



Australian Government

**Australian Government Response to the Senate Select
Committee Inquiry report:
Funding for Research into Cancers with Low Survival Rates**

November 2018

Introduction

On 29 November 2016, the Senate established the Select Committee into Funding for Research into Cancers with Low Survival Rates (the committee) to inquire and report by 28 November 2017 on:

- a. the current National Health and Medical Research Council (NHMRC) funding model, which favours funding for types of cancer that attract more non-government funding, and the need to ensure the funding model enables the provision of funding research into brain cancers and other low survival rate cancers;
- b. the obstacles to running clinical trials for brain cancers and other cancers with relatively lower rates of incidence, with regard to:
 - i. funding models that could better support much-needed clinical trials, and
 - ii. funding support for campaigns designed to raise awareness of the need for further research, including clinical trials;
- c. the low survival rate for brain cancers, lack of significant improvement in survival rates, and strategies that could be implemented to improve survival rates; and
- d. other relevant matters.

The committee tabled the report *Funding for Research into Cancers with Low Survival Rates* in Parliament on 28 November 2017 making 24 recommendations.

The Australian Government notes the recommendations made in the report and provides a response to these recommendations in this document. Many of the report's recommendations address issues most appropriately dealt with at a state and territory level, particularly those related to education and early intervention programs.

Development of the Australian Government Response

This response is a whole of government response including activity within a number of Australian Government departments and agencies including

- Department of Health;
- Department of Social Services;
- Department of Human Services;
- Department of Industry, Innovation and Science;
- NHMRC;
- Australian Institute of Health and Welfare; and
- Cancer Australia

The Government acknowledges the significant contribution that state and territory governments make in the provision of research efforts.

Current Australian Government Efforts

The Australian Government provides funding and other support for a range of services and programs for research into cancers with low survival rates. These include those outlined below:

Medical Research Future Fund (MRFF)

Clinical Trial Activity

The current focus of the MRFF clinical trial investment program is rare cancer, rare diseases and unmet need and provides \$219 million over six years to stimulate efforts to find cures and transformative new drugs and treatments for those impacted by

devastating conditions, including low survival cancers. This investment in activity also serves to build capacity to position Australia as a preferred destination for clinical trials.

To date \$36.6 million has been announced for clinical trial activity under the MRFF addressing rare cancers, rare diseases and unmet need. This includes \$10 million specifically for clinical trials targeting cancers and diseases with low survival rates.

Applications for the recent \$33 million grant round are being assessed and outcomes will be announced in due course.

Brain Cancer Mission

On 29 October 2017, the Australian Government announced a \$100 million fund for the Australian Brain Cancer Mission, which has since grown to \$105 million and is encouraging more generous contributions from the philanthropic, state government and private sector. The MRFF contribution to this Mission is \$55 million. The Mission's aim is to double the survival rates and improve the quality of life of patients with brain cancer over the next 10 years to 2027, with the longer term aim of defeating the disease. Cancer Australia is administering the Mission on behalf of the Australian Government supported by a strategic advisory group.

National Health and Medical Research Council

The Australian Government, through the NHMRC is the premier funder of cancer research in Australia, accounting for 56 per cent of all funding nationwide. In the period 2000 to 2017, NHMRC provided over \$2.33 billion to support cancer research - 22 per cent of NHMRC's research funding.

Cancer Australia

Cancer Australia was established by the Australian Government in 2006 to benefit all Australians affected by cancer, and their families and carers. Cancer Australia's purpose is to minimise the impact of cancer, address disparities, and improve the health outcomes of people affected by cancer in Australia by providing national leadership in cancer control.

Cancer Australia leads a national and collaborative approach to supporting cancer research including in low survival and low incidence cancers through the Priority-driven Collaborative Cancer Research Scheme (PdCCRS) and Support for Cancer Clinical Trials program.

The PdCCRS provides a dedicated and coordinated pool of funding for cancer research from government and other funders to maximise the number of cancer research grants funded in Australia. PdCCRS is priority driven, using an evidence-based approach to determine research. These priorities include the provision of funding for research focused on populations with poorer cancer outcomes – such as those diagnosed with low survival rate cancers. Under the PdCCRS 2007-2017 funding rounds, more than \$25 million has been awarded to 72 research projects for cancers with low survival rates. The 2018 and 2019 rounds of the PdCCRS include a dedicated funding stream for children's cancers of low survival that will provide up to \$3.26 million to support research.

The Support for Cancer Clinical Trials program leads a national and collaborative approach to growing Australia's capacity to develop industry-independent cancer clinical trials protocols. Since 2008, Cancer Australia has provided more than \$80

million in funding to Australia's 14 multi-site Collaborative Cancer Clinical Trials Groups and a further \$13.7 million to six National Technical Services to support the Collaborative Clinical Trials Groups in the development of new industry independent trial protocols including for cancers with low survival rates.

In addition, in 2013 Cancer Australia established and funded the Genomic Cancer Clinical Trial Initiative. The initiative recognises the importance of genomics and enables the collaborative development of mutation-specific clinical trial protocols for mutations that are common across several tumour types. The initiative has supported the development of 20 new clinical trials concepts, including concepts for trials in cancers of low survival rates.

In the 2017-18 Budget under the *Investing in Medical Research – Fighting childhood cancer* initiative, Cancer Australia received \$5.8 million over four years to increase Australia's research capacity to advance diagnosis, treatment, management and analysis of childhood cancer, and improve data and awareness of childhood cancer. The measure also saw the establishment of a specific funding stream for low survival childhood cancers through the PdCCRS. Of the \$5.8 million, \$1.4 million is to fast track international collaborations for research into paediatric brain cancer in Australia, including the Access to Innovative Molecular diagnostic Profiling for paediatric brain tumours (AIM-BRAIN) initiative. Through this funding, Cancer Australia is also supporting participation of Australian children with brain cancer in the Low Grade Glioma (LGG) Avastin international Phase II clinical trial.

The Australian Government's Response to Recommendations

Recommendation 1

2.160 The committee recommends that the Chief Executive Officer of the National Health and Medical Research Council considers identifying low survival rate cancers as a National Health Priority Area in the upcoming 2018-19 Corporate Plan.

Response:

This recommendation is noted.

NHMRC's strategic priorities, as set out in the Corporate Plan, are based on health system needs, evidence gaps, advice from the Council of NHMRC and government policies, including the National Health Priority Areas (NHPAs) and the Australian Government's Science and Research Priorities.

Major Health Issues such as Low Survival Rate Cancers will be taken into consideration in the development of NHMRC's annual work plan as part of the Corporate Plan.

Recommendation 2

2.164 The committee recommends that the National Health and Medical Research Council introduces the option for extensions to the duration of funding to recipients of research grants, provided that these recipients satisfy certain performance criteria.

Response:

This recommendation is noted.

The NHMRC has reviewed the structure of its research funding as part of the Structural Review of NHMRC's Grant Program and based on feedback sought from the research sector developed a new grant program that is currently being implemented. Applications for funding under NHMRC's new grant program will open in late 2018-early 2019 for peer review in 2019, and funding commencing in 2020.

In the new grant program all Investigator Grants will be for five years duration and include a research support package which allows for longer term projects and more research funding than was previously provided. Synergy Grants will also be for five years and Ideas Grants will be for up to five years. Collectively these three funding schemes will account for about 70 per cent of NHMRC's research expenditure.

NHMRC is considering its peer review processes in 2018 and the option to extend grant funding or streamline new applications that are linked to an existing grant may be considered as part of this process.

Recommendation 3

3.85 The committee recommends that the Australian government improves AustralianClinicalTrials.gov.au so it is more accessible and user-friendly.

Response:

This recommendation is supported in principle.

The Australian Government recently announced a *Helping Our Health* awareness campaign to raise the profile of the role and value of clinical trials.

AustralianClinicalTrials.gov.au is a central reference for trusted information in the campaign for information on clinical trials.

The clinical trial information provided on AustralianClinicalTrials.gov.au is sourced from the Australian New Zealand Clinical Trials Registry (ANZCTR), a critical piece of national research infrastructure. ANZCTR lists trials being conducted in Australia and New Zealand and also includes trials registered on the United States registry ClinicalTrials.gov that have a trial site in Australia.

The ANZCTR is also part of the worldwide initiative to make public all clinical trials being conducted. Trial registration through ANZCTR has the potential to improve research transparency, facilitate trial participation, avoid research duplication, identify research gaps, and promote collaboration. Improving information on ANZCTR would directly benefit consumers searching for trials on AustralianClinicalTrials.gov.au.

NHMRC is actively working with ANZCTR, the Department of Health, the Department of Industry, Innovation and Science and key stakeholders such as the states and territories, researchers and the pharmaceutical industry to improve the quality and timeliness of the information provided to ANZCTR.

The Department of Health recently commissioned a review of ANZCTR as part of a program of work being progressed by all jurisdictions through the Council of Australian Governments (COAG) Health Council. The review includes an assessment of current performance and the extent to which the ANZCTR meets the needs of

stakeholders, aligns to contemporary best practice, and will consider options to inform a potential next generation clinical trials registry. The outcomes of the ANZCTR Review will be considered as part of a spectrum of related initiatives underway to improve the environment for clinical trials in Australia, which includes a focus on improving ease of navigation and patient access to trials.

Recommendation 4

3.91 The committee recommends that state and territory governments consider:

- allowing low survival rate cancer patients participating in clinical trials to access patient travel subsidy schemes; and
- agreeing on consistent subsidy rates based on the distance and method of travel, and the average cost of accommodation in the city in which the patient is participating in the trial.

Response:

As noted in the Report, patient travel subsidy schemes are the responsibility of state and territory governments.

Recommendation 5

3.93 The committee recommends that Australian governments improve access to international clinical trials for people with low survival rate cancers, including by:

- exploring ways to reduce the financial barriers to accessing international trials to the extent possible; and
- further developing the existing capacity for international collaboration on trials.

Response:

This recommendation is supported in principle, noting that not all responsibilities for the conduct of clinical trials rest with governments. In particular, costs associated with specific clinical trials are a matter for sites and sponsors.

The Australian Government has committed \$261 million over the six years from 2016-17 under the MRFF to support new clinical trial activity with a focus on rare and low survival cancers and diseases, and international collaboration. A total of \$36.6 million in funding has already been announced, with \$10 million specifically targeting low survival cancers and diseases. These clinical trials will be undertaken in Australia.

Australia has a reputation for excellence in clinical trial research, internationally recognised researchers and medical experts, quality infrastructure and high standards of healthcare. In Australia, clinical trials are conducted within a strong regulatory framework determined by the International Conference on Harmonisation (ICH) and Good Clinical Practice (GCP).

In addition, the *Encouraging More Clinical Trials in Australia* initiative will provide \$7 million nationally over four years from 2017-18 to incentivise streamlining of state-based operating systems for trials. The aim is to establish state-based central hubs or coordinating units to fast track trial recruitment and start up. These hubs/units will make it easier for domestic and international sponsors and researchers to establish and run trials and for patients to participate. The initiative is supported by the COAG

Health Council's revitalised clinical trials agenda that recognises that patients are at the centre of clinical trials and clinical trials are essential health system activities.

In recognition of the importance of international collaboration, the Government has committed a total of \$42 million over five years specifically to support international clinical trial collaborations. This investment will allow Australian researchers to expand trial activity overseas and bring new trial arms to Australia to benefit patients.

The Australian Government will continue its efforts to fund the best quality clinical trials and foster international collaborations to increase access to emerging therapies of potential for Australians, including those with low survival cancer.

Recommendation 6

3.129 The committee recommends that Australian governments, as a priority, further streamline ethics and governance approval processes for clinical trials, particularly where those processes differ between states and territories, and public and private research institutions.

Response:

This recommendation is supported in principle, noting that not all responsibilities associated with streamlining clinical trial approval processes rest with the Australian and state and territory governments.

In Australia, clinical trials are conducted within a strong regulatory framework determined by the International Conference on Harmonisation (ICH) and Good Clinical Practice (GCP), enabled by the following processes:

- review by a Human Research Ethics Committee (HREC) according to the National Statement on Ethical Conduct in Human Research (2007, updated in 2018 by the NHMRC);
- Site-Specific Assessments (SSA) undertaken at each trial site by local governance offices, to confirm the capability of the site to conduct the trial;
- notification to the TGA if the trial uses an unapproved therapeutic good or identifies an adverse event during implementation; and
- registration on a publically available WHO primary clinical trials registry such as Australian New Zealand Clinical Trials Registry (ANZCTR).

The Australian Government is already working collaboratively with all jurisdictions to progress important clinical trial reform. The \$7 million *Encouraging More Clinical Trials in Australia* initiative (refer Recommendation 5) is a demonstration of this joint government effort.

In partnership with jurisdictions, the Commonwealth is also leading the development of a National Clinical Trials Governance Framework through the Australian Commission on Safety and Quality in Health Care. The outcome will be an important first step towards nationally consistent accreditation of health services undertaking clinical trials in Australia. National consultations on a draft Governance Framework are planned for late 2018 and early 2019. The sector is highly supportive of this initiative, which has the potential to significantly improve the environment for conducting clinical trials in Australia, and to further streamline approval processes.

Significant work has already been completed to improve ethics and governance approval processes under the NHMRC's *National Certification Scheme of*

Institutional Processes related to the Ethical Review of Multi-centre research, which provides a level of assurance that an institution's ethics review processes conform to nationally consistent standards. In 2018, NHMRC will revise a number of key documents and processes underpinning the National Certification Scheme, with the aim of further streamlining and refining the scheme.

In addition under the Government's *Expediting Clinical Trial Reform in Australia (2013-14 Budget)* and *Simplified and Consistent Health and Medical Research* initiative (2014-15 Budget), the following resources have also been developed:

- a streamlined and contemporary national Human Research Ethics Application form for research involving humans;
- e-learning modules that provide an introduction to the clinical trials environment, clinical research ethics and ethics review, and research governance processes to further support and streamline the approval process;
- a National Good Practice Process for Research Governance in Clinical Trials, which through a national pilot program was demonstrated to significantly reduce governance approval times, and
- National Scientific Review Committees to provide independent expert advice to HRECs, sponsors and researchers on the scientific merit and integrity of research protocols.

National Mutual Acceptance (NMA) is a national system for mutual acceptance of scientific and ethical review of multi-centre human research projects conducted in publicly funded health services across jurisdictions. Single ethical and scientific review for a multi-centre human research project can now be provided across the six participating states/territories (Australian Capital Territory, New South Wales, Queensland, South Australia, Victoria and Western Australia). The scope of NMA includes any form of human research as defined in the *National Statement on Ethical Conduct in Human Research* for which an application must be made to a HREC. All jurisdictions are working towards participation, and NHMRC is working with other agencies to identify opportunities for the Commonwealth to become a formal party to the scheme.

Recommendation 7

3.132 The committee recommends that the National Health and Medical Research Council develops a standard template and associated guidelines, including timeframes, for ethics and other governance approvals for consideration and possible adoption by each state and territory.

Response:

This recommendation is partially supported, noting that complementary work is already underway.

NHMRC has developed a number of templates, guidelines and other resources and is working to encourage their wide-spread adoption by the sector as part of the National Certification Scheme. Over 200 Human Research Ethics Committees (HRECs) are registered with NHMRC, 48 of which are also 'certified' under the National Certification Scheme. NHMRC conducts annual monitoring of all registered HRECs

and has adopted timely approval processes as part of its certification standard, namely, 60 calendar days for the ethics review of an application.

Responsibilities for the governance of clinical trials rest with sites, with state and territory governments having a role for trials that occur in public hospitals. Separate work to develop a Clinical Trials Governance Framework is currently underway in collaboration with all jurisdictions. When complete, the Governance Framework will be an important first step towards nationally consistent accreditation of health services undertaking clinical trials in Australia.

Recommendation 8

4.33 The committee recommends that, through the Council of Australian Governments Health Council, the Australian government leads a process to ensure that arrangements for transitioning children and young people from paediatric to adult oncology services occurs in a consistent and co-ordinated way that preserves continuity and quality of care in the best interests of each individual patient.

Response:

The responsibility of transitioning young people from paediatric to adult oncology services rests with state and territory government health services.

Recommendation 9

5.20 The committee recommends that the Australian government undertakes communication activities targeted at the public with the objective of reducing the amount of time taken to detect and diagnose low survival rate cancers.

Response:

This recommendation is supported in principle.

The Australian Government supports a number of initiatives that aim to provide information and raise awareness of cancers including low survival rate cancers.

Cancer Australia promotes cancer awareness and provides evidence-based cancer information, resources and data for consumers and the community.

Cancer Australia uses a range of channels and approaches to present information and raise awareness of cancer, including low survival rate cancers. These include:

- the Cancer Australia website, which provides a central source of knowledge that facilitates access to information;
- Cancer Australia's Children's Cancer website;
- Cancer Australia's National Cancer Control Indicators website;
- dissemination of media releases, media interviews and targeted digital strategies including use of social media platforms, digital channels, animated multimedia and engaging key social media influences;
- a dedicated Consumer Learning portal to develop consumer confidence and expertise to participate in research and clinical trials; and
- promoting cancer awareness, during key cancer awareness months/weeks, including for low survival cancers, such as Lung Cancer Awareness Month,

Ovarian Cancer Awareness Month, Pancreatic Cancer Awareness Month and Brain Cancer Action Week.

Through the National Cancer Expert Reference Group (NCERG), the Australian Government is also supporting the promotion of Optimal Cancer Care Pathways to clinicians, consumers and policy makers.

Recommendation 10

5.25 The committee recommends that the Australian government works in collaboration with the Royal Australian College of General Practitioners and the Australian Medical Association to improve awareness of low survival rate cancers amongst general practitioners, including through continuing professional development.

Response:

The Australian Government supports this recommendation in principle, noting that extensive and broad-ranging collaboration already occurs with the Royal Australian College of General Practitioners (RACGP) and the Australian Medical Association (AMA) to improve awareness and professional development of general practitioners.

Cancer Australia works in collaboration with the RACGP and the AMA across a number of areas, including gaining their input and endorsement of clinical practice projects and guidance; and membership of Cancer Australia working groups and expert reference groups. In addition, Cancer Australia works with practitioners to:

- improve awareness of cancers, including low survival rate cancers;
- develop position statements, clinical guidance and principles;
- target communication strategies to provide health professionals with information on cancer prevention, detection, diagnosis and treatment, including for low survival rate cancers such as gynaecological cancers and lung cancer; and
- provide a range of evidence-based professional development learning activities, resources and information via the Cancer Australia website.

Cancer Australia also engages its Intercollegiate Advisory Group (ICAG), to inform national approaches to reducing variations in cancer outcomes, promote the use of best available evidence to achieve effective cancer care, identify collaborative approaches to address cancer control challenges and provide advice on emerging issues nationally and internationally to inform Cancer Australia's work. ICAG includes representation from relevant colleges and cancer organisations, including the RACGP.

Recommendation 11

5.59 The committee recommends that the Australian Government, in collaboration with state and territory governments:

- considers expanding the Australian Cancer Database to capture all cancers, including benign tumours of the brain and other parts of the central nervous system;
- in so doing, consults with medical researchers to identify what clinical and lifestyle data might be included in order to benefit oncology research; and

- addresses current barriers to data collection and considers ways in which data collection can be improved across Australia, in both public and private health settings.

Response:

This recommendation is supported.

The Australian Institute of Health and Welfare (AIHW) works in collaboration with states and territories to produce the Australian Cancer Database (ACD), which is a collection of all notifiable primary cancers (malignant tumours) diagnosed in Australia. This information is collected by state and territory cancer registries and provided to the AIHW to produce the ACD. Common non-melanoma skin cancers (basal and squamous cell carcinomas of the skin) are the only cancers that are not notifiable diseases and therefore not required by legislation to be reported to state and territory cancer registries.

Non-malignant tumours of the brain and other central nervous system are notifiable diseases in Victoria, Queensland, Western Australia and Tasmania so these states can provide data on these tumours to the AIHW to include in the ACD. The AIHW published these data in the report Brain and other central nervous system cancers in October 2017. However, these benign tumours are not currently notifiable diseases in other states and territories so data are not available to these cancer registries or for national data.

The AIHW has a Cancer Monitoring Advisory Committee that includes medical researchers, and will seek their advice on the clinical and lifestyle data requirements that might be included for the benefit of oncology research. This work is now underway within AIHW to enhance the ACD to include key treatment and health services data sets will capture information on the treatments and health services provided to all people diagnosed with cancer, which may fill some of the current gaps in relation to clinical data.

Commonwealth, state and territory stakeholders currently work together to identify barriers to cancer data collection and ways in which cancer data collection can be improved across Australia, in both public and private health settings. The AIHW will continue to take a leading role in improving these cancer data.

Cancer Australia also undertakes a variety of initiatives to enhance the collection and reporting of national cancer control data in Australia to improve outcomes for people with cancer, including low survival rate cancers. This includes addressing national data gaps, through the cancer data on Stage, Treatment and Recurrence (STaR) initiative. Through this initiative, the first of its kind in Australia, Cancer Australia is progressing and implementing methods for collecting, collating and reporting national cancer data on stage, treatment and recurrence through routinely-collected data. Cancer Australia collaborated with state and territory population-based cancer registries to develop and test business rules for the collection of cancer stage at diagnosis for five cancers, female breast, prostate, melanoma, colorectal and lung cancer. The data is published on the Cancer Australia National Cancer Control Indicators (NCCI) website and will help explore the relationship between cancer stage at diagnosis and survival outcomes and the role of public health initiatives, early detection and awareness campaigns.

Through the Fighting Childhood Cancer initiative, Cancer Australia is working to enhance childhood cancer data by collecting multi-year national cancer stage at diagnosis data for 16 paediatric cancer types. These data enable reporting of childhood cancer incidence by stage on Cancer Australia's childhood cancer website and NCCI website.

In addition, Cancer Australia's NCCI website provides a resource for monitoring national cancer trends and benchmarking internationally across the cancer control continuum. The website provides high quality data which allows for monitoring and reporting of national data trends across seven cancer control domains of prevention, screening, diagnosis, treatment, psychosocial care, research and outcomes. The data reported on the NCCI website encompasses multiple tumour types, including cancers of low survival and low incidence and will help improve data availability and access for low survival cancers.

Recommendation 12

5.62 The committee recommends that the Australian government gives serious consideration to implementing a national network medical and population biobank that includes tumour samples and relevant clinical and lifestyle data associated with each tumour sample.

Response:

This recommendation is noted.

Limited support for specific biobanks is currently provided through the Australian Government's investment in the National Collaborative Research Infrastructure Strategy.

The Research Infrastructure Investment Plan, announced in the May 2018 Budget, has provided funding for a scoping study that will look to maximise the broad range of biobanks across individual, institutional, state and Commonwealth collections. This aims to provide significant improvement in research effectiveness across a range of medical, agricultural and biodiversity research.

Recommendation 13

5.98 The committee recommends that the Australian government ensures ongoing funding for genomic research into low survival rate cancers.

Response:

This recommendation is supported, noting that the Australian Government has committed \$500 million towards a landmark ten year commitment to the Genomics Health Futures Mission.

The Mission will help Australians to live longer and better through access to genomics knowledge and technology, and accelerating precision diagnosis and treatment. Anticipated first priorities for the Mission are rare cancers (including low survival) and rare diseases as these conditions are thought to be more receptive to applied genomics. This Mission is supported by the *National Health Genomics Policy Framework 2018-2021* agreed by all governments with the purpose of creating a shared direction and commitment to consistently and strategically integrating genomics into the health system.

The investment in the Genomics Health Futures Mission is additional to the following significant commitments to harnessing the power of genomics in cancer treatment and cure:

- Australian Genomics Health Alliance (AGHA or Australian Genomics), which brings together more than 80 partner organisations across Australia, including Rare Cancers Australia. AGHA's two flagship programs – rare diseases and cancer are underpinned by strong national and international clinical, diagnostic and research partnerships as outcomes usually depend on sharing genomic data from many centres. This NHMRC grant began in 2016 and is worth \$25 million over five years.
- under the Australian Brain Cancer Mission, further funding has been provided for the Zero Childhood Brain Cancer program that brings together all eight children's hospitals with clinical and research groups working in childhood cancer to offer Australia's first ever personalised medicine program for children with high-risk brain cancer. The funding will allow all children with high risk brain cancer to access a range of genetic and drug testing for their tumours, to identify the most effective personalised treatment. It will also fast track access to novel targeted treatments through national and international clinical trials and establish an immune profiling platform to expand treatment options to include immunotherapies.
- Access to Innovative Molecular diagnostic Profiling for paediatric brain tumours (AIM BRAIN) clinical trial, which includes fast tracking of access for Australian and New Zealand children with brain cancer to an innovative international molecular diagnostic profiling platform. This project is being led by the Australian New Zealand Children's Haematology and Oncology Group (ANZCHOG) with support from Cancer Australia. The aim is ultimately to accelerate Australia's capacity to undertake advanced molecular testing for paediatric brain tumours, to provide more accurate diagnoses and ultimately better target treatment to improve survival and decrease side effects.
- Australian arm of the International Cancer Genome Consortium (ICGC), which has the goal of obtaining a comprehensive description of genomic changes in 50 different tumour types and/or subtypes of clinical and societal importance across the globe. Australia's focus is on sequencing pancreatic and ovarian cancer types, both of which have low survival rates. The project aims to link the large volume of genomic data already accumulated to clinical and health information to facilitate the development of markers for early disease detection, specific criteria and methods for diagnoses and prognoses, and interventions based on matching the molecular subtype of the patient's disease with the most effective combinations of therapies for low survival cancers. Between 2010 and 2015, NHMRC invested \$27.5 million in this project.
- Genomic Cancer Clinical Trial Initiative (GTI), through which Cancer Australia supports the provision of expert advice and technical services to Australia's 14 Multi-site Collaborative Cancer Clinical Trials Groups (CTGs) to facilitate collaborative development of genomics-based clinical trial protocols for mutations that are common to several tumour types, including low incidence cancers such as ovarian and pancreatic cancer. This initiative is facilitating personalised medicine approaches by understanding specific

genetic changes that are common to different cancers, and through development of drugs which target particular cancer mutations.

- NHMRC funding for basic genomics research into low survival cancers.

Recommendation 14

5.99 The committee recommends that the Australian government implements any recommendation from the Medical Services Advisory Committee to list genetic tests for low survival rate cancer patients on the Medicare Benefits Schedule so that these tests are routinely available to these patients and reimbursed.

Response:

This recommendation is noted.

The Medical Services Advisory Committee (MSAC) has been working with industry since 2014 to develop streamlined arrangements to assess the clinical utility of germline genetic (or genomic) testing to help manage specific disease areas, such as cancer, cardiovascular disease or mental illness. This approach is to be used to inform consideration of the circumstances under which germline genomic testing for these diseases could be publicly funded. Clinical utility refers to the ability of a test to significantly affect clinical management and patient outcomes. Each assessment covers all elements relevant for assessing risks, benefits and costs of a proposed genomic test.

Genomic testing of the BCRA1 and BRCA2 genes for breast and ovarian cancer, which was listed on the MBS from 1 November 2017, was the first example of such an assessment. Applications for genomic testing for Alport syndrome and childhood syndromes were assessed by MSAC in March 2018 and July 2018 respectively. MSAC supported MBS funding of genetic testing for Alport syndrome. At this point in time, MSAC could not support public funding for childhood syndromes, given the breadth of testing, limited evidence on changes in clinical management, and equity and ethical issues. MSAC is engaging with all relevant stakeholders to develop a way forward. Applications for colorectal and endometrial cancers are currently in the process of being considered by MSAC.

Recommendation 15

5.102 The committee recommends that the Therapeutic Goods Administration, if necessary following the medicines and medical devices review, and the Pharmaceutical Benefits Advisory Committee:

- (re-)examine their assessment processes and the appropriateness of those processes for innovative treatments for low survival rate (LSR) cancers, such as immunotherapies; and
- pending that examination, consider adopting more flexible and innovative approaches to approving innovative treatments for LSR cancers and assessing them for listing on the Pharmaceutical Benefits Scheme.

Response:

This recommendation is supported in principle.

The Australian Government agrees that improving and streamlining existing regulatory and assessment processes for new medicines are key strategies that will offer the best prospects of maintaining Australia's record of supporting timely access to cost-effective cancer medicines that deliver proven health gains. The Government understands that a strong partnership between industry, prescribers and consumers is vital for this process and is actively working with stakeholders in this area.

Each cancer drug is approved for marketing by the Therapeutic Goods Administration (TGA), and thus demonstrated to have acceptable quality, safety and efficacy, in a limited range of cancer settings only. It is possible for sponsors to make submissions to the Pharmaceutical Benefits Advisory Committee (PBAC) requesting the Pharmaceutical Benefits Scheme (PBS) listing of medicines to treat rare conditions or cancers with low survival rates. In such cases, the PBAC can assess the sponsor's claims of the medicine's comparative effectiveness, even in small numbers of patients, and can advise on a range of tools to manage uncertainty such as special pricing and risk sharing arrangements.

There are currently three immunotherapy medicines subsidised on the PBS for five different tumor types: melanoma, kidney cancer, lung cancer, Hodgkin's lymphoma and head and neck cancer. Subsidy has recently been recommended by the PBAC for two further tumor types: Merkel cell cancer and urothelial cancer. The Government will continue to engage constructively with all stakeholders to expand the indications for this important breakthrough in cancer treatment.

In October 2016, the PBAC finalised the revision of its Guidelines to ensure that the Health Technology Assessment (HTA) methodologies used are consistent, transparent and incorporate international best practice. The revision provided an opportunity to address matters such as clinical evidence needs, handling the consequences of allowing cross-over in cancer medicine trials and the use of surrogate outcomes to estimate the overall effectiveness of new medicines. The revised Guidelines have enhanced assessment processes for cancer medicines for timely inclusion on the PBS.

The Australian Government and Medicines Australia signed a Strategic Agreement in April 2017 under which they undertook to work together to improve timeliness, transparency and efficiency in PBS listing processes. This work will assist in improving PBS listing times for innovative cancer medicines recommended by the PBAC.

In response to the recommendations of the Review of Medicines and Medical Device Regulation (MMDR Review) and as part of ongoing business improvements, the TGA has recently delivered several reforms which are likely to contribute to the timely registration of medicines for low survival rate cancers.

On 1 July 2017, the TGA implemented a Priority review pathway for the registration of prescription medicines. The Priority review pathway involves faster assessment of vital and life-saving prescription medicines. The target timeframe of 150 working days is up to three months shorter than the standard prescription medicines registration process which is 220 days. As at 15 October 2018, seventeen prescription medicines have received priority determination since launch of the pathway, of which eleven were for use in oncology.

Changes to the Orphan Drug Program also commenced on 1 July 2017. The Orphan Drug Program provides an incentive to lodge an application for registration of eligible medicines by waiving the associated fees. One of the new eligibility criteria provides

a more generous orphan disease prevalence threshold (fewer than five in 10,000), potentially allowing additional conditions to classify as Orphan on the basis that they are recognised as distinct conditions. Since the change five medicines for use in oncology have been designated as orphan through this scheme.

On 20th March 2018, a provisional registration pathway was implemented to allow sponsors to seek time-limited provisional registration of certain prescription medicines on the basis of preliminary clinical data. This pathway allows medicines to be registered on the Australian Register of Therapeutic Goods (ARTG) up to two years earlier than under the standard prescription medicines registration process but are evaluated under the same milestones and evaluation time as for standard prescription medicines of 220 working days. Provisional registration of prescription medicines is limited to two years but up to two extensions of two years can be applied for by the sponsor resulting in provisional registration for a maximum of six years. As at 15 October 2018, five prescription medicines had received provisional determination since launch of the new pathway, of which five are for use in oncology.

Recommendation 16

5.126 The committee recommends that the Australian government ensures funding is available to researchers investigating whether existing drugs may be suitable for treating low survival rate cancers.

Response:

This recommendation is supported, noting that the Australian Government has a number of existing research funding schemes via the NHMRC, Cancer Australia and the MRFF that provide opportunities for research into repurposed drugs to tackle low survival cancer.

Recommendation 17

5.128 The committee recommends that the Australian government works with industry to consider a mechanism to repurpose drugs.

Response:

This recommendation is supported in principle, noting that through the \$1.3 billion National Health and Medical Industry Growth Plan the Australian Government is seeking to collaborate with industry on a number of fronts, including exploring opportunities to access libraries of drugs for further research.

The TGA does have various mechanisms to encourage sponsors to make timely applications for low survival cancers by making the registration process faster and/or easier such as: the expedited pathways, Orphan drug program, literature based submissions and the Comparable Overseas Regulator report-based process.

However, the TGA is not able to compel a company to apply to register a medicine in Australia, and approval for marketing in Australia cannot be given in the absence of an application. In the past, the TGA has occasionally approached sponsors to request that an application to extend the indications of a registered medicine be lodged with the TGA to address known off-label use. For example, the TGA worked with a sponsor to facilitate an application and subsequently approval of tamoxifen for

primary reduction of breast cancer risk in women who are in the moderate or high risk category.

Recommendation 18

5.131 The committee recommends that the Australian government considers a mechanism to permit access to and properly supervise use of off-label drugs for low survival rate cancer patients without further treatment options, on compassionate grounds.

Response:

This recommendation is noted.

Prescribing a registered medicine for indications other than the approved indications is what is commonly referred to as off-label prescribing. Off-label prescribing is a clinical decision made between the prescriber and their patient based on the risks and benefits of the use of the medicine in those individual circumstances. Off-label use should always occur in the setting of informed consent. TGA does not regulate clinical practice.

In the case of prescribing unapproved medicines, the TGA administers a number of schemes to enable prescribers to access these for their patients. These include the Special Access Scheme and Authorised Prescriber Scheme. Doctors who access unapproved medicines through these pathways must do so in the setting of informed consent and in accordance with the Medical Board of Australia's code of conduct, Good Medical Practice.

Recommendation 19

5.133 The committee recommends that the Therapeutic Goods Administration and Pharmaceutical Benefits Advisory Committee examine the appropriateness of their approval and assessment processes for existing drugs repurposed for use in low survival rate cancers.

Response:

This recommendation is supported.

In 2017, the Minister for Health requested the PBAC Chair to find options within the Committee's scope (as per current legislation) for mechanisms to consider medicines to treat rare conditions. The PBAC Chair is currently progressing this request with the Department and other key stakeholders. As part of this consideration, the committee has requested further work be conducted, and this work is continuing. The advice from the PBAC on this matter will also feed into the broader reforms to PBAC processes being developed with the pharmaceutical industry in response to commitments given in the Australian Government's Strategic Agreement with Medicines Australia.

As noted in the responses to Recommendations 15 and 17 above, the new expedited pathways and Orphan drug program reforms, literature-based submissions and the use of reports from comparable overseas regulators are likely to contribute towards more timely assessment and approval of medicines repurposed for use in low survival rate cancers.

Recommendation 20

5.136 The committee recommends that the Australian government considers whether the Medical Services Advisory Committee and Pharmaceutical Benefits Advisory Committee processes can be streamlined where a diagnostic test and treatment for a low survival rate cancer are co-dependent.

Response:

This recommendation is supported.

The Department, together with MSAC and the PBAC, has developed an assessment process for ensuring integrated and streamlined consideration of co-dependent applications, including where a pathology test and a medicinal treatment are co-dependent. This type of application allows MSAC to consider the test and the PBAC to consider the medicine through a parallel assessment process, to maximise alignment of timelines and outcomes. This uses a time schedule that results in coordinated advice being provided to the Minister for Health by the two committees within three weeks of each other.

Since 2011, about 30 co-dependent technology applications have been assessed through this coordinated assessment approach involving MSAC and the PBAC. In addition, through a coordinated process, the 2016 PBAC Guidelines and 2016 MSAC Investigative Guidelines updated the published guidance on these arrangements. The Department operates in an environment of continuous improvement, and a planned review of the MSAC Guidelines (and associated co-dependent processes) is anticipated to commence in 2019. The emphasis will be on process efficiencies for applicants, and timely access to treatments for Australian patients.

Recommendation 21

5.176 The committee recommends that the Australian government, in conjunction with its state and territory counterparts, works to improve access to specialist cancer care co-ordinators or nurses for low survival rate cancer patients in every state and territory.

Response:

This recommendation is noted.

State and territory governments have primary responsibility for the employment of nurses and care coordinators.

The Australian Government's Integrated Team Care (ITC) program does provide funding for Care Coordinators. Funding is currently being provided through the Northern Territory Primary Health Network to train a number of Care Coordinators in the Northern Territory in cancer care. The ITC program, funded under the Indigenous Australians' Health Program, aims to improve access to coordinated and multidisciplinary care for eligible Aboriginal and Torres Strait Islander people with chronic disease, including cancer.

Recommendation 22

5.179 The committee recommends that the Australian government asks the

Medical Services Advisory Committee to review the criteria for reimbursement of ongoing diagnostic testing for low survival rate cancer patients.

Response:

This recommendation is noted.

The MSAC considers applications for public funding of medical services, including ongoing diagnostic tests such as magnetic resonance imaging (MRI) and genomic testing. Applications are currently being assessed for MRI for the diagnosis of prostate cancer, colorectal cancer and breast cancer. An application is currently in process using MSAC's Clinical Utility Card Proforma for genomic testing in the context of colorectal cancer and endometrial cancer.

Recommendation 23

5.181 The committee recommends that the Australian government further simplifies and streamlines the application process for low survival rate cancer patients and their carers when seeking to access the Disability Support Pension, or carer allowance or payment.

Response:

This recommendation is noted.

The Australian Government considers the current Disability Support Pension (DSP) application process for people with low survival rate cancers is already sufficiently streamlined. Similarly, the current application process for carer payments (Carer Payment and Carer Allowance) provides an abridged and more simplified process for those who are caring for someone with a terminal illness.

In certain circumstances a claim for DSP can be granted manifestly. This means that on the basis of medical evidence alone the person is considered eligible for DSP without the need for a Job Capacity Assessment (JCA) or a Disability Medical Assessment, subject to meeting all other eligibility criteria. Of particular relevance for people with cancer, DSP may be granted manifestly where a person has a terminal illness with a life expectancy of less than two years or a condition requiring a nursing home level of care. Manifest qualification is accepted if medical evidence indicates the claimant's current medical condition is chronic and debilitating with a prognosis that the condition is terminal, the average life expectancy of a patient with this condition is 24 months or less, and there is a significant reduction in work capacity within this period.

A claimant who has evidence that they are a long term patient of a hospital or nursing home, or require nursing home level care (or equivalent) because of illness or infirmity and are unlikely to be discharged in the foreseeable future, is accepted as manifestly qualified for DSP. The medical evidence needs to provide details of: the nature of the impairment and reason for long term hospitalisation; the likelihood of discharge; and ability to perform activities of daily living.

Two lists of conditions are available in the *Guide to Social Security Law* to help Centrelink decision makers determine manifest eligibility for DSP on the grounds of terminal illness, nursing home level care requirements, and/or intellectual disability. It is important to note that the lists supplement, rather than replace manifest guidelines. Therefore manifest grants can still be made for claimants with conditions that are not

listed, that is any condition, including cancer, that meets the terminal illness or people requiring a nursing home level of care categories detailed above.

List 1 catalogues conditions which are accepted as manifest (clearly and obviously meet all the DSP qualification criteria) on diagnosis alone. If the condition listed in the DSP claimant's medical evidence is on this list eligibility will be established without the need for a JCA allowing more timely granting of payment.

The second list of conditions includes those which may upon some further investigation, be manifest on the grounds of terminal illness, nursing home level care requirements, or intellectual disability. The Centrelink decision maker will obtain on the spot advice about the condition, treatment regime and likely prognosis by contacting the treating doctor and/or the Centrelink Health Professional Advisory Unit (HPAU). The treating doctor or the HPAU may be able to confirm the expected prognosis, including whether terminal, or would necessitate nursing home level care, or indicates a manifest intellectual disability, and thereby expedite the claim as manifest without a JCA.

To receive **Carer Payment and/or Carer Allowance**, carers of an adult (over 16 years) are assessed under the Adult Disability Assessment Tool (ADAT), while carers of children (under 16 years) have their care assessed under the Disability Care Load Assessment (DCLA). Both tools contain provisions that streamline the claim process for carers of an adult or child who has a terminal illness, although the provisions differ between adult and child qualification. As the payments target assistance to carers it is necessary to establish the level of care provided to determine payment qualification, and the questions on the claim forms are designed to assess care provision across a broad range of medical conditions and disabilities, including those with a terminal illness such as cancer.

For carers of an adult where the treating health professional indicates the care receiver is in the final stage of a terminal illness and is not expected to survive for more than 3 months, the medical component of the Carer Payment or Carer Allowance claim form is significantly abridged. The carer is required to complete the carer questionnaire to determine that a qualifying level of care is being provided.

Qualification for Carer Allowance for a child diagnosed with a terminal condition may be fast tracked through the *List of Recognised Disabilities* – a List that includes certain disabilities or conditions that are consistently severe enough to qualify the parent or carer for the allowance automatically. If the child's disability or condition is not on the List the DCLA is used to determine payment eligibility, and the carer must complete the care needs assessment form to establish qualification.

An abridged process exists for carers of a child with a terminal condition when claiming Carer Payment. If the medical practitioner certifies that the average life expectancy for a child with the same or similar condition is not substantially longer than 24 months, and the child will need personal care for a significant period every day for the duration of the condition, the carer qualifies for payment without completing the care needs assessment form. Carer Allowance is also automatically granted. These terminal child provisions also allow the carer to remain qualified for payment until the child turns 18, rather than having to apply for Carer Payment and/or Carer Allowance under the adult assessment process.'

Recommendation 24

5.223 The committee recommends that the federal, state and territory governments develop and implement a comprehensive Australia-wide strategy to increase 5-year survival rates for low survival rate cancers to above 50 per cent by 2027:

- taking into account the recommendations in this report;
- consulting with researchers, clinicians, patients and patient groups;
- considering the roles of research, early diagnosis and access to medicines; and
- assessing the applicability of international approaches, such as the *Recalcitrant Cancer Research Act of 2012 (US)*, to the Australian context.

Recommendation 25

5.225 The committee recommends that annual progress reports on the development and implementation of an Australian strategy to improve survival rates for low survival rate cancers are provided to the Council of Australian Governments Health Council and made publicly available.

Response:

Recommendation 24 and 25 are noted.

The Minister for Health will continue to work collaboratively and productively with jurisdictions via the COAG Health Council on the range of initiatives important to the sector and to improve health outcomes for all Australians.