

National Haemopoietic Progenitor Cell (HPC) Framework

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Introduction

Purpose

The National Haemopoietic Progenitor Cell (HPC) Framework (the Framework) aims to guide the effective, evidence-based future operations and management of the Australian HPC sector.

The Framework is the response of all Australian governments to the PricewaterhouseCoopers (PwC) Report: Review of the HPC Sector (the Report). It seeks to:

- acknowledge the role of the Australian HPC sector in providing life-extending and life-saving treatments to Australian and international patients
- support better coordination and consistency of action across the sector
- strengthen governance arrangements
- complement and accommodate relevant state-based, national and international policies
- flexibly accommodate future and emerging priorities and innovation.

The Framework:

- is patient-focused
- takes into account changing clinical evidence
- reflects the evolving nature of the HPC sector.

The Framework is focused on national activities to support those patients who need allogeneic HPC transplants. Currently, patients undergoing an HPC transplant fall into one of three categories:

- Allogeneic-related transplant: using the stem cells of a matched related donor – often a sibling – to give a patient a new blood-forming system.
- Allogeneic-unrelated transplant: using the stem cells of an unrelated donor.
- Autologous transplant: a patient's own stem cells are collected before treatment and the returned to the patient to re-establish their blood-forming system.

The patient's condition determines which category is relevant to their treatment. For allogeneic transplant patients, the source of HPCs will be primarily determined by the closeness of the donor match, identified through tissue typing. If a patient does not have a suitably matched relative who is willing to act as a donor, the treating transplant centre will initiate a search of the registry for a match to use in an allogeneic-unrelated transplant. The match will look at the compatibility of tissue typing between patient and volunteer donors.

PricewaterhouseCoopers Report: Review of the HPC Sector

The Report was commissioned by all governments and completed in January 2018. The Review considered whether the Australian HPC sector was efficiently, effectively and appropriately structured to meet future needs.

The Review highlighted a range of structural, funding and governance issues across the HPC sector, further impacted by an ever-changing clinical environment, and provided options for future improvements to the HPC sector.

Key Findings of the Report

Key findings identified in the Report include:

1. Governance of the HPC sector is fragmented, with responsibilities spread across many different organisations.
2. Currently, Australian HPC donors are sourced from the wider pool of blood donors, but there is a paucity of individuals recruited from this pool who may fulfil the optimal clinical criteria to become an HPC donor, on the basis of their demographics, sex and age.
3. The current size of the bone marrow registry aligns with contemporary domestic needs. However, due to the diversifying profiles of potential recipients and available local donors, Australia is increasingly relying on international donors to support its HPC needs.
4. Reporting of recruitment and tissue typing activities (for example, number of searches and newly recruited donors) is not required under current arrangements.
5. At the time of the Report the resolution of initial tissue typing of donors was different around the country and had been mostly low resolution, which did not provide clinicians with upfront information required to inform decision-making. *(Note: Since the Report, all Australian tissue typing laboratories have implemented high resolution platforms providing more accurate and comprehensive information, improving initial matching possibilities with recently recruited donors.)*
6. Improvements are required in the marketing approach and communication with donors to promote their engagement.
7. Current reporting arrangements do not promote the comprehensive data capture required to inform business analytics and enable strategy development, monitoring and implementation.
8. The primary funding agreements do not include objectives, activities and milestones that reflect future needs or strategic goals of the HPC sector. *(Note: recent agreements include improved reporting.)*
9. Corporate knowledge and understanding of the sector and the operation of the Australian Bone Marrow Donor Register (ABMDR) is concentrated in a few key staff, which exposes the sector to operational risks if that knowledge is lost.
10. The sector is costly, with investment from both Commonwealth and state and territory governments.

Government response

As an initial step, the Review outlined that governments should develop an intergovernmental position, which considers the strategic objectives for the HPC sector for the next five to ten years. To address this, and the issues identified in the Report, the Jurisdictional HPC Committee (JHPCC) agreed that this Framework be developed to provide the policy basis for robust decision-making and future arrangements to ensure continued and improved access to HPC transplants for Australian patients.

Following the finalisation of the Report and taking into account its findings, the Commonwealth entered into transitional contractual arrangements with the ABMDR, ending on 30 June 2022, to maintain the Australian donor registry and undertake search activity of international registries. In addition, all Australian governments agreed to pause collection of Cord Blood Units (CBUs) from 1 July 2020 until 30 June 2022 while continuing to maintain funding for CBU storage and release. The funding used for collection has been redirected to activities supporting future HPC sector sustainability.

Scope of the Framework

This Framework describes policy principles and actions relating to publicly-funded allogeneic HPC donation for transplantation programs designed to address the findings of the PwC Review, and the ongoing changes occurring in the sector. The principles extend to governance and oversight, funding and sustainability, donor registration and retention, collection, searching and matching, and ethics and research. The HPC sector is taken to refer to organisations, staff and participants across the breadth of these activities.

While the Framework may be applicable to both allogeneic and autologous HPC donation for transplantation, the scope of the Framework is limited to allogeneic HPC donation services and in particular unrelated donor transplants. The system of registration, domestic donation and overseas sourcing of HPCs exists to support unrelated donor transplantation, which accounts for 18.7 per cent of all HPC transplants.¹

The approach outlined in the Framework, including the implications for risk management, governance and operation of the sector, also considers any impacts of the COVID-19 pandemic. Implementation will reflect any changes needed through inter-jurisdictional liaison. The Framework also reflects some first steps towards sector improvement as agreed by all governments during 2020.

Audience

This document is intended to provide the Australian HPC sector, professional associations, health service providers, and the community with a clear framework within which the sector will operate to support patient access to donated HPCs.

Acknowledgements

This Framework is a result of collaboration under the oversight of the JHPCC, which was established to oversee the implementation of the Report, and provide advice on development of this Framework. Membership comprises a Commonwealth Chair and members from each state and territory health department, as well as a representative from the Therapeutic Goods Administration (TGA).

Key stakeholders from a range of organisations within the HPC sector and health system also provided valuable input that supported the development of this Framework, including through targeted consultation in April/May 2020.

¹ Sourced from ABMTRR Annual Data Summary 2019. The activity and outcome data for this report are based on information received by the ABMTRR as at October 2020, noting this excludes patients who had not provided consent for data collection.

Strategic Context

Current Arrangements

HPCs, or stem cells, are used for life-saving transplants for many Australian patients suffering from certain haematological malignancies (such as leukaemias), bone marrow failure syndromes and genetic abnormalities. In Australia, the use of HPCs for life-saving transplantation has been increasing over time, with most HPC transplants sourced from the patient undergoing the transplant (autologous) or a related donor (allogenic).

Bone marrow donor registries in Australia and overseas recruit, register and search for unrelated HPC donors. This type of allogenic transplant accounted for 18.7 per cent of HPC transplants in 2019 of which 80.8 per cent were sourced from overseas.²

In Australia, the ABMDR manages the national registry and is responsible for these activities, on behalf of all governments. Under the Haemopoietic Progenitor Cell Program, the Australian Government currently provides funds to the ABMDR for its services, including maintaining the Australian registry of potential HPC donors. The ABMDR also conducts searches of the international registries for compatible donors, where a domestic donor is not available, through the Commonwealth funded International Search Program (ISP).

Integral to the Australian HPC sector are HPC transplant centres and pathology services. Transplant centres are located in major hospitals throughout Australia and facilitate transplants by working closely with the ABMDR and tissue typing laboratories. Australian Red Cross Lifeblood (Lifeblood), Pathology Queensland and PathWest provide key specialised tissue typing and pathology services in support of donor recruitment and pre-transplantation verification testing and maintain close relationships with transplant centres in their respective jurisdictions.

All Australian governments also provide funding to the ABMDR to distribute to cord blood banks (cost-shared by all jurisdictions in accordance with the previous Australian Health Ministers' Advisory Council cost-share formula). Cord blood banks collect and store CBUs, which are another source of HPCs.

If a compatible donor is found overseas, patients may be eligible for financial assistance under the Bone Marrow Transplant Program (BMTP) to cover the costs of collecting and transporting HPCs from an unrelated person overseas, or to cover the costs for a relative to come to Australia for the purpose of donation. The BMTP is funded by the Australian Government and administered by the Commonwealth Department of Health and is intended to cover relevant costs. Funding for the BMTP has been increasing since 2013-14 as the number of international donors has increased.

Funding for these programs is detailed in Table 1 below. It shows increasing costs over time and significant funding of cord blood collection and storage.

Table 1 – Public expenditure for HPC sector 2017-18 to 2021-22 (GST exc)

Activity	2016-17 \$'000 (actual)	2017-18 \$'000 (actual)	2018-19 \$'000 (actual)	2019-20 \$'000 (actual)	2020-21 \$'000 (estimate)	2021-22 \$'000 (estimate)
ABMDR – ISP	1,784	1,893	2,034	2,267	2,357	2,395

² Sourced from ABMTRR Annual Data Summary 2019

Activity	2016-17 \$'000 (actual)	2017-18 \$'000 (actual)	2018-19 \$'000 (actual)	2019-20 \$'000 (actual)	2020-21 \$'000 (estimate)	2021-22 \$'000 (estimate)
ABMDR – operations Commonwealth funded	1,041	1,062	1,083	1,105	1,127	1,145
ABMDR – cost shared projects					4,962	5,042
BMTP	8,713	9,753	11,663	12,144	14,574	16,533
Cord blood banks – Commonwealth	4,699	4,775	4,807	4,884	2,400	2,400
Cord blood banks – States and Territories	4,699	4,775	4,807	4,884	2,400	2,400
Total	20,936	22,258	23,920	25,664	27,820	29,915

State based legislation

States and territories provide the legislative framework for the Australian HPC sector through their Human Tissue Acts or equivalent. This legislation provides for the consensual donation of blood, tissue and organs for transplantation and for scientific, therapeutic or medical purposes.

Australian Bone Marrow Donor Registry

The ABMDR has operated since 1991 as Australia’s only World Marrow Donor Association accredited stem cell donor registry, providing unrelated donors for patients requiring HPC transplantation. It has done so in collaboration with international registries, building strong links to ensure Australian patients have access to the best donor match for their treatment.

The Report found that clinicians prefer to rely on a HPC transplant from a patient’s genetically matched relative. However, where this is not possible, a patient must rely on an unrelated donor.

As a measure of success, evidence shows that very few patients do not find a match. However, many patients may find a less desirable donor (for example, a mismatched donor) or need to rely on an international donor who is a better match than an Australian donor. In some cases, a clinician may pursue an alternative treatment pathway altogether. The ABMDR is supported by public hospital-based transplant centres, Lifeblood and pathology laboratories.

Australasian Bone Marrow Transplant Recipient Registry

The Australasian Bone Marrow Transplant Recipient Registry (ABMTRR) was established in 1992. Operating under the auspices of the Australia New Zealand Transplant and Cellular

Therapy Society,³ it records details of bone marrow, peripheral blood and cord blood HPC transplants throughout Australia and New Zealand. As well as an Annual Data Summary, the ABMTRR provides data for research projects and ad hoc requests from clinicians, researchers and government officials. The ABMTRR is funded by all governments through a contract between ABMDR and St Vincent’s Hospital.

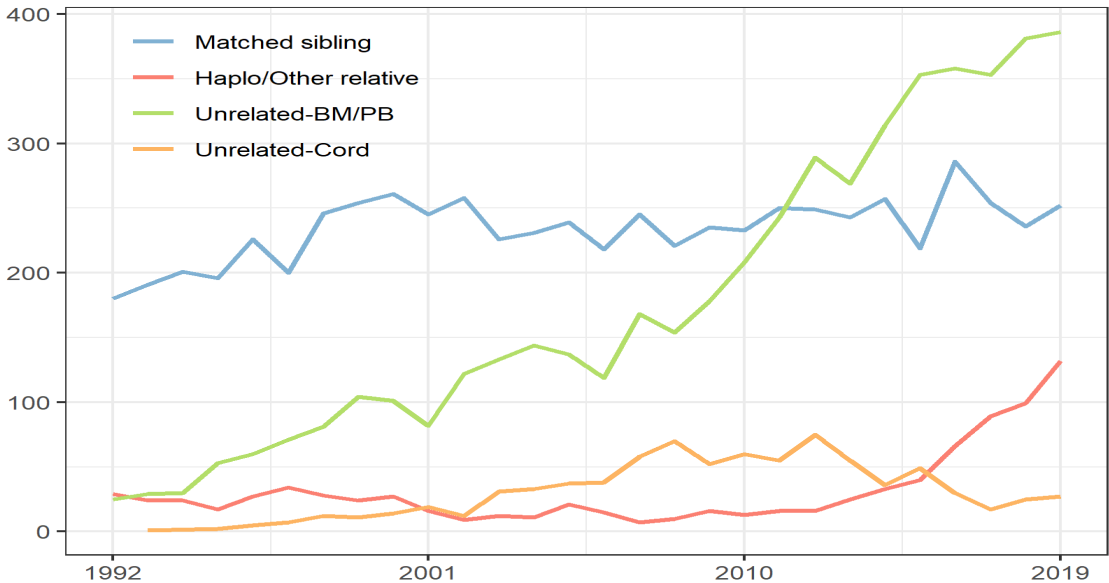
Changes in HPC supply and demand

There have been significant changes in the clinical application of HPC transplants, the diversity and clinical profile of recipients, and subsequent recruitment criteria, and a large increase in the number of transplants occurring over the last 25 years. It is timely to reconsider Government-funded HPC sector programs, structure and funding to adjust to these changes.

Demand for transplants continues to increase with search activity increasing by almost 400 per cent in recent decades, from 237 in 1996-97 to over 900 in 2019-20. In 2019, 691 allogeneic HPC transplants were undertaken in Australia, accounting for 36 per cent of HPC transplants, with the remainder using autologous HPCs.⁴

Further, the proportion of transplants from different sources has changed over time (Figure 1). Matched sibling rates have remained relatively static and unrelated cord use has declined. While other relatives as a source have increased slightly, unrelated bone marrow and peripheral blood have had a strong upward trajectory.

Figure 1 – 2019 ABMTRR Data Summary – Donor source for allogeneic transplants⁵



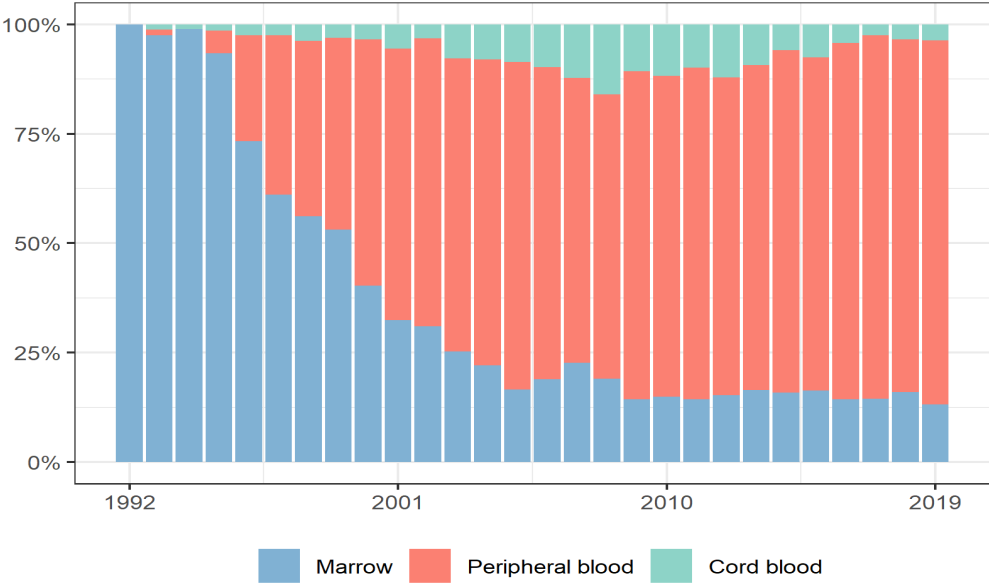
The HPC source preferred by clinicians is also changing. The vast majority (approximately 80 per cent) of HPCs are now collected from peripheral blood collected via a blood withdrawal from a donor. The number of HPC transplants using bone marrow and CBUs has been declining over the past few years. This is shown in Figure 2 below.

³ Note: The Australia New Zealand Transplant and Cellular Therapy Society was formerly known as the Bone Marrow Transplant Society of Australia and New Zealand

⁴ Sourced from ABMTRR Annual Data Summary 2019

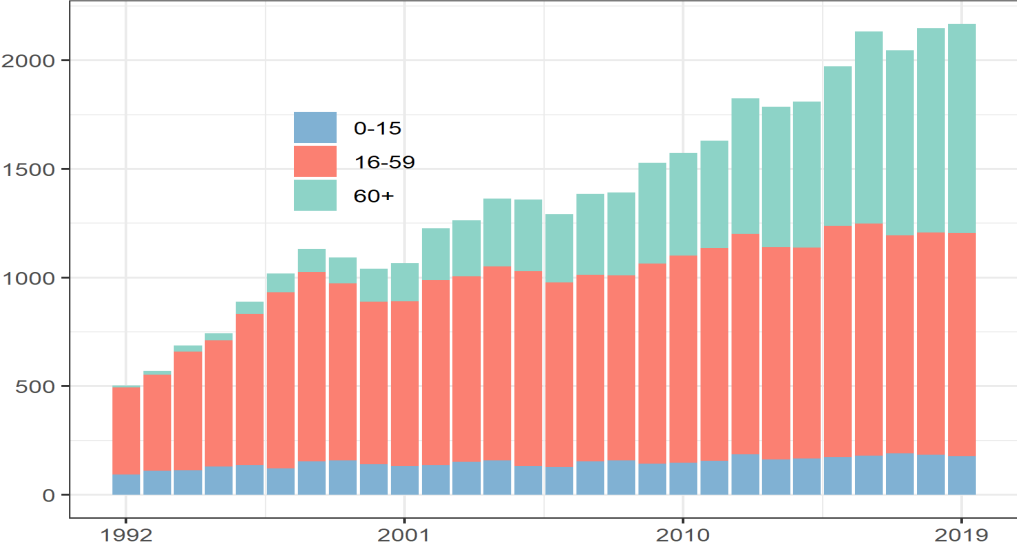
⁵ ABMTRR Annual Data Summary 2019, page 5

Figure 2 – HPC source for allogeneic transplants⁶



Demand for unrelated HPCs is growing as clinical indications increase, family sizes decrease, and the ageing population combined with clinical advances means that older patients are increasingly being treated through transplantation. These drivers have increased demand for volunteer donors. This change is shown in Figure 3 below.

Figure 3 – 2019 ABMTRR Data Summary – Transplant activity by age group⁷



The Australian HPC donor registry has a donor profile which does not match the Australian population. The HPC sector has traditionally relied on Lifeblood, which recruits blood donors, to also recruit donors to the ABMDR. Registered donors from this source have predominantly been middle-aged, female and of North West European background (60 per cent of ethnic distribution). Further, the Report found donors on the Australian registry have historically been tissue typed to a lower level than is required for clinical decisions about matching

⁶ ABMTRR Annual Data Summary 2019, page 3

⁷ ABMTRR Annual Data Summary 2019, page 5

patients. Although all Australian tissue typing laboratories now provide high resolution results for new donors, poor quality data remains an issue for the existing Australian donor pool, with data elements missing for many registered donors. There will therefore be an increasing reliance on international registries, which provide ethnic diversity and greater quality data, until such time as the Australian registry recruits enough ethnically diverse donors that are high-resolution typed to refresh the Australian donor pool. This reliance results in a corresponding increase in Australian government expenditure on international searches and financial assistance provided under the BMTP.

While blood donors are an important and committed cohort, many of the characteristics of these donors do not align with the clinical needs of HPC recipients unless donor recruitment is targeted to the ideal donor cohort. The ideal donor pool is made up of young ethnically diverse male donors (aged 18 to 35 years). Globally, donors in this age group have increased while the Australian donor pool in this age group is less than 30 per cent, with males in this age group making up only 10 per cent of the donor pool.⁸

The World Health Organization states that 'For patients without a family donor, unrelated donor registries have been set up to find a tissue type match but the chances are small e.g. one out of 500,000 individuals and many volunteers are necessary from all ethnic backgrounds in order to maximise the chance of meeting needs'.⁹

Cord Blood Banks

Since 2001, all governments have funded cord blood banks to undertake the collection, banking, storing, searching and supply of CBUs for Australian patients requiring HPC transplantation.¹⁰ Due to low usage, government funding for collection and banking of CBUs is currently paused for two years until June 2022.

Funding for the cord blood banks is managed by the ABMDR. The cord blood banks are also part of a worldwide donor pool which has access to a global inventory of CBUs. ABMDR receives export revenue from cord blood export fees received from international donor registries, less costs incurred in this activity, to improve cord blood banks' operations. The cord blood banks aim to maintain a high-quality, coordinated, collaborative, cost-effective network through:

- maintaining information required for the national registry to provide suitable matched unrelated cord blood to patients requiring HPC transplantation through collection, storage and release of CBUs
- funding three cord blood banks located in Brisbane, Sydney and Melbourne
- facilitating international access to CBUs to meet Australia's needs
- collecting and reporting the details of HPC transplants.

The operation of the cord blood banks has been reviewed several times since 2001, with the most recent review completed in September 2016. The Review of the HPC Sector considered the findings of that review, including that the current usage pattern of CBUs both in Australia and internationally shows a significant decrease in demand. It is clear that CBU transplantation is not a usual treatment option, but it remains a treatment option for a small number of patients suffering from certain diseases and genetic disorders.

⁸ Communication with ABMDR

⁹ [World Health Organization 'Haematopoietic Stem Cell Transplantation'](#)

¹⁰ The operation of privately funded cord blood banks is outside the remit of this Framework.

In line with global trends, the use of CBUs in Australia for HPC transplants continues to decline. In 2020, a total of 20 CBUs were transplanted to Australian patients; this included 16 from international sources and only eight locally-sourced CBUs.¹¹

Funding

Around \$50 million (using 2014-15 estimate) is spent on clinical HPC transplant activity each year (excluding readmission costs).¹² The cost of recruiting donors, tissue typing (initial and verification), maintaining the ABMDR, ISP, funding to cord blood banks and funding the BMTP was a further \$25 million in 2019-20.

The Report suggests that the increasing costs of accessing suitable donors means that funding appears to be insufficient for the ABMDR to fulfil its functions to maintain and manage the registry.¹³ Funding levels for the ABMDR's activities have been constant since 2007-08, with sector structures remaining largely unchanged since the commencement of the ABMDR in 1991 and government funding for the cord blood banks in 2001. ABMDR services and related programs (BMTP and ISP) are wholly Commonwealth funded (see Table 1 above).

The 2020-2022 funding arrangement redirects cord blood collection funding to ABMDR operating costs and special projects to improve HPC sector sustainability and COVID-19 response measures. The heavy reliance on internationally sourced HPCs has driven steady increases in Commonwealth funded HPC programs, including the BMTP and ISP.

¹¹ Communication with ABMDR, note some patients require two CBUs for transplantation.

¹² PwC Report vi – sourced from Independent Hospital Pricing Authority (IHPA)

¹³ Review of HPC Sector 2017, page vi

Future Arrangements

The PwC Review identified five options for future improvements to the HPC sector:

- Maintain the status quo in the HPC sector – PwC’s assessment did not favour Option A because it provides no improvements to the challenges identified in the sector and does not address the growing reliance on international donors, which increases costs and means the sector would not meet its goal of self-sufficiency.
- Improve tissue typing of donors by batching them for high-resolution typing at a single supplier or through demand hubs.
- Builds on Option B plus improved donor recruitment activities such as targeted recruitment and centralised donor coordination, with searching and matching arrangements aligned to tissue typing arrangements.
- Builds on Option C plus an overhaul of governance and service delivery arrangements, with one entity or body having full responsibility for directing and managing arrangements for donor recruitment and coordination, tissue typing, searching and matching in line with a nationally agreed strategy.
- Builds on Option D plus a central model for all elements of service delivery, including batching tissue typing, searching and matching, and recruiting to significantly expand the registry to meet domestic and international needs.

All governments have agreed that no option in its entirety is suitable for immediate implementation. Option D plus some enhancements maintains the status quo for some elements and is the preferred model. This is the basis of this Framework. Based on Option D, the Framework includes enhancements to improve the governance arrangements while retaining the operational aspects of the sector that are working well. Broadly this will capture:

- changes to both oversight and strategic direction provided by governments
- strengthened governance arrangements that clearly delineate roles and responsibilities for a national body, inter-jurisdictional governance committee, and the registry manager
- current activities with improvements to donor tissue typing, recruitment and coordination
- giving the registry manager further responsibilities for implementing some improvements through clearer contractual arrangements, key performance indicators and reporting.

Implementation will enhance the overarching and strategic governance arrangements, support the identification and implementation of donor focused priorities (such as high resolution tissue typing and recruitment) and establish suitable financial mechanisms for the sector. As previously noted, since the PwC review the five tissue typing laboratories across Australia have introduced higher resolution typing. Any future improvement strategies to HPC tissue typing arrangements must be considered in the context that tissue typing laboratories will still be required to support solid organ donation and transplantation and consider the impact of changes on the efficiency of affected laboratories.

It is acknowledged that a transitional period may be required to effectively and carefully deliver on agreed objectives. Once new arrangements are established, focus could then shift to improving efficiency and effectiveness. The balance of this document sets out a National Framework for the HPC sector that meets agreed objectives and addresses shortcomings identified in the review of cord blood arrangements and the HPC review.

The National HPC Framework

Long-term Strategic Objectives

The Framework has five Strategic Objectives:

1. Facilitate safe, standardised, high quality clinical HPC services for all Australians.
2. Facilitate equitable access to life-saving HPC transplantation for all Australian patients, ensuring the needs of vulnerable groups are met.
3. Ensure HPCs are supplied through efficient, effective, appropriate service delivery and that the supply addresses clinical and patient needs.
4. Reduce reliance on internationally-sourced HPCs for transplantation through improvements to tissue typing and improved donor recruitment that is evidence-based (i.e. based on true clinical demand with consideration of emerging trends).
5. Enable appropriate development and implementation of national and state and territory strategies to support governance and operations that enhance coordination across the sector.

Stakeholders

All stakeholders have shared responsibility for health outcomes through their role and contribution within the health care system. Greater cooperation between stakeholders will support the achievement of better outcomes for Australian patients.

The effective operation of the Australian HPC sector is strongly influenced by the contributions made by a wide range of stakeholders, including:

- the Australian community, including donors, recipients and their families
- peak bodies and support organisations
- the public and private health sectors, including all end-user clinicians
- all levels of Australian government including regulators
- the ABMDR
- ABMTRR
- Australian Red Cross Lifeblood
- AusCord, including all Australian cord blood banks¹⁴
- Pathology Queensland
- PathWest
- professional representative associations
- researchers and academics.

¹⁴ AusCord is the Australian National Network of Umbilical Cord Blood Banks and Cord Blood Collection Centres.

National Policy Statements

PwC, in undertaking the Report, recommended as an initial step that all governments develop an intergovernmental position which considers the strategic objectives for the HPC sector for the next five to ten years.

To address this recommendation, all Australian governments have agreed National Policy Statements for the following focus areas, in line with the key findings of the report:

1. Future governance arrangements
2. Sustainability and self-sufficiency
3. Donor demand, recruitment and retention
4. Donor pathways and coordination
5. Stakeholder engagement
6. Funding arrangements
7. Data and reporting
8. Ethics and research.

1. Future governance arrangements

The PwC Report found that governance and oversight of the HPC sector was fragmented and responsibilities are spread across many different organisations.

All governments agree with the Report's finding that governance and oversight of the Australian HPC sector should be centralised and managed on behalf of all governments by a National Entity, in partnership with key stakeholders. The National Blood Authority (NBA) is the most appropriate body to assume the role of the National Entity, subject to agreement by all governments. The NBA's functions as outlined in legislation¹⁵ and the National Blood Agreement¹⁶ include management of blood and blood related products or services.

Further, the key government decision-making for the sector will be provided through a high-level governance committee comprising officials from all Australian governments, to report to Health Ministers. The National Entity would attend meetings as an observer, and could bring forward issues for the committee's consideration. The governance committee would provide advice to Health Ministers on HPC matters, and consider and resolve issues as authorised.

This will enhance existing overarching and strategic governance arrangements, allow for identification and consistent implementation of priorities (such as high-resolution tissue typing and recruitment), and allow sector resourcing to be focused appropriately.

The National Entity will operationalise the National HPC Framework to deliver on the agreed objectives on behalf of all governments. In meeting this purpose, the National Entity will:

provide a national system of governance, oversight and coordination for the Australian HPC sector

promote national alignment of state-based policies and protocols with regard to HPC donation and transplantation

promote compliance with national and international obligations, accreditation and standards

¹⁵ [National Blood Authority Act 2003](#)

¹⁶ [National Blood Agreement](#)

ensure best practice based on a contemporary evidence base

support ethical, consistent, coordinated and appropriate donor recruitment pathways

promote continued public support and confidence in the Australian HPC sector.

Under the direction of the National Entity, a registry manager will be responsible for delivering on set objectives, with clear key performance indicators, and will have a key role in advising the National Entity on recruitment, retention and donation objectives and activities.

Following establishment of revised of governance arrangements, governments should review these arrangements after three years to determine if further changes are required to the operation of the sector.

2. Sustainability and self-sufficiency

All Australian governments agree that the Australian HPC sector should aim to be sustainable and self-sufficient, where possible. Self-sufficiency means that Australia is able to largely meet its own needs for HPCs, with international sourcing of unrelated allogeneic HPC material to be less than the current 81 per cent.¹⁷ It is important to recognise that full self-sufficiency is highly unlikely to be attainable, and there will always be some reliance on the international donor pool.

Australia aims to be self-sufficient, where possible, through the use of HPCs, donated by Australians, to support safe, ethical, sustainable and cost-effective treatments for Australian patients. However, all governments acknowledge that importation of appropriately-sourced HPCs may be required for the treatment of some Australian patients when an appropriate match cannot be located in the domestic registry.

Australia has an ethical responsibility to strive to meet the population's need for human tissues, including HPCs, using its own resources. Achieving self-sufficiency is desirable for a number of reasons, including:

- improving the ability of the sector to meet the needs of the community in an equitable and timely manner
- ensuring resources are ethically obtained and are of reliable quality and safety
- decreasing the need to rely on the importation of HPCs
- decreasing the risk of exposure to global unplanned shifts in supply or demand for tissues and tissue products
- decreasing the risk of placing the burden of donation on other populations that may lack equitable access to the benefits of HPC transplantation.

Australia's current dependence on imported supply of HPCs was evident during the COVID-19 pandemic, with supply chain issues for imported HPCs creating increased risk for Australian patients during this period.

The reliance on internationally-sourced HPCs should be monitored and reviewed over time to inform contemporary recruitment and retention strategies for the domestic registry. Any importation and exportation activity should occur in accordance with Australia's international obligations and standards, national ethical frameworks and national and jurisdictional legislative requirements.

¹⁷ Sourced from ABMTRR Annual Data Summary 2019

3. Donor demand, recruitment and retention

Demand for unrelated HPCs for transplantation is growing. The majority (approximately 80 per cent) of HPCs are now collected from peripheral blood apheresis. The use of CBUs for HPC transplants also continues to decline, with only 20 used for Australian patients in 2020, and only eight of these obtained from locally-sourced donations.¹⁸

The PwC Report found improvement in marketing and communication with donors is needed to promote their engagement. The Report also found that the current national recruitment approach which mostly relies on blood donors additionally volunteering to become an HPC donor is mismatched to clinical need in respect of donor demographics, age and sex, as blood donor demographics do not necessarily fit the profile of donors preferred by clinicians to achieve the most optimal transplant outcomes. Since the Report was delivered, jurisdictions have had the opportunity to work with Lifeblood to target ideal HPC donors, with some very good results where this has occurred.

The Report also stated that the current size of the registry aligns with domestic needs. However, given the diverse ancestry of Australia's population and the diminishing return on increased matching, donor recruitment needs to be more targeted to increase diversity in the future as the current profile of donors is not anticipated to be universally aligned with the future clinical need.

All governments agree that recruitment, education and retention strategies should reflect contemporary clinical trends and demand, and should seek to actively engage ideal donors (young, male and ethnically diverse) to best meet the needs of Australian patients and reduce reliance on internationally sourced HPCs. This should include changing the approach for engaging donors, to include active targeted recruitment for ideal donors in addition to the largely passive recruitment through Lifeblood.

Further, all governments agree that public funding for the collection of CBUs should be paused over a two year period from 2020-2022, with current cost-shared investments and effort refocused to improve the broader domestic registry. During this period, there should be consideration of the value of any further CBU collection.

In 2021, PwC was engaged to conduct a review on current international best practice in HPC donor recruitment and retention. It is expected this review will inform future approaches to HPC donation that are likely to be suitable in the Australian context.

¹⁸, Communication with ABMDR

4. Donor pathways and coordination

The PwC Report found that the resolution of initial tissue typing of donors is different across Australia, and when the report was prepared was mostly of low resolution, meaning clinicians did not have clinically precise upfront information to inform decision making. Although all Australian tissue typing laboratories now provide high resolution results for new donors, poor quality data remains an issue for the Australian donor pool, with data elements missing for many registered donors.

The patient's condition determines which transplant pathways are relevant to their treatment. As such improving the available donor data will support clinicians to make the best clinical decision for their patients.

All governments agree that operational arrangements for donor searching and matching should continue, with local linkages between transplant centres, tissue typing and coordination. Objectives relating to searching and matching should be set by the National Entity to ensure national consistency and compliance with international best practice.

All governments agree that improvements should be made to guidance on appropriate resolution for initial donor work-up and extended-tissue typing. This guidance should be based on international best practice and contemporary clinical need, comply with Australian regulatory requirements and regularly reviewed through robust clinical governance and reporting arrangements.

The quality, safety and efficacy of directed, minimally manipulated HPCs is provided by the National Pathology Accreditation Advisory Council, including through its Requirements for procedures related to the collection, processing, storage and issue of human haemopoietic progenitor cells and accreditation of facilities by the National Association of Testing Authorities. The safety of CBUs banked in Australia is regulated by the TGA according to the Therapeutic Goods Act 1989.

5. Stakeholder engagement

All Australian governments recognise that engagement between all HPC sector stakeholders, including consumers, is vital to the ongoing sustainability of the sector, and to ensure that Australians have access to clinically-appropriate high quality HPC treatment options.

Strong stakeholder engagement is essential to informing evidence-based policy and the efficient and effective delivery of HPC services. All governments agree that the following guiding principles should underpin stakeholder engagement for the HPC sector:

- engagement with stakeholders, including the Australian community, is nationally coordinated, clear and consistent to inform the operations of the Australian HPC sector
- professional associations, where appropriate, are actively engaged in sector organisation, development and innovation through recognised governance, accreditation and oversight arrangements
- development of clinical standards is undertaken in a collaborative and inclusive manner within nationally agreed structures and frameworks.

In order to facilitate constructive stakeholder engagement within the sector, the National Entity should develop and implement a stakeholder engagement strategy. This should include engagement between governments, regulators, the National Entity, the registry manager, the HPC sector and end-users: the Australian community, including donors, recipients and their families.

The National Entity should also develop appropriate clinical feedback loops through improved clinical governance and engagement with end-users to inform donor recruitment activity.

6. HPC sector funding

The PwC Report found that the HPC sector is costly per HPC transplant provided. Total government spending for donation, registry, tissue typing and overseas sourcing is projected to be \$27.7 million in 2020-21 and \$30.2 million in 2021-22. This does not include the cost of hospital transplantation services.

Funding of the sector is complex and shared between the Commonwealth and the state and territory governments. The Commonwealth will provide funding of \$7 million over two years (ceasing 30 June 2022) to the ABMDR for core activities including bone marrow and peripheral blood donation, registration and search activity. In addition, all governments collectively are providing funding of \$20 million to the ABMDR over the same period to manage the donor registry, fund cord blood banks and ABMTRR, and conduct specific projects to improve HPC sector sustainability.

The use of CBUs for transplant has declined over time. The high level of government investment in collection, banking and storage of CBUs and the low usage of CBUs means that CBU transplantation is a high-cost therapy when costs are considered on a per-transplant basis. All governments have agreed to pause investment in further collection until 30 June 2022 while longer term arrangements are considered.

Commonwealth investment is an additional \$12 million annually to source international HPC donations. The reliance and cost associated with the use of international donors has steadily risen over time. This reliance is reflective of an increasing volume of HPC transplants undertaken in Australia, and reflective of the need to improve the domestic capacity overseen by the registry.

In acknowledging changing clinical practice, all governments agree that shared funding arrangements for the Australian HPC sector should reflect contemporary clinical need and clinical preference for HPC treatment source, be sufficiently flexible to respond to changing clinical environments and drive operational efficiencies to ensure funding continues to be targeted appropriately.

All governments agree that no additional investment should be provided to support HPC donation services beyond the total level of funding provided under current arrangements. To this end, the temporarily ceasing CBU collection has seen funding redirected to support the broader registry.

With the refocusing of investment by all governments, there could be consideration of cost-sharing of sector-relevant national HPC costs based on the agreed 50:50 cost-shared budget formula between the Commonwealth and states and territories into the future. This could both take into account activities currently solely funded by the Commonwealth and delivered by ABMDR.

In addition, export revenue is sourced from the international export of CBUs. Currently, export revenue from the reimbursement of CBUs for overseas patients can be made available for the improvement of the cord blood bank operations. Funds are held by the ABMDR, but agreement is required from all governments for the use of these funds.

Consideration by all governments should be given to the current scope of use for cord blood export revenue funds being broadened to HPCs more generally. This will allow enhancements to the broader registry, and allow sufficient flexibility for the registry manager to seek agreement from governments to use these funds to respond to changing clinical needs, drive operational efficiencies and ensure funding continues to be targeted appropriately.

7. Data and reporting

The PwC Report found that current reporting lines do not promote comprehensive data capture or inform business analytics to support strategy development, monitoring and implementation.

The Report stated that the ABMTRR is inadequately funded and operates without formally documented responsibilities. It also reported that the clinical community wanted the ABMTRR to collect Australian data of a higher quality to further clinical insights. In response, all governments have agreed to provide increased funding to ABMTRR for the two year period 2020 to 2022 to align its operations with developments in registry functions in the US and Europe. Future funding arrangements will be considered as part of the Framework's implementation.

The PwC Report also identified that reporting of recruitment and tissue typing activities and drivers of demand is not centrally captured or reported, because it is not required under existing arrangements. All Australian governments recognise that an essential part of ensuring the ongoing development and sustainability of the Australian HPC sector is the collection, analysis and reporting of data on processes and outcomes.

Targets for outcomes reporting should be set by all governments, and an annual report against objectives provided to all governments. The annual report will be embedded within funding arrangements until 30 June 2022 and reviewed thereafter. Future contractual arrangements should also consider appropriate investment for reporting activities. The National Entity will be responsible for identifying outcome measures, in consultation with all governments.

Appropriate arrangements for data and reporting will ensure the best available data and analysis is used to inform clinical practice and decision making.

8. Ethics and Research

All governments agree that the Australian HPC sector, including allogeneic and autologous donation, should act in accordance with available National Health and Medical Research Council (NHMRC) ethical guidance in undertaking its activities.¹⁹ The Australian HPC sector should also act in accordance with NHMRC guidance on ethical conduct in human research.²⁰

All Australian governments recognise that research and development is required to address gaps in clinical demand, be responsive to emerging new technologies, and ensure ongoing sustainability. The ABMDR currently exercises ethically appropriate processes for accessing HPCs for the purposes of research, whereby commercialisation of donated HPCs is not considered appropriate. All governments agree that these processes be maintained in future arrangements.

Consideration will need to be given to developing an ethics and policy framework through new governance arrangements to ensure a consistent and strategic response to emerging issues such as bio-banking, release for research, and disposal.

¹⁹ [NHMCR - Ethical guidelines on organ and tissue donation and transplantation](#)

²⁰ [NHMCR - National Statement on Ethical Conduct in Human Research 2007 - Updated 2018](#)

Implementation and Ongoing Review

The jurisdictional committee and National Entity will periodically review the Framework as emerging issues arise to ensure that the Framework fulfils its primary purpose of guiding the effective, evidence-based future operations and management of the Australian HPC sector.

Governments will be updated annually on the progress of implementation of the Framework. This will provide the flexibility to take into account new and emerging clinical advances and evidence to keep pace with the international HPC sector. If required, the Framework will be refined to meet changing needs, environments and emerging evidence and to incorporate any changes or revisions to referenced documents or guidance in the Framework.

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All information in this publication is correct as at October 2021

