutations that are common to several tumour types.[94]

4.80 Despite this investment, the Trans-Tasman Radiation Oncology Group stated that 'there is a dearth of randomised controlled trials originating in Australia'. [95] As the majority of funded trials are comparison trials between one treatment and another, the Trans-Tasman Radiation Oncology Group stated that there is subsequently little known about how to treat skin cancer 'with the best oncological, functional, cosmetic and economic outcomes'.[96] The Trans-Tasman Radiation Oncology Group further advocated that Australia is missing an opportunity for global leadership in the skin cancer research sphere.[97]

Concluding Comment

4.81 The Committee notes the challenges posed by treating melanoma and NMSC, the range of clinicians involved and the importance of support services in ensuring holistic patient care.

4.82 The Committee is also of the view that further research and clinical trials will continue to uncover improved treatment options for patients, and that this research will find long-term solutions for patients diagnosed with skin cancer.

Clinical Practice Guidelines

4.83 The Committee was concerned by reports from professional bodies that the clinical practice guidelines, *Clinical practice guidelines for the management of melanoma in Australia and New Zealand* and *Basal cell carcinoma, squamous cell carcinoma (and related lesions) – a guide to clinical management in Australia* have not been updated since their initial release in 2008.

94 Cancer Australia, *Submission 23*, p. 10.
95 Trans-Tasman Radiation Oncology Group, *Submission 47.1*, p. 1.
96 Trans-Tasman Radiation Oncology Group, *Submission 47.1*, p. 1.
97 Trans-Tasman Radiation Oncology Group, *Submission 47.1*, p. 2.

4.84 The Committee notes that the National Health and Medical Research Council (NHMRC) reviews registered clinical guidelines every ten years.[98] However, the Committee is of the view that these guidelines should be updated prior to the upcoming review in 2018.

4.85 The absence of updated agreed best practice and medicines which have not only been approved by the TGA, but also placed on the PBS, from these guidelines is a problem identified by many participants in the inquiry, and one that the Committee seeks to rectify.

4.86 The Committee therefore recommends that these guidelines be updated.

4.87 The *Clinical practice guidelines for the management of melanoma in Australia and New Zealand* were developed by the NHMRC, and the Committee recommends that the Council urgently update these guidelines, and continue to update them after new medicines are approved by the TGA for the treatment of skin cancers, or when consultations with the profession indicate that an update is necessary.

4.88 The *Basal cell carcinoma, squamous cell carcinoma (and related lesions) – a guide to clinical management in Australia* was the result of a collaborative effort by Cancer Council Australia and the Australian Cancer Network to update the then outdated *Clinical Practice Guidelines on non-melanoma skin cancer: guidelines for the treatment and management in Australia* (1992) by the NHMRC. The Committee recommends that the NHMRC seek to collaborate with Cancer Council Australia and the Australian Cancer Network to update clinical guidelines for the treatment and management of NMSC and assist with their subsequent approval by the NHMRC.

4.89 Although the Committee considers that these updates are critical, the Committee acknowledges that updating printed publications is an involved process, takes time, and inevitably encounters difficulties with distribution. Consequently, the Committee recommends the Department of Health further investigate whether clinical practice guidelines, particularly those relevant to this inquiry, be moved into an online platform which is amenable to more regular updates, is easily and quickly distributed and accessible.

4.90 In undertaking this work, the Committee recommends that the Department of Health work with the Cancer Council to benefit from its experience in this area.

98 National Health and Medical Research Council, *How the NHMRC develops its guidelines*, https://www.nhmrc.gov.au/guidelines/how-nhmrc-develops-its-guidelines, viewed November 2014.

Patients in Regional and Remote Locations

4.91 Evidence gained at the Committee's hearings in regional and remote locations throughout Australia revealed the extent of the challenges faced by skin cancer patients located in regional and remote Australia.

4.92 To assist patients, their families and carers, and the health practitioners providing treatments, the Committee is of the view that better multidisciplinary care can be provided through greater use of new technologies and virtual platforms. The Committee believes that the utility of the 26 new regional cancer centres can be maximised through such programs. The Committee also believes there is some duplication in the coordination of service delivery in these locations.

Patient Management

4.93 The Committee heard compelling evidence that multidisciplinary care leads to improved outcomes for patients. The complexity of the disease, and the complexity of treatment, including psychosocial care, indicates that a multidisciplinary approach to patient care will best address these challenges.

4.94 Consequently, the Committee is of the view that the multidisciplinary care model should be more widely adopted throughout Australia.

4.95 The Committee commends the work of Cancer Australia in developing a range of multidisciplinary care policies, and is of the belief that this work can be further developed specifically in relation to skin cancer. The Committee also believes there are opportunities for Australia's regional and remote health services, including Medicare Locals, to be utilised in improved patient management for those patients located in these regions.

4.96 The Committee recommends that the Department of Health work with State and Territory counterparts to further develop and implement best practice models for multidisciplinary care for the treatment of skin cancer patients.

Psychosocial and Non-Medical Support for Patients and their Families

4.97 The Committee notes the vital role of psychosocial and non-medical support for skin cancer patients and their families. These services – particularly for melanoma patients – ensure that the patient, and their family, friends and carers, receive holistic care and make available important support networks available which can assist in navigating such enormous personal challenges.

4.98 The Committee is of the view that these psychosocial and non-medical support services are particularly important for patients located in regional

or rural areas of Australia which require significant travel to treatment centres.

4.99 The Committee therefore recommends that the Australian Government ensure that adequate funds are provided for the non-medical support services of skin cancer patients and their families, particularly support services for those rural patients who have to travel for treatment.

New Treatments and Emerging Research

4.100 As noted above, the Committee received evidence throughout its inquiry from pharmaceutical companies regarding new and emerging treatments. The Committee also notes that the efficacy of some of these treatments was questioned by other stakeholders during the inquiry. As many of these treatments are being considered by the TGA and/or the PBS (themselves independent processes from government) the Committee does not consider it appropriate to comment on these new treatments further.

Recommendation 10

4.101 **The Committee recommends the National Health and Medical Research Council:**

- **work with relevant stakeholder to urgently update the registered *Clinical practice guidelines for the management of melanoma in Australia and New Zealand* (2008) and *Basal cell carcinoma, squamous cell carcinoma (and related lesions) – a guide to clinical management in Australia* (2008), and that these guidelines be updated:**
  - ⇒ **shortly after each new treatment is approved by the Therapeutic Goods Administration; or**
  - ⇒ **as frequently as recommended by the profession after relevant consultation; and**

that the Department of Health undertake research and analysis of whether clinical guidelines relating to skin cancer treatments can be placed on a digital platform, thereby allowing regular updates and quick and easy distribution of updated best practice for clinicians and practitioners.

Recommendation 11

4.102 **The Committee recommends that the Department of Health work with State and Territory counterparts to:**

- **establish a virtual platform for the multidisciplinary treatment of skin cancer for patients located in regional and remote Australia; and**
- **further develop and implement best practice models for multidisciplinary care for the treatment of skin cancer patients.**

Recommendation 12

4.103 **The Committee recommends that the Australian Government ensure that adequate funds are provided for the non-medical support services of skin cancer patients and their families, particularly support services for those rural patients who have to travel for treatment.**

Steve Irons MP
Chair

17 March 2015