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**Allogeneic haematopoietic cell transplant services in Australia and New Zealand in the first year of the COVID-19 pandemic: A report from Australia and New Zealand Transplant and Cellular Therapies**

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## **Abstract**

### Background

The COVID-19 pandemic has caused major disruption to health systems, with allogeneic haematopoietic cell transplant (alloHCT) services a particularly vulnerable area. Ongoing provision of alloHCT has required dynamic responses at national and local levels. In Australia and New Zealand (ANZ), a high reliance on unrelated donors from overseas registries has posed an additional challenge.

### Aims

To describe the impact of COVID-19 on alloHCT services in ANZ in the first year of the pandemic.

### Methods

Data from the national alloHCT recipient and unrelated donor registries was extracted for a 2-year time frame. Comparisons were made between a pre-pandemic period of 1st March 2019 to 29th February 2020 and the corresponding dates during the pandemic, 1st March 2020 to 28th February 2021.

### Results

There was a 13% decrease in the number of allogeneic transplants, a reversal of steady increases in previous years, with the largest decrease in unrelated donor transplants. Local donors supplied a greater proportion of unrelated stem cell products. With a switch to universal cryopreservation, the time from request of a product to infusion increased by a median of 25.5 days for overseas products and 14 days for local products. There was a significant increase in the number of products collected but not used.

### Conclusions

A strong public health response and coordinated transplant community activities allowed for safe provision of alloHCT in ANZ, however our data suggests that the timely delivery of allogeneic transplants was affected by the COVID-19 pandemic. Continued dedicated efforts are required to minimise further impacts.

Key words: Allogeneic Transplantation; COVID-19; Registry; Transplant Donor; Stem Cell Transplantation, Hematopoietic

## Introduction

The COVID-19 pandemic continues to cause major disruption to communities and health systems worldwide. Allogeneic haematopoietic cell transplant (alloHCT) services have faced particularly profound challenges around donor safety and availability, cellular product quality, recipient vulnerability and health system capacity limitations. Transplant centres have been required to dynamically adapt to rapid changes in levels of community transmission, healthcare burden and government restrictions. The response to these challenges in Australia and New Zealand (ANZ) has been assisted by the Australia and New Zealand Transplant and Cellular Therapies society (ANZTCT), the Australian Bone Marrow Donor Registry (ABMDR) and the New Zealand Bone Marrow Donor Registry (NZBMDR).

The impacts of COVID-19 have varied significantly between countries, with ANZ among a small number able to effectively control community transmission prior to widespread vaccine availability. The first confirmed cases of COVID-19 were on 25th January 2020 in Australia and 28th February 2020 in New Zealand. Throughout 2020 and the first half of 2021, case numbers were kept low through a strong public health response incorporating particularly strict border controls, localised and national lockdowns, and contact tracing and isolation systems. These measures minimised community transmission, permitting alloHCT services to be largely maintained, albeit with significant challenges. The challenges were amplified by a high reliance on overseas donors, who provided over 80% of unrelated products in 2019(1,2). Here we describe the response of the clinical transplant community to COVID-19 and outline the impacts on alloHCT activity in ANZ at the recipient and donor level during the first year of the pandemic.

## Methods

Data were collected from recipient and donor transplant registries to capture paediatric and adult transplants occurring over a 2-year time frame. The Australasian Bone Marrow Transplant Recipient Registry (ABMTRR) which functions under the auspices of the

ANZTCT, is a clinical quality registry that captures data on transplant outcomes in ANZ with near complete enumeration. The ABMDR coordinates and records unrelated donor and cord blood transplants in Australia. Comparisons were made between a pre-pandemic time period of 1st March 2019 to the 29th February 2020 and the corresponding dates during the pandemic, 1st March 2020 to the 28th February 2021. Medians were compared using the Mann-Whitney U test, and categorical variables with the chi-squared test. The study was approved by the ABMTRR and ABMDR Steering Committees and covered by the ABMTRRs ethics protocol (2019/ETHI0317).

## Results

### Transplant community response

Transplant physicians and centres faced significant uncertainty in the early months of 2020. The first wave of infections in ANZ initially grew at a similar rate to large outbreaks in other countries, and there was significant concern that the health care system could be overwhelmed. AlloHCT patients are particularly vulnerable to healthcare resource scarcity due to the high level of acute care required including the possibility of intensive care support, and safe and timely procurement and delivery of stem cell products is a logistical challenge at the best of times. As such there were justifiable concerns that the pandemic would have major impacts on alloHCT services.

ANZTCT, a society of transplant clinicians, provided a forum for coordination of the community's response to these challenges. The society facilitated communication between transplant departments, developed consensus position statements, offered expert advice to government bodies and advocated for resources. In early March 2020 two bulletins were published online to provide practical suggestions on department preparedness, patient triage and to highlight international guidance(3,4). These were subsequently formalised into a consensus guideline which provided more detailed information on donor choice, cryopreservation, infection screening and recipient triage(5). Concurrently, ANZTCT

communicated with state and federal governments to raise concerns about the safe arrival of stem cell products across national and international borders and called for increased access to therapeutics to facilitate safer transplant and avoidance of hospitalisation. More recently a vaccination position statement has been published advocating for prioritisation of vulnerable alloHCT patients and their close contacts and providing guidance on timing of vaccination(6).

Geographic isolation and strict border closures have likely protected ANZ from the worst of the pandemic, however they also compounded the difficulty of procuring timely stem cell products. Also of concern was the possibility of nosocomial transmission of SARS-CoV2 to donors. To help address these issues, ANZTCT and ABMDR collaboratively established the COVID-19 Australian BMT Group (CABG), under ABMDR's existing governance structures for the unrelated transplant sector. Representatives from all Australian state governments were also included. The aim of CABG was to provide a central point of communication, formulate and coordinate key activities and provide sector-wide guidance. CABG assisted centres with the switch from hand-delivered fresh products to cryopreserved airfreight, connecting with cryopreservation and transport hubs in Europe, the USA and the UK. A guidance published in May 2020 provided suggestions on testing of donors, procedures to maintain donor safety and the importance of delaying conditioning until confirmation of cell arrival and product viability (7). ABMDR also provided assistance in facilitating medical assessments of related donors closer to their place of residence, reducing the need for long distance travel. A similar process was coordinated in New Zealand via the national bone marrow transplant special interest group (BMTSIG).

#### Transplant activity – recipients

AlloHCT activity in the first year of the pandemic (1st March 2020 to 28th February 2021) was compared to the corresponding pre-pandemic time period (1st March 2019 to 29th February 2020) (Table 1). The total number of transplants dropped from 811 to 705, a decrease of 13%. This is in contrast to trends in previous years, where there has been a

year-on-year increase in numbers of allogeneic transplants in 8 of the past 10 years, and an average yearly increase of approximately 5% (Figure 1a)(1). A breakdown by calendar month reveals that the largest decrease was in May to August 2020 (Figure 1b).

The decrease in numbers of allogeneic transplants was especially pronounced for matched unrelated donors (MUD), with 17% fewer transplants in the pandemic period (Figure 1a, Table 1). This drop is particularly marked given trends in previous years, with a near doubling of MUD transplants over the past decade. Related donor transplants were also reduced while haploidentical donor transplants increased by a small amount, a continuation of recent trends and not sufficient to compensate for the drop in MUD transplants. AlloHCT numbers decreased for the majority of disease categories, particularly so for diseases where alloHCT might be less urgent, such as MDS, MPN, plasma cell disorders and inherited diseases. A larger reduction in transplants for ALL than AML was noted, which may be due to the availability of novel therapeutics and cellular therapies.

To assess whether the transplant process was delayed by the added logistical challenges, the median time from diagnosis to alloHCT for patients with acute leukaemia in first complete remission in each time period was analysed. Overall, there was an increase from 161 days in March 2019 to February 2020 (interquartile range [IQR] 125 – 198) to 168 days in March 2020 to February 2021 (IQR 136.5 – 220.75) ( $p=0.01$ ). When stratified by donor, an increase was clearly evident for unrelated donors (162 days vs 170 days,  $0.02$ ) a non-significant increase seen for matched related donors (145.5 days vs 159.9 days,  $p=0.183$ ), but no change for haploidentical donors (179.5 vs 175.0 days,  $p=0.99$ ).

#### Transplant activity – unrelated donors

Prior to the pandemic over half of all alloHCT donors in ANZ were unrelated, and more than three quarters of these were sourced from overseas registries(1). Lengthy travel distances between ANZ and the major registries have long created difficulties in procuring stem cell



donations, with a median graft transit time pre-pandemic of 32 hours(8). With the requirement for strict border closures and the reduced availability of commercial flights during the pandemic, timely and safe access to MUD stem cell products has posed an extremely difficult challenge.

Table 2 summarises the changes which occurred in the chain of events between initiating a search for an unrelated donor and infusing a product into the recipient, for Australian MUD transplants. Clinicians continued to request searches for unrelated donors, with only 4% fewer requests in the later period. The number of requests for product collection and the number of collections increased. Of the unrelated donor stem cell products collected, there were fewer bone marrow harvests and an increase in the proportion from local donors. The vast majority of products were cryopreserved, as recommended by ABMDR and ANZTCT. A significant increase was seen in the proportion of products which were collected but not used (0.3% to 12.9%). The most common reason for this was a change in the clinical condition (24.8%), or death (41.3%), of the recipient. There was no difference in the rate of unused product between international (13.1%) and national (12.5%) donors.

The switch to routine cryopreservation and delaying the start of conditioning until safe arrival of products produced a significant increase in the time period between requesting collection of a product and its infusion. For overseas products this increased from a median of 44 to 69.5 days and for Australian donors from 37.5 to 51.5 days (Table 3). These delays occurred despite a decrease in the time from request of a product to its collection.

Changes were noted in the demographic characteristics of MUDs. The median age of Australian MUDs increased from 34 years in the pre-pandemic time period to 36 years in the March 2020 to February 2021 period, and the proportion of female donors decreased from 56.7% to 28.1%. For donors from overseas registries, the median age decreased from 37 years to 35 years and the proportion of female donors was unchanged (40.8% vs 39.2%).

## Discussion

Healthcare services have been particularly exposed to the profound societal disruptions caused by the COVID-19 pandemic. This has been highlighted in the setting of alloHCT service delivery which is an especially vulnerable area. In the first year of the pandemic ANZ saw a decline in alloHCT procedures, a reversal of the steady increase over previous years. Safe and timely access to stem cell products has required significant adaptations, particularly in a region with high reliance on overseas registries for MUD products. Routine cryopreservation was associated with an increase in the time between product request and infusion, and there was a notable rise in collected stem cell products which were not infused(9).

Novel transplant platforms including reduced intensity conditioning, haploidentical transplant and improved supportive care have made allogeneic transplant available to a wider cohort of patients. These advances have led to alloHCT numbers consistently increasing in ANZ(1) and worldwide(10–12). The effects of the COVID-19 pandemic appear to have reversed this trend, with a 13% reduction in the number of transplants, consistent across most disease groups and donor types. Haploidentical transplants were the only donor source which increased, however they did not compensate for the decline in other transplant types. A similar decrease, although to a lesser degree (2.4%), was noted in an Italian survey(13). Potential contributing factors to a lower utilisation of alloHCT may have included donor unavailability, logistical challenges including international and national border closures, clinician or patient preference for lower-risk therapies at a time of significant uncertainty or delays in starting conditioning allowing for disease progression or intercurrent illness. Another possible cause could be reduced numbers of haematological malignancy diagnoses during the pandemic, the data for which are yet to be published.

Both Australia and New Zealand traditionally rely heavily on overseas registries, with over 80% of MUD transplants in 2019 using an international donor(2,14). This vulnerability has been magnified during the pandemic by travel restrictions and increases in donor withdrawal. A 60% increase in the use of local unrelated donors has somewhat compensated for this, but there are suggestions that this resulted in the selection of older donors, with an increase by 2 years in the median age of Australian unrelated donors. These experiences are mirrored by those of the DKMS registry, where 15% less products were provided, domestic donors were more heavily relied upon and donor recruitment dropped significantly(15). Coordinated efforts and increased funding are urgently needed to boost recruitment of local donors in ANZ(14). An increase in the local donor pool would potentially help mitigate against ongoing delays in sourcing stem cell products, with the median time from request to infusion being 18 days shorter for local compared to overseas donors during the pandemic.

Another major change during the pandemic has been a significant reduction in the use of bone marrow stem cells, decreasing from 10.7% to 3.4%. While there was a general transition to peripheral blood stem cells in the years 2000 to 2010, the proportion of transplants from bone marrow in ANZ had been stable at around 10% for the past decade (1). Difficulty in accessing bone marrow stem cells could particularly impact certain patient groups such as those with aplastic anaemia, for whom outcomes are best with this graft source (16). The increase in peripheral blood grafts may also lead to an overall increase in rates of chronic GVHD and its associated morbidities, which should be assessed once registry data are more mature (17).

While collection, cryopreservation and delivery and viability testing of products before the beginning of conditioning have facilitated safe transplants for recipients, there has been a significant increase in products being collected but not used. This was a rare event prior to the pandemic but occurred in up to 12.9% of collections between March 2020 and February 2021. The main reasons provided by transplant centres were a change in the clinical

condition or death of the recipient. As the cryopreservation process was the major logistical change between the two time periods, it may be that the increased interval between request and infusion contributed in some of these cases. Both DKMS and NMDP report a similar phenomenon, with 6.2% and 4.4% of products not infused in the respective time periods examined(15,18). Ethical concerns are clearly raised from exposing a healthy donor to the potential adverse events of a stem cell collection and then not utilising the product.

### **Conclusions**

A successful early public health response and coordinated transplant community activities made possible the ongoing safe delivery of alloHCT in ANZ during the first year of the pandemic. However, the reduction in overall alloHCT numbers suggests that despite relatively good control of COVID-19 during 2020, patients with haematological malignancies may have been adversely impacted by postponement or abandonment of a potentially curative therapy. The delay from request to infusion, particularly pronounced for unrelated donor transplants, appears to have been a contributor to this reduction. Therefore, while alloHCT services continued to function safely and the majority of patients in need were able to receive a transplant, there has been an impact of COVID-19 in the timely delivery of allogeneic transplant in ANZ. With both Australia and New Zealand now transitioned away from a COVID-19 elimination strategy, ongoing efforts will be required to protect vulnerable patients and maintain services.

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**Figure legends**

Figure 1 – A) Number of allogeneic transplants in ANZ each calendar year from 2011 to 2020. B) Number of allogeneic transplants in ANZ each month.

MRD, matched related donor; MUD, matched unrelated donor.

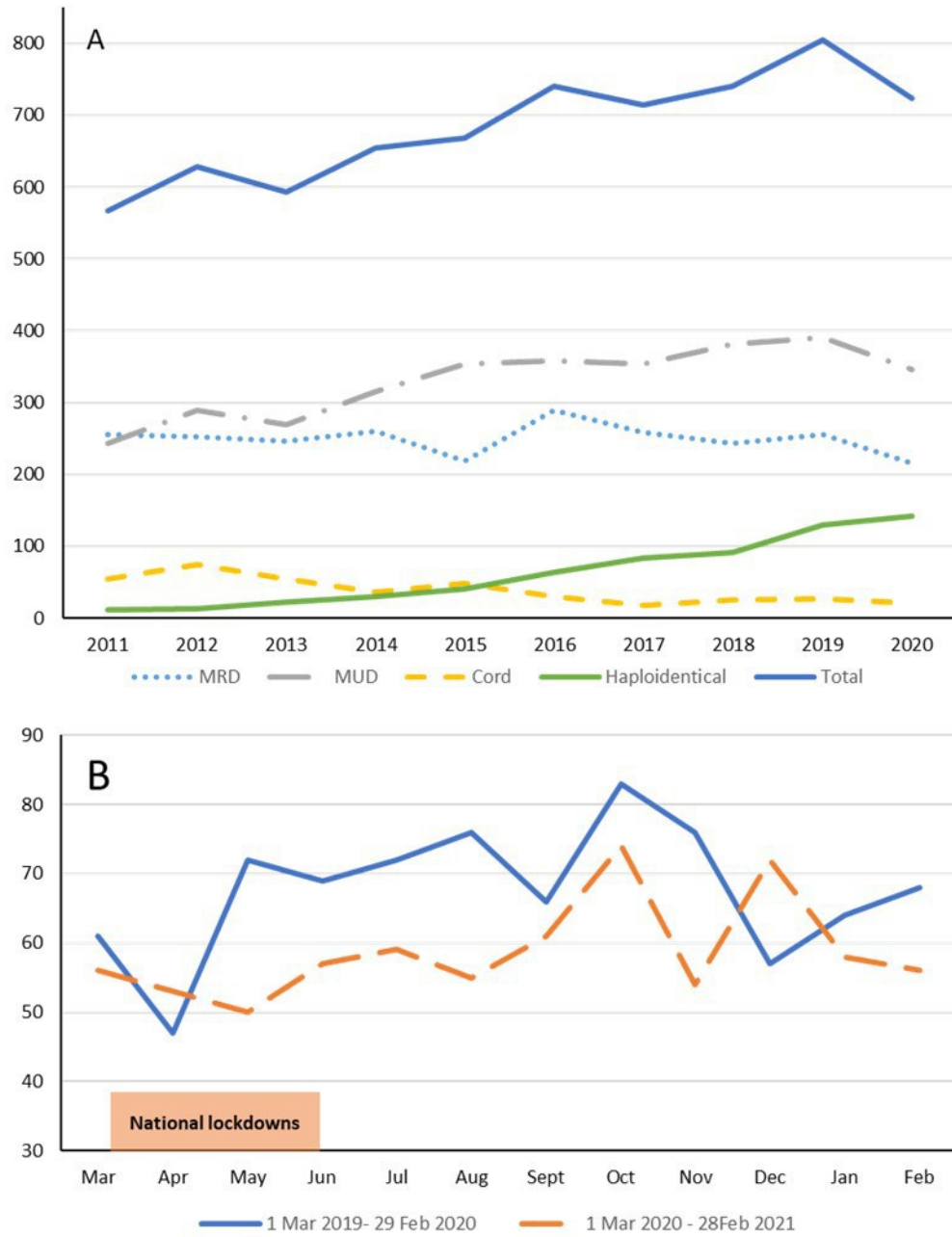


Figure 1.jpg



## Tables

Table 1 – number of transplants by donor and disease indication				
	Mar 2019 – Feb 2020	Mar 2020 – Feb 2021	% change	p value
Total number of allogeneic transplants	811	705	– 13.1%	
Donor type*				
Unrelated donor	397 (49.0%)	328 (46.5%)	– 17.4%	0.33
Related donor	250 (30.8%)	213 (30.2%)	– 14.8%	
Haploidentical donor	132 (16.2%)	140 (19.9%)	+ 6.1%	
Cord blood	29 (3.6%)	22 (3.1%)	– 24.1%	
Disease group				
ALL	123	93	– 24.4%	p<0.001
AML	298	290	– 2.7%	
LPD	79	83	+ 5.1%	
MDS (including MDS/MPN)	113	96	– 15.0%	
MPN (including CML)	71	45	– 36.6%	
Plasma cell disorders	19	5	– 73.7%	
Other malignant	42	31	– 26.2%	
AA or marrow failure syndrome	30	41	+ 36.7%	
Inherited disorders (including haemoglobinopathy)	35	19	– 45.7%	
Other (autoimmune, not specified)	1	2	+ 100%	
*Not reported for 3 transplants in 2019-2020 time period and 2 transplants in 2020-2021 time period				

AA, aplastic anaemia; ALL, acute lymphoblastic leukaemia; AML, acute myeloid leukaemia; CML, chronic myeloid leukaemia; LPD, lymphoproliferative disorders; MDS, myelodysplastic syndromes; MPN, myeloproliferative neoplasms

Table 2 – ABMDR data for unrelated donor requests, collections, and transplants*				
	Mar 2019 – Feb 2020	Mar 2020 – Feb 2021	% change	p value
Number of requests for MUD search	911	871	– 4.4%	
Number of requests for MUD stem cell collection	517	572	+ 10.6%	
Number of products collected	337	356	+ 5.6%	
Donor location				0.005
International donor	277 (82.2%)	260 (73%)	– 6.1%	
Australian donor	60 (17.8%)	96 (27.0%)	+ 60%	
Graft source				<0.001
Bone marrow	36 (10.7%)	12 (3.4%)	– 66.7%	
Peripheral blood	301 (89.3%)	344 (96.6%)	+ 14.3%	
Cryopreservation				<0.001
Cryopreserved product	13 (3.9%)	311 (87.4%)	+ 2292%	
Fresh product	324 (96.1%)	45 (12.6%)	– 86.1%	
Products collected but not infused	3 (0.9%)	46 (12.9%)*	+1433%	<0.001
Reason for product not being used				
Change in recipient condition	1 (33.3%)	16 (34.8%)		
Recipient deceased	2 (66.7%)	19 (41.3%)		
Product quality	0	3 (6.5%)		
Unknown	0	8 (17.4%)		
*unrelated donor transplants in Australia only				
†as of data cut-off 31/10/2021				
ABMDR, Australian Bone Marrow Donor Registry; MUD, matched unrelated donor				

Table 3 – time from requesting unrelated donor product to collection and infusion*				
	<b>Mar 2019 – Feb 2020</b>	<b>Mar 2020 – Feb 2021</b>	<b>Difference in medians</b>	<b>p value</b>
Overseas donors – median days [interquartile range]				
Request to collection	42 [33, 55.75]	35 [28, 48]	– 7 days	<0.001
Collection to infusion	2 [2, 2]	30 [23, 38]	+ 28 days	<0.001
Total (request to infusion)	44 [35, 58]	69.5 [55, 84]	+ 25.5 days	<0.001
Australian donors – median days [interquartile range]				
Request to collection	35.5 [29.75, 49.25]	33 [23.75, 41.25]	– 2.5 days	0.027
Collection to infusion	1 [1, 1]	19 [1, 25]	+ 18 days	<0.001
Total (request to infusion)	37.5 [32, 52]	51.5 [38.75, 64.5]	+ 14 days	<0.001
* unrelated donor transplants in Australia only				