Australia and New Zealand Transplant and Cellular Therapies (ANZTCT) Position Statement: COVID-19 Management in Haematopoietic Stem Cell Transplant and Chimeric Antigen Receptor T cell Patients

Background

Two years into the SARS-CoV-2 (COVID-19) pandemic, novel challenges continue to emerge. As the community moves towards high daily case numbers and circulating virus, or so called “COVID normal”, the risk for adult immunocompromised patients remains high. [1] In the paediatric setting data is lacking and the risks of morbidity and mortality are likely lower than in the adult setting.

In addition to the physical risk of COVID-19, there are additional psychosocial implications for patients who have received haematopoietic stem cell transplants and chimeric antigen receptor T cell therapies (TCT). Many patients report significant anxiety about COVID-19, and it is not always safe to isolate in the early post TCT period as patients recuperate at home post discharge.[2] Another challenge in this cohort is prolonged post infection viral shedding, which can create challenges for access to medical care as well as other household members needing to isolate.

Transplant and cellular therapies are life-saving interventions and cannot routinely be postponed due to the risk of intervening disease relapse. This has forced great innovation and collaboration internationally by TCT clinicians to ensure access to safe and timely therapy against COVID-19 for TCT patients.

This position statement is intended to highlight relevant clinical issues unique to TCT patients and was developed in accordance with the ANZTCT policy for consensus practice/position statement development. The relevant literature has been reviewed and selected by the expert authors. The authorship group includes ANZTCT board members who have sought representatives from all TCT centres in Australia and New Zealand and key stakeholders including the Australasian Society of Infectious Diseases, the Haematology Society of Australia and New Zealand, the Australian and New Zealand Bone Marrow Donor Registries, Leukaemia foundation and Leukaemia and Blood Cancer New Zealand. The ANZTCT is committed to equity, diversity and inclusion so geographic representation, gender balance and diversity of backgrounds

and disciplines was considered where possible. This position statement will be regularly reviewed and updated as further data on COVID-19 therapeutics emerge. Updates will be made on the ANZTCT website www.anztct.org.au.

Risk Mitigation and Service Strategies for TCT Units

Site-specific protocols for COVID-19 mitigation and management have been required to address the evolving challenges. Some strategies employed include the use of Telehealth to limit face-to-face contact, hospital and clinic visitor restrictions, surveillance screening of staff, patients, and visitors with rapid antigen or PCR tests, and provision of appropriate PPE to staff and patients. Rotating staff rosters have also been employed at some sites to minimise workforce shortages due to furlough requirements. Ensuring that staff, contractors, and visitors are vaccinated is also important.[3]

Adding complexity to risk mitigation strategies, there are significant logistic challenges related to the management of COVID-19 positive TCT outpatients. Where feasible, positive patients are seen outside of haematology/oncology clinical areas to reduce risk of transmission to other immunosuppressed patients. Pathways to facilitate ongoing care of such patients vary according to local resources, however, may include pop-up clinics for phlebotomy, transfusion, and outpatient COVID-19 treatment, or segregated areas within established clinical services. If no other resources are available, patients may be referred to emergency departments with dedicated COVID-19 patient care spaces. Remote care services designed to manage SARS-CoV-2 positive patients in the home are valuable for TCT patients with minimal symptoms however require oversight by TCT clinicians.[4]

Symptomatic testing and surveillance strategies have also evolved, with an increasing reliance on rapid antigen tests for case diagnosis. For patients unable to privately access rapid antigen tests, or with significant symptoms despite a negative rapid test, PCR testing is recommended. Ensuring availability of a dedicated testing space has been a challenge for many sites with the gradual move away from hospital PCR clinics. Testing facilities are also needed for patients requiring repeat PCR or viral culture to confirm clearance of COVID-19 in the event of persistent rapid antigen test positivity.

Patients with COVID-19 requiring admission in the peri-TCT period present a further challenge, due to the need to minimise risk of exposure to other haematology patients. We recommend that TCT patients who are known or suspected to be positive for COVID-19, be isolated on dedicated COVID-19 wards. To limit exposure risk to other inpatients, where possible, dedicated TCT staff should be assigned for management and review of COVID-19 positive patients, to ensure that required TCT-related monitoring takes place. Where possible, TCT patients without COVID-19 should be placed in single rooms to minimise their inpatient exposure risk.

Because TCT are only available at major urban centres, many patients receiving these therapies are required to relocate from regional and rural areas during their treatment. Organisations such as the Leukaemia Foundation in Australia assist in provision of accommodation for these patients, often to facilities with communal kitchen and/or bathroom facilities. The best way to isolate COVID-19 infected TCT patients in this setting, or indeed to protect them from infected co-habitants requires attention, and solutions will need to be locally specific depending on resource availability.

Prevention

Vaccination

The ANZTCT has recently published a COVID-19 vaccination position statement which outlines Australian and New Zealand expert consensus on vaccination of TCT patients, but advice in this area is likely to change with infection rates, emerging variants, and contemporaneous evidence of immune response durability.[5,6] There is evidence of poor serological vaccination responses amongst TCT recipients,[7,8] although T cell responses appear to be reasonable. When to start vaccination to achieve optimal protective humoral and cellular immune responses is yet to be determined in this population, however current recommendations are to vaccinate between 3 to 6 months post TCT. If patients receive tixagevimab and cilgavimab (Evusheld™) post TCT, it may be optimal to revaccinate at 6 months post TCT, when immune response is more likely to be achieved. Importantly, all TCT patients require a full revaccination course following transplant or CAR-T therapy, regardless of their pre-treatment vaccination status. There is also limited data on the response durability or the impact of post TCT immunosuppression and/or graft versus host disease on vaccine response.

Pre-exposure prophylaxis

Tixagevimab/cilgavimab is a dual monoclonal antibody therapy which binds to the SARS-CoV2 spike protein to prevent viral entry into host cells.[9] Tixagevimab/cilgavimab may offer up to 6 months protection following two intramuscular doses which can be given simultaneously at two different intramuscular sites.[9] This agent is recommended for immunocompromised patients at highest risk of poor response to vaccination.[10] It is recommended that tixagevimab/cilgavimab administration is delayed by at least 2 weeks following COVID-19 vaccination. Tixagevimab/cilgavimab could be considered prior to TCT, based on vaccination history and disease risk, but ideally should be given as soon possible post TCT in clinically stable patients with adequate count recovery, or with platelet support for safe intramuscular injection. Identifying an appropriate facility for the rapid delivery of this treatment requires consideration of both patient exposure risks versus resource-constrained haematology/oncology ambulatory care units.

Treatments

The ANZTCT supports treatment guidelines by the National COVID-19 Clinical Evidence Taskforce, and the New Zealand Ministry of Health and Cancer Agency Te Aho o Te Kahu COVID-19 Guidelines.[11,12] The authors acknowledge that at the time of writing, monoclonal therapies are not available in New Zealand. Furthermore, the data supporting the treatments discussed below does not include younger children.

<u>Mild to Moderate COVID-19</u>

Anti-SARS-CoV-2 Monoclonal antibodies: Sotrovimab is a recombinant human IgG1-kappa monoclonal antibody which binds extracellular COVID-19, facilitating both antibody dependent cell-mediated cytotoxicity and antibody dependent cellular phagocytosis.[13] Based on local experience, it has been widely used and well tolerated in TCT patients infected with COVID-19 during the Omicron wave. The terminal half-life of sotrovimab is less than 2 months, limiting it to treatment rather than prophylaxis, and vaccination should be deferred until 3 months following sotrovimab infusion to maximise vaccination responses. Importantly, efficacy has only been shown when administered within 5 days of symptom onset, in patients with mild to moderate disease. Several other anti-SARS-CoV-2 monoclonal antibodies are available for mild to critical COVID-19 infection, including casirivimab and imdevimab. Of note, the

activity of monoclonal antibodies depends on the underlying strain of SARS-CoV-2 and currently casirivimab/imdevimab is thought to be less effective against the Omicron strain, and it is unlikely that sotrovimab is effective against the B.1.1.529/BA.2 strains.[14,15]

Other Agents to Consider in TCT patients with Mild to Moderate Disease: Both local and international guidelines on COVID-19 treatment often group TCT patients with immunocompromised or high risk patients, despite evidence of low vaccine responses and particularly high mortality rates in recipients of TCT [1,7,8,16]. In addition to monoclonal antibody therapy, other agents that can be considered in TCT patients with mild to moderate disease include remdesivir, inhaled budesonide, nirmatrelvir with ritonanir (Paxlovid) and molnupiravir. Of note, molnupiravir has been associated with increased SARS-CoV-2 mutagenesis,[17] which is of particular concern in a population of patients at risk of prolonged viral shedding. Caution is recommended with the use of molnupiravir in TCT patients for this reason. Nirmatrelvir with ritonavir (Paxlovid) is contraindicated in patients using calcineurin inhibitors or sirolimus due to major drug interactions via the CYP450 pathway, as well as patients with significant renal or liver impairment. Ritonavir interacts with many agents, so a thorough medication review should be undertaken if this agent is considered. Sarilumab and tocilizumab are IL-6 inhibitors which have shown some benefit in reducing the immune response to infection.

<u>Considerations for TCT Patients with Severe COVID-19</u>

In patients requiring treatment for severe or critical COVID-19, optimal management requires a multidisciplinary approach. This should include a TCT Haematologist to monitor and manage TCT complications such as therapeutic drug monitoring, graft-versus-host disease, viral reactivation, cytokine release syndrome, immune effector cell associated neurotoxicity syndrome (ICANS), and hypogammaglobulinaemia. This is in addition to standard COVID-19 management strategies such as anticoagulation, prone nursing and oxygen supplementation. A summary of COVID therapeutics and their potential adverse effects in TCT patients is shown in **Table 1**.

Therapeutic agent	Indication	Used in patients requiring oxygen	Use in ventilated patients	Potential CYP P450 interaction	Relevant Adverse Effects
Tixagevimab/cilgavimab	• Sars-CoV-2 prophylaxis	No	No	No	
Sotrovimab	• Some Omicron variants	No	No	No	*Hypersensitivity reaction, hypertension*
Casirivimab plus imdevimab *Anti-spike protein monoclonal antibodies*	• Non-Omicron infection • mild disease	Yes	No		*pruritis, urticaria, erythema, dizziness lymphadenopathy post S/C injection*
Remdesivir *RNA polymerase inhibitor*	• Mild-moderate disease • Within 7 days of symptom onset	Yes	No	Yes	*rash, headache transaminitis*
Molnupiravir *Ribonucleoside analog*	• Mild disease • Within 5 days of symptoms onset	No	No		*dizziness*
Nirmatrelvir with ritonavir *Protease inhibitors*	• Mild-moderate disease • unvaccinated • Within 5 days of symptoms onset	No	No	Yes *Contraindicated with calcineurin inhibitor use*	
Sarilumab *IL-6 inhibitor*	• Moderate to severe disease	Yes	Yes		*neutropenia, leukopenia*
Tocilizumab *IL-6 inhibitor*	• Moderate to severe disease • Evidence of systemic inflammation	Yes	Yes		
Dexamethasone	• Severe disease	Yes	Yes	Yes	
Baricitinib *JAK1 inhibitor*	• Moderate to severe disease			Yes	*rare cytopenias*

Table 1. COVID-19 therapeutics and potential challenges in TCT patients[18]

Monitoring of TCT Patients with COVID-19

Rates of severe and critical COVID-19 disease are high in TCT patients, with international reports of 30-day mortality of 32% in haematopoietic stem cell transplant recipients during the initial COVID-19 wave.[19] Mortality amongst chimeric antigen receptor T cell (CAR T cell) recipients is reportedly as high as 41%.[16] We recommend informed consent regarding these risks when TCT treatment is proposed, and facilitation of access to COVID-19 therapeutics if patients are infected. We recommend that TCT patients with COVID-19 receive standard of care monitoring via their local hospital COVID-19 pathway, as well as regular review, by Telehealth where appropriate, by a TCT clinician, to advocate in the event of deterioration, to monitor disease resolution, and to ensure that TCT related follow up is not overlooked. We recommend that TCT recipients are provided with clear instructions regarding what to do if they are diagnosed with COVID-19 in the community. The risk of prolonged viral infection in TCT patients is well documented, and prolonged infection has been associated with viral evolution and development of resistance mutations.[15]

Deisolation of TCT Patients with COVID-19

One challenge in post-TCT patients is persistent viral RNA shedding and resultant difficulty establishing safety for deisolation. In addition to resolution of symptoms, the exclusion of replication-competent viral shedding must be established in order for patients to deisolate. While there is some variability internationally on specific deisolation criteria for immunosuppressed patients, there is increasing use of PCR cycle threshold (Ct) and viral culture to inform deisolation eligibility in patients with persistent PCR positivity.[20,21] Cycle threshold on PCR testing correlates inversely with viral load, and is one surrogate marker proposed for clearance testing. Assays vary in sensitivity making identification of a universal Ct cut-off difficult, however higher Ct values are thought to indicate a low risk of infectivity. TCT units should liaise with local infection control, microbiology and infectious diseases teams to identify local laboratory cut-offs. Viral culture is also useful if positive, however test accuracy is dependent on specimen quality so negative results should be interpreted with caution, and in conjunction with Ct values. Correlation between high Ct and negative viral culture has been established.[22] It is important to acknowledge that significant variability in availability of Ct and viral culture has been reported across Australian

TCT centres. If viral culture is not available, then high Ct, symptom resolution and negative rapid antigen test must be relied on to determine safety to deisolate. Importantly symptom recurrence in TCT patients following resolution of symptoms should prompt re-testing.

For patients who remain viral culture positive or with low Ct values beyond twenty days, ongoing isolation may cause significant psychosocial pressure for both the patients and their household members. No recommendation to deisolate can be made whilst there is evidence of ongoing replication-competent viral shedding however additional psychosocial support should be offered if this resource is available. In a persistently positive patient who remains SARS-CoV-2 culture positive or who has falling Ct values following treatment, the decision to release from isolation should be made by the treating clinician and local infectious diseases/infection prevention teams.

Mitigating COVID related obstacles in TCT

TCT donors should be screened prior to cell product collection as per the Australian Bone Marrow Donor Registry guidelines. We recommend screening for COVID using PCR within 24-72 hours of collection initiation. We recommend cryopreservation of cellular product where possible to avoid delays due to donors testing positive. There is a latency from infection to shedding so where fresh product infusion is planned, an isolation period of 7 days as well as PCR testing prior to mobilisation should be considered. Donors should also be encouraged to take precautions to reduce the risk of contracting COVID-19 in the weeks leading up to donation. If donors of fresh product test positive for COVID-19, we recommend a 7-day deferral period after full recovery or 7 days after the most recent positive result, for asymptomatic infections. If a donor becomes positive following mobilisation but prior to collection, we recommend consultation with the donors' transplant physician with regards to safety to proceed with collection. We recommend a 14-day donor deferral after close contact. In the setting of urgent allogenic stem cell transplantation, earlier donations should be considered on a case by case basis.[23]

Within 72 hours prior to initiation of conditioning or lymphodepleting therapy, patients should undergo PCR screening for COVID-19. If positive, treatment delay is recommended until PCR negative and asymptomatic. Optimal delay between infection

and TCT is unknown, however transplant has been performed as early as 44 days following infection and this may need to be weighed against the severity of symptoms and the urgency of proceeding to transplant.[24] If patients are a close contact prior to TCT we recommend a 14 day deferral if possible. We recommend that patients who become positive following conditioning or lymphodepleting therapy should proceed with infusion of cell products in conjunction with COVID appropriate treatment and monitoring as outlined above, acknowledging the paucity of evidence to guide patient management in this situation.

Long COVID

The long term impact of COVID on TCT patients is yet to be established, particularly in terms of quality of life and potential interaction with graft versus host disease. We recommend where possible, considering multidisciplinary approaches in managing TCT patients with long COVID, in collaboration with respiratory and rehabilitation physicians. Local models for screening, assessment and management of long COVID are emerging.

Summary of recommendations

Mitigation Strategies

- Reduce contact: Telehealth visits where feasible, visitor restrictions
- Barriers: use of appropriate PPE by staff and patients
- Surveillance: staff, patient and visitor screening programs using rapid antigen or PCR tests

Service Strategies

- Where possible, a dedicated site for serial testing and review of COVID-19 positive TCT outpatients
- Where possible, a dedicated site for surveillance or symptomatic testing
- Detailed emergency department review pathways for TCT patients to minimise risk of iatrogenic COVID-19 exposure
- Where possible, dedicated TCT clinician oversight of COVID-19 positive TCT inpatients

- Provide clear patient education regarding actions to take in the event of community COVID-19 diagnosis
- Remote care services to manage COVID-19 positive patients in the home require oversight by TCT clinician

Prevention

- Vaccination of both recipient and donor is recommended, where possible, prior to TCT
- Regardless of prior vaccination status, post-TCT patients should receive 3 primary vaccine doses and boosters as per local guidelines
- COVID vaccination should commence 3-6 months following transplant or cell therapy administration
- Tixagevimab/cilgavimab could be considered prior to TCT based on vaccination history and disease risk but ideally soon post TCT in clinically stable patients after count recovery or with platelet support for safe intramuscular injection
- If patients receive tixagevimab/cilgavimab post TCT, it may be ideal to revaccinate at 6 months post TCT

Treatment

- TCT patients with mild to moderate COVID-19 should be offered treatment as early as possible.
- COVID-19 infection should be managed in accordance with best practice at the time of diagnosis, as advised by Infectious Diseases, Respiratory and Intensive Care specialists, and in line with current guidelines from the National COVID-19 Clinical Evidence Taskforce and the New Zealand Ministry of Health and Cancer Agency Te Aho o Te Kahu COVID-19 Guidelines.
- Local availability of therapies varies, and site-specific agreements regarding treatment pathways in TCT patients with COVID-19 are encouraged to ensure supply and facilitate timely administration of treatments

Post-infection Monitoring and Deisolation

- Guidelines in this area are rapidly evolving, and confirmation with local regulations is recommended
- Patients can deisolate after two negative SARS-CoV2 PCR or rapid antigen tests

- Patients with persistent positivity beyond 20 days should have viral culture and PCR Ct where possible to guide deisolation; where viral culture is not available, Ct value and symptom resolution should guide deisolation
- In persistently positive patients beyond 20 days, discussion with local Infectious Disease specialist is recommended, and extended psychosocial supports should be offered where possible
- Symptom recurrence in TCT patients following resolution of symptoms should prompt re-testing
- Patients with long COVID where possible should be managed with the support of a multidisciplinary team including respiratory and rehabilitation physicians

Mitigating COVID related obstacles in TCT

- Donor screening should be performed within 24-72 hours of collection
- Cell therapy products should be cryopreserved when possible, to avoid critical delays due to donor positivity
- Donor isolation for 4-7 days prior to collection, with PCR at time of collection, should be undertaken when fresh cellular product use is planned
- In the case of COVID positive allogenic haematopoietic stem cell donors or those who are close contacts, ABMDR guidance on donor deferral should be followed
- Patients should be screened by PCR within 72 hours prior to commencing conditioning or lymphodepletion
- Patients who are close contacts prior to TCT should be deferred for 14 days if possible
- Optimal delay between patient infection and proceeding to TCT is unknown but this needs to balance the urgency of transplantation and severity of symptoms
- Once conditioning or lymphodepletion has commenced, TCT should proceed in patients with interval COVID-19 positivity with appropriate COVID-19 treatment

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